

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

OR

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

For the transition period from _____ to _____

Commission file number: 001-32979

MOLECULAR TEMPLATES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

9301 Amberglen Blvd, Suite 100, Austin TX 78729
(Address of principal executive office)

94-3409596

(IRS employer
Identification number)

78729
(Zip Code)

(512) 869-1555

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class

Common Stock, \$0.001 Par Value Per Share

Name of Each Exchange
On Which Registered

The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Accelerated filer

Smaller reporting company

Large accelerated filer

Non-accelerated filer

Emerging growth company

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of \$5.23 of the Common Stock on The Nasdaq Capital Market on June 29, 2018 was approximately \$59,774,264. The calculation of the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant excludes shares of Common Stock held by each officer, director and stockholder that the registrant concluded were affiliates on that date. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On March 22, 2019 there were 36,736,012 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2019 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days of the registrant's fiscal year ended December 31, 2018 are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

Molecular Templates, Inc.
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PART I

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K, including the sections entitled “Business,” “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended or the Exchange Act. We may, in some cases, use words such as “project,” “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “should,” “would,” “could,” “potentially,” “possible”, “will,” or “may,” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements may include statements about:

- the implementation of our business strategies, including our ability to pursue development pathways and regulatory strategies for MT-3724 and other engineered toxin body, or ETB, product candidates;
- our ability to advance the development of our product candidates;
- our plans to pursue discussions with regulatory authorities, and the anticipated timing, scope and outcome of related regulatory actions or guidance;
- our ability to establish and maintain potential new partnering or collaboration arrangements for the development and commercialization of ETB product candidates;
- our financial condition, including our ability to obtain the funding necessary to advance the development of our product candidates;
- the anticipated progress of our product candidate development programs, including whether our ongoing and potential future clinical trials will achieve clinically relevant results;
- our ability to generate data and conduct analyses to support the regulatory approval of our product candidates;
- our ability to establish and maintain intellectual property rights for our product candidates;
- whether any product candidates that we are able to commercialize are safer or more effective than other marketed products, treatments or therapies;
- our ability to discover and develop additional product candidates suitable for clinical testing;
- our ability to identify, in-license or otherwise acquire additional product candidates and development programs;
- our anticipated research and development activities and projected expenditures;
- our ability to complete preclinical and clinical testing successfully for new product candidates that we may develop or license;
- our ability to have manufactured active pharmaceutical ingredient, or API, and drug product that meet required release and stability specifications;
- our ability to have manufactured sufficient supplies of drug product for clinical testing and commercialization;
- our ability to obtain licenses to any necessary third-party intellectual property;
- our ability to retain and hire necessary employees and appropriately staff our development programs;
- the sufficiency of our cash resources; and
- 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 I, Item 1A of this Annual Report on Form 10-K. 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.

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

ITEM 1. BUSINESS

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

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

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

Molecular's initial approach to drug development in oncology involves the selection of lead compounds to validated targets in cancer. Molecular has developed ETBs for various targets, including CD20, CD38, HER2, and PD-L1. CD20 is central to B cell malignancies and is clinically validated as a target for the treatment of lymphomas and autoimmune disease. CD38 has been validated as a meaningful clinical target in the treatment of multiple myeloma. PD-L1 is central to immune checkpoint pathways and is a target expressed in a variety of solid tumor cancers. Molecular's lead compound, MT-3724, is an ETB that recognizes CD20, a B cell marker and is currently in multiple phase II studies. The Phase I program consisted of a dose escalation portion, followed by a Phase Ib expansion cohort. Molecular recently initiated two Phase II studies for MT-3724, one monotherapy study that has the potential to be pivotal and a combination study with chemotherapy. Molecular expects to initiate a second combination study with Revlimid in the second quarter of 2019. Molecular expect two new ETBs, MT-5111 and TAK-169 to enter clinical trials in 2019. Molecular also expects to file an IND for its PD-L1 targeted ETB in the second half of 2019.

Molecular has built up multiple core competencies around the creation and development of ETBs. Molecular developed the ETB technology in-house and continues to make iterative improvements in the scaffold and identify new uses of the technology. Molecular also developed the proprietary process for manufacturing ETBs under Good Manufacturing Process, or GMP standards and continues to make improvements to its manufacturing processes. Molecular has conducted multiple GMP manufacturing runs with its lead compound and believes this process is robust and could support commercial production with gross margins that are similar to those seen with antibodies.

Challenges in Oncology

Existing mechanisms of action, the specific biochemical interaction through which a drug substance produces its pharmacological effect, are subject to numerous limitations in oncology. The clinical benefit of a given drug is a function of the biological properties of the drug, the target with which the drug interacts and the tumor indication being treated, but the relative contribution of each of these factors is difficult to separate. To date, significant challenges exist in identifying the most appropriate cancer targets, applying the most effective mechanisms of action and selecting the appropriate disease indications and most responsive patient populations for a particular drug. These challenges, including the following:

- *Availability of viable targets.* The limited number of cancer targets addressable with currently available mechanisms of action; for example, targets appropriate for ADC approaches are relegated to those extracellular targets that already readily and efficiently self-internalize;
- *Drug resistance.* ADC approaches generally use chemotherapy payloads which damage DNA, or disrupt or prevent microtubule assembly, and can be subject to the same mechanisms of resistance as in general chemotherapy;
- *Limits of monotherapy.* Established single-agent therapies are only effective in a minority of cancer patients;
- *Target identification and prioritization.* Current approaches to target prioritization are not comprehensively systematic and do not leverage a complete understanding of a drug's effect on a given tumor type to best identify high value targets in certain patient populations;
- *Clinical predictability of preclinical data.* *In vitro* epitope selection on a given target may not be predictive of clinical optimization; and
- *Biomarker use and utility.* Predictive biomarkers, the value and use of which are relatively new, are not uniformly used to proactively select responsive patient populations and/or preferred indications, which can drive longer development timelines with higher associated costs.

Molecular's Differentiated Approach

Molecular was founded on the principle that differentiated mechanisms of action are crucial for improving outcomes in oncology. Molecular has created a new ETB scaffold with a differentiated mechanism of action, coupled with a predictable PK and ADME profile. Molecular's ETB scaffold permits rapid screening for lead identification and easily scalable production, which Molecular believes offers an opportunity to provide meaningful clinical benefits in oncology with more cost efficient research and development than current treatments. Molecular believes the differentiated biological activity inherent to the ETB scaffold, particularly the ability to induce internalization and employ a differentiated mechanism of cell kill, may allow for differentiated clinical benefit in patients as monotherapy and in combination with standard of care therapies.

Molecular likens the extensive de-immunization work it has conducted on SLTA to the chimerization of monoclonal antibodies. Monoclonal antibody chimerization is a process for reducing immunogenicity when an antibody from one species is introduced into a different species. Chimerization has allowed for the wide-spread use of antibodies as human therapeutics across multiple disease settings. Molecular believes that the de-immunization of SLTA may allow for ETB use across multiple indications in oncology, including solid tumors, as well as other potential non-oncology indications.

Molecular has seen in both preclinical models and in its Phase I trials to date that the differentiated mechanism of action employed by its ETBs can be effective in chemo-resistant tumor cells. Molecular believes this creates the potential for a rapid characterization of efficacy in carefully designed clinical trials in relapsed and refractory settings, particularly when targeting tumor markers that persist after treatment with multiple lines of therapy and whose targeting has been shown to provide a survival benefit. Molecular also has seen preclinically that its ETBs can have additive or synergistic activity in combination with a number of small molecule agents including chemotherapeutics, immunomodulatory agents and tyrosine kinase inhibitors. Molecular believes that the ability of ETBs to be additive or synergistic to a variety of current treatments may allow for combination therapy in earlier lines of disease.

Molecular believes it can develop ETBs against well-validated targets and new targets, enabling a phenotypically based clinical trial design that may result in shorter development timelines with lower associated costs. More specifically:

- *Molecular's research and design platform allows it to select lead ETBs from a comprehensive screen.* Molecular's ETB platform utilizes a suite of integrated technologies to screen ETB libraries for lead identification. Molecular performs initial preclinical screens on ETBs with lead selection around potency, affinity and expression. Critical components of Molecular's approach include:
 - the proprietary optimization of the genetic fusion between the immunoglobulin-targeting domain and Molecular's proprietary SLTA scaffold;
 - the proprietary de-immunizing modifications made to the SLTA scaffold, which reduce both adaptive and innate immune responses to ETBs;
 - comprehensive screening for potency, affinity and specificity against target expressing versus non-expressing cells; and
 - early evaluation of protein expression and stability of potential lead ETB candidates.
- *Molecular's ability to create lead ETBs to well-validated targets reduces the risk of target-mediated side effects and increases the likelihood of obtaining meaningful clinical benefit.* Molecular has deployed its technology against targets in oncology that are central to disease progression and that are known to persist after a given modality has failed. Molecular believes these targets reduce the risk of clinical failure from either unacceptable target-mediated adverse events or from a failure to impact disease outcome because of loss of the target. For example, Molecular's lead compound, MT-3724, targets the B-cell surface marker CD20. CD20 appears central to B-cell malignancies, and the FDA has approved multiple antibody therapies targeting CD20. Destruction of CD20-expressing cells has been generally safe and has not been found to cause significant damage to the patient, known as severe toxicity. CD20 cell surface expression persists in the majority of patients who have progressed after treatment with a CD20 monoclonal antibody. Molecular chose targeting of CD20 for Molecular's lead ETB program because of its known lack of internalization upon antibody binding, centrality to disease progression, lack of associated toxicities and persistence after treatment failure. Molecular used a similar rationale in the selection of Molecular's current pipeline, including ETBs targeting CD38, HER2, and PD-L1, which are targets central to disease outcome that persist after a given modality has failed.
- *Molecular's ETB platform allows Molecular to identify ETBs to targets and select patients in the Phase I clinical trials that phenotypically match that ETB program.* Molecular can screen a library of single chain variable fragments, or scFvs, expressed in Molecular's ETB scaffold to a given target. The pharmacokinetic and ADME profile of these compounds are similar and relatively predictive in humans based on animal models. Once the lead is selected and Investigational New Drug Application, or IND-enabling studies are completed, Molecular can enrich a Phase I clinical trial with only patients expressing the target of the ETB. In these Phase I clinical trials, Molecular can get a faster read on safety as well as efficacy than is possible in many drug development programs. Molecular's Phase I trial in non-Hodgkin's lymphoma with MT-3724 established the PK, ADME, dose-limiting toxicities, or DLTs, maximum tolerated dose, or MTD, and recommended Phase II dose and monotherapy efficacy after just 21 patients were treated.

Molecular's Strategy

Molecular's goal is to bring the right ETBs to the right patients to provide long-lasting benefits that ultimately improve patients' lives. To achieve its goal, Molecular is:

- *Implementing development strategies that capitalize on the differentiated pharmacological features of Molecular's ETB technology and the validated nature of the targets it has chosen.* Molecular believes the target specificity of its ETBs, their ability to self-internalize, their potent and differentiated mechanism of cell kill and their safety profiles will provide opportunities for the clinical development of these agents to address multiple cancer types. For example, Molecular is aggressively developing its lead product MT-3724 as a single agent therapy for relapsed and refractory diffuse large B-cell lymphoma, or DLBCL, patients and in combination with approved therapies in earlier stages of high-risk DLBCL. The targeting of CD20 with antibody therapeutics is known to confer clinical benefit in these settings. MT-3724's differentiated mechanism of action, safety and pharmacological profiles targeting CD20 may provide an advantage over other modalities. Given the unique mechanism of direct cell-kill, via ribosome inactivation, Molecular believes there is the potential for combination or sequential drug strategies that may be unique to its ETB drug candidates. Further, based on MT-3724 safety

data to date, Molecular believes the different PK and ADME profiles of its ETBs may allow them to be more appropriate therapies for certain patient populations, particularly those who are unable to tolerate intensive chemotherapy as primary or conditioning therapy. For example, in the Phase I clinical trial for MT-3724, the median age was 67 and the median number of prior therapies was four. Molecular believes all of these attributes will enable Molecular to pursue development strategies not feasible with other therapeutic approaches.

- *Efficiently building a broad pipeline of ETB therapeutics targeting defined patient populations through the use of Molecular's research and design platform* Molecular believes its research and design platform is an efficient and productive discovery and development engine that can identify new targets across multiple cell types with the aim of creating a portfolio of novel, cell targeting ETBs. By selecting tumor targets best suited to ETB biology, Molecular can prioritize indications, including potential niche indications and/or niche subsets of indications. Molecular believes this will enable the identification of patients who may be more likely to respond to its therapies, allowing Molecular to potentially shorten development timelines and lower associated costs.
- *Maximizing the value of Molecular's early pipeline through the continual improvement of Molecular's technology.* Since its founding, Molecular has made substantial progress in improving its ETB technology. Molecular has created a proprietary SLTA that has been heavily modified to dramatically reduce innate and adaptive immunogenicity. In addition, new approaches have been developed for the genetic fusion of the SLTA and antibody domain that enhances the potency of Molecular's ETBs. Molecular has also developed ETBs that have the ability to deliver foreign class I antigens into target cells for expression in complex with MHC class I molecules on the target cell's surface. Molecular has shown preclinically that certain foreign antigens can be functionally recognized by endogenous human T-cells thereby enabling a potentially new and differentiated approach to immuno-oncology.
- *Building a fully integrated discovery-to-commercial oncology company focused on compounds with unique and differentiated biology* Molecular believes that differentiated mechanisms of action are crucial for improving outcomes in oncology. Molecular has created a robust translational platform that Molecular believes allows it to create a sustainable, novel pipeline of ETBs with differentiated mechanisms of tumor destruction, relatively predictable PK and ADME, and scalable and economical manufacturing. If MT-3724, MT-111, or any future product candidates Molecular may develop are approved, Molecular will consider commercializing them itself in select markets.

Molecular's Engineered Toxin Body (ETB) Platform Technology

Although chemotherapy remains the cornerstone of treatment for most cancers, the advent of new and targeted classes of therapies has dramatically changed outcomes in the treatment of disease. The advent of monoclonal antibodies, signal transduction inhibitors and, most recently, immune-oncologics have provided substantial clinical benefit in both the relapsed and refractory setting and, when used in combinations, in earlier lines of therapy. Molecular believes that ETBs represent a new class of targeted agents with differentiated biology that are well-positioned to improve outcomes in cancer patients.

ETBs appear to induce the internalization of non- or poorly-internalizing targets, have a differentiated mechanism of action (enzymatic and irreversible ribosome inactivation), have relatively predictable PK and ADME profiles and can be readily manufactured to GMP standards. From a library of antibody targeting domains, Molecular's research and design platform allows for the comprehensive (six to eight weeks) *in vitro* selection of a lead ETB to a given target based on affinity and specificity, potency and expression. Lead selection is confirmed through the use of animal models to verify PK, ADME and potency. ETBs possess potent direct cell killing effects via a differentiated mechanism of action, can force receptor internalization, and can be used to deliver payloads such as foreign class I antigen to the cytosol. MT-3724, Molecular's lead ETB candidate, is being developed for treating B-cell malignancies and utilizes the wild-type SLTA. Because of the immune-compromised nature of patients with B-cell malignancies, Molecular did not believe de-immunization of SLTA was critical in these patients; this hypothesis has been supported by clinical data in DLBCL patients.

In subsequent ETBs, Molecular utilizes a highly potent and proprietarily de-immunized SLTA scaffold that elicits significantly reduced innate and adaptive immunogenic responses as demonstrated in preclinical and animal studies (presented at the 2017 American Association for Cancer Research, or AACR, Annual Meeting). For indications where tumors have been demonstrated to be sensitive to T-cell engagement, Molecular has developed ETBs that deliver foreign class I viral antigens for presentation on the surface of the tumor: Molecular's Antigen Seeding Technology (AST), a differentiated approach to immune-oncology. Molecular is currently building out animal models to further validate and screen ETB candidates support this approach.

Molecular believes that its proprietary ETB technology platform represents a differentiated approach in oncology. ETBs possess the targeting specificity of antibody-based therapeutic approaches but deliver highly potent payloads that disrupt protein synthesis, a fundamental function of a cancer cell, in a manner not subject to traditional chemotherapy resistance mechanisms or target internalization limitations, as with ADCs. Molecular is also seeking to expand the universe of potential targets subject to pharmaceutical treatments by exploiting the ETB's ability to force internalization against receptors that do not normally internalize to MT-3724 highlightsthis capability and approach. MT-3724 targets CD20, which is a canonical non-internalizing receptor that is not susceptible to traditional chemo-based ADC approaches.

Novel mechanisms of action are needed in oncology treatment, and Molecular believes that its ETB platform technology's differentiated mechanisms of action may offer unique benefits over existing treatment modalities.

ETB Product Pipeline

Molecular is developing a pipeline of ETBs that Molecular believes will provide a meaningful and long-lasting benefit to cancer patients. Molecular plans to develop each of these as single agents and/or in combination with other therapies, as applicable. The following table depicts Molecular's current pipeline:

Program	Partner	Indication (Target)	Preclinical	Phase 1	Phase 2	Phase 3
MT-3724	 Millennium MOLECULAR TARGETED THERAPEUTICS	DLBCL ^a monotherapy (CD20)				
	 Millennium MOLECULAR TARGETED THERAPEUTICS	DLBCL combinations (CD20)				
MT-5111	 Millennium MOLECULAR TARGETED THERAPEUTICS	Multiple – solid tumors (HER2)				
TAK-169	  Millennium THE IMMUNOTHERAPY COMPANY	Multiple Myeloma (CD38)				
MT-6035 (antigen seeding)	 Millennium MOLECULAR TARGETED THERAPEUTICS	Multiple – solid tumors (PD-L1)				
Takeda Target 1	  Millennium THE IMMUNOTHERAPY COMPANY	Undisclosed				
Takeda Target 2	  Millennium THE IMMUNOTHERAPY COMPANY	Undisclosed				

^a) Potential for Phase 2 to be pivotal in relapsed/refractory setting as mono therapy

■ Completed ■ In-Progress ■ Planning

MT-3724—ETB Targeting CD20

Overview

CD20 is expressed on 90% of B-cell non-Hodgkin's lymphoma, or NHL, cells and is a non-internalizing receptor. Rituxan (rituximab), an antibody to CD20, is approved for treatment of NHL in both the front and second-line settings. Rituxan has limited direct cell-kill effects against CD20-expressing cells. Instead, it works through indirect methods of recruiting immune responses to CD20-expressing cells through antibody dependent cell-mediated cytotoxicity, or ADCC, and/or complement dependent cytotoxicity, or CDC. Rituxan's indirect cell-kill mechanism's reliance on a favorable tumor microenvironment for immune stimulation is problematic because it allows opportunities for resistance to emerge. Therefore, direct cell-kill approaches that target CD20-expressing lymphomas are attractive. Two such agents are currently approved: the radioisotope-conjugated antibodies Bexxar, developed by GlaxoSmithKline, and Zevalin, developed by IDEC Pharmaceuticals (now part of Biogen), both of which use ionizing radiation to induce direct cell-kill without internalization being necessary. These radioisotope conjugated antibodies are more effective than naked anti-CD20 antibody approaches such as Rituxan and HuMax-CD20 in the relapsed or refractory indolent NHL setting because they are far less dependent on the physiology of the tumor. However, despite their favorable efficacy profile, Bexxar and Zevalin are considered commercial disappointments and have not been widely adopted by oncologists primarily due to the constraints associated with the administration of nuclear medicines. Radioimmunotherapies are difficult to administer, with few institutions licensed for nuclear medicine. Because of these factors, the combined use of Bexxar and Zevalin accounted for only a minimal share of all administered second-line therapies for indolent NHL patients worldwide (seven major markets) despite superior clinical data in this setting. Bexxar was subsequently taken off the market in 2013. Molecular believes this provides a significant opportunity for a CD20-targeting therapy, such as MT-3724, that directly kills cells without the use of radioisotopes, and utilizes a mechanism of action of cell kill that is not subject to cross-resistance with chemotherapy or antibody approaches.

MT-3724 is a ETB specific to the B-cell marker CD20 protein. Molecular developed MT-3724 to provide a non-radioactive means of direct cell-kill targeted to CD20 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. Following the completion of the Phase I dose escalation trial in 2017, Molecular conducted a Phase Ib expansion trial of MT-3724 in patients with relapsed/refractory DLBCL. Molecular recently initiated a Phase II monotherapy study that has the potential to be pivotal as well as a Phase II study of MT-3724 in combination with chemotherapy in earlier lines of DLBCL. In the second quarter of 2019, Molecular is also planning to a Phase II study of MT-3724 in combination with Revlimid.

Clinical Overview

MT-3724 is being developed for the treatment of patients with relapsed or refractory NHL who have failed one or more chemotherapeutics and anti-CD20 antibody therapies and for whom all other approved therapies (biologic, chemotherapeutic or stem cell transplantation) are not an option. The primary objectives of the multicenter Phase I clinical trial of MT-3724 was to assess the tolerability of MT-3724 and to establish the maximum tolerated dose, or MTD of the drug. The secondary objectives of the Phase I clinical trial were to assess the pharmacokinetic profile of MT-3724 after intravenous dosing as well as to assess any biological and clinical activity. This Phase I clinical trial was not designed to show statistical significance of the study endpoints.

Molecular initially filed an IND application with the U.S. Food and Drug Administration, or FDA, on July 31, 2014, and Molecular received the notification from the FDA that it could proceed with the Phase I trial on August 29, 2014 with the first patient dosed in March of 2015. The Phase I trial was a multi-center, open-label, multiple-dose Phase I, dose-escalation study of MT-3724 in subjects with relapsed, refractory B-cell NHL or chronic lymphocytic leukemia, or CLL. A total of 21 patients were treated with MT-3724 with doses ranging from 5 to 100 mcg/kg. Patients were dosed 3 times per week over two weeks (6 doses) followed by a two-week hiatus for the first cycle, as mandated by the FDA. Subsequent cycles were dosed over two weeks with a one-week hiatus. Originally, up to five cycles of treatment were allowed per protocol. This was subsequently amended to allow for extended dosing beyond five cycles.

Twenty-one patients were treated with escalating doses of MT-3724 starting at the 5 mcg/kg dose level. Nearly all patients experienced at least one adverse event, with peripheral edema, diarrhea, myalgia, cough, fatigue, constipation, nausea, anemia, stomatitis, pyrexia, dizziness, headache, insomnia, dyspnea, being the more commonly reported adverse events. During the study, there were no treatment-related deaths.

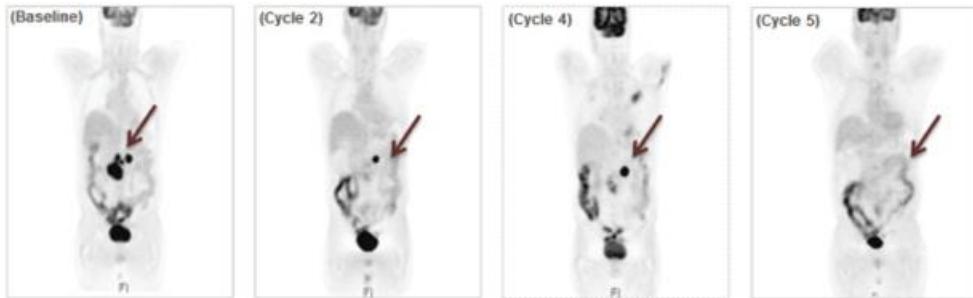
The first two patients treated in the 100 mcg/kg/dose cohort developed signs and symptoms of a systemic inflammatory response (a constellation of adverse events including a grade 2 decrease in serum albumin levels, which together were consistent with capillary leak syndrome) in the first cycle of treatment. Upon thorough evaluation of each case, the Data Monitoring Committee, or DMC, deemed the capillary leak syndrome the DLT and determined that the 100 mcg/kg/dose had exceeded the MTD and the cohort was closed to further enrollment. The symptoms related to the DLT were non-life threatening and resolved upon cessation of dosing MT-3724. Six patients were dosed at a reduced dose level of 75 mcg/kg cohort with no DLTs reported. Upon identifying 75 mcg/kg as the maximum tolerated dose, or MTD, the recommended Phase Ib/II dose was designated to be 75 mcg/kg.

To date, 31 serious adverse events, or SAEs have been reported. Most these events were attributed to exacerbation of a pre-existing condition or disease progression. Both subjects in the 100 mcg/kg/dose cohort were withdrawn in cycle 1 for SAEs which the investigator and DMC assessed as DLTs and determined that the MTD had been exceeded.

Molecular has observed promising signals of single-agent activity with MT-3724. Patients in the Phase I trial were of older age (median age = 67) and heavily pre-treated, with a median of four prior therapies. Those patients with \leq four prior therapies (n=5) were generally chemo-intolerant patients who could not sustain multiple lines of chemo-based regimens. The majority of patients were of the DLBCL subtype (n=15). Of the 14 evaluable DLBCL patients who received MT-3724, eight patients entered the trial with low levels of serum anti-CD20 antibody while six patients had high levels of anti-CD20 antibody. As reported in Molecular's presentation to the 2016 American Society of Hematology Annual Meeting, or the 2016 ASH Meeting, patients with high anti-CD20 antibody did not respond to MT-3724, presumably due to target inaccessibility. In the eight DLBCL patients with low anti-CD20 antibody, the observed objective response rate, or ORR, was 25% (2/8) including a partial response, or PR, and a complete metabolic response, or CMR. Molecular observed clinical responses starting at the lowest dose level of 5 mcg/kg as shown in Figure 4. The patient who achieved a CMR was eligible for and received an allogeneic stem cell transplant, or SCT. Three patients had stable disease, or SD, with tumor reductions of 19%

(10 mcg/kg), 48% (75 mcg/kg), and 49% (100 mcg/kg), respectively. The patient at 100 mcg/kg with 49% tumor reduction had received only a single dose of MT-3724 at the time of measurement. The remaining three patients had progressive disease, or PD. Notably, three of the eight DLBCL patients received fewer than two cycles of MT-3724 due to early withdrawal from the study (including the two patients at the DLT dose of 100 mcg/kg). Significant ADAs were not observed among DLBCL patients and did not appear to neutralize the efficacy of MT-3724 in patients.

Figure 4. PET images for DLBCL patient in the 5 mcg/kg dose cohort



Based on the clinical effect observed among DLBCL patients, Molecular opened a Phase Ib expansion study to further explore the potential of MT-3724 in DLBCL. A brief update on the first three patients dosed in the MT-3724 Phase Ib expansion was delivered at the World ADC Summit Europe on March 28, 2018. Observations included the following:

- One patient was assessed in a partial response (PR) after the first dose of MT-3724. The PR was confirmed at the end of cycle 2 per protocol and the patient remains on study with continued dosing of MT-3724. The other patients were assessed as stable disease (SD) and progressive disease (PD).
- A dose interruption and reduction was required in 2 of the first 3 patients in Phase Ib expansion (including the patient with the PR). These patients had high body weights, which resulted in high absolute doses of MT-3724 based on 75 mcg/kg dosing. The adverse events observed (grade 2 and 3 headache, arthralgia, and myalgia) were non-life threatening and dosing resumed at 50 mcg/kg dose, which has been generally well tolerated.
- Based on these data and the clinical activity of MT-3724 observed at doses as low as 5 mcg/kg, a decision was made to define the MTD of MT-3724 as 50 mcg/kg with a maximum total drug per dose of 6 mg.

Molecular has since enrolled additional patients at the 50 mcg/kg dose. Molecular recently initiated a Phase II monotherapy DLBCL study that has the potential to be pivotal.

Furthermore, Molecular is developing MT-3724 in earlier lines of therapy in combination with chemotherapy and non-chemotherapy based regimens. Molecular recently initiated a Phase IIA study combining MT-3724 with a chemo regimen in transplant-ineligible DLBCL patients. Additionally, a second Phase IIA study evaluating MT-3724 in combination with Revlimid in DLBCL patients is planned to begin in the second quarter of 2019.

Recent Presentations

MT-3724 AACR presentation: In April 2017, Molecular presented preclinical data for Molecular's MT-3724 lead compound at the AACR annual conference. MT-3724 is an ETB with wild-type SLTA and is not de-immunized. Nevertheless, to date, Molecular has not seen a high level of neutralizing antibodies in patients treated with MT-3724, likely because of the nature of their disease (B-cell malignancy) and their prior therapies (B-cell depleting agents), which leave these patients with compromised immune systems. The MT-3724 presentation at AACR demonstrated the reduction in anti-drug antibodies, or ADAs, seen when MT-3724 was co-administered with sirolimus in both murine and non-human primate, or NHP, models. These data may be useful in guiding clinical development of MT-3724 if significant levels of ADAs are seen in patients treated with MT-3724. Additionally, researchers at MD Anderson Cancer Center presented preclinical data on MT-3724 potency against mantle cell lymphoma samples. Researchers demonstrated a substantial survival advantage in a xenograft model using a patient-derived mantle cell lymphoma.

TAK-169—ETB Targeting CD38

Overview

CD38 is a single-chain type II transmembrane glycoprotein that is expressed by a variety of hematologic cells in an activation- and differentiation-dependent manner. Its cellular functions are involved in the regulation of cell proliferation and survival. CD38 is expressed at high rates on patient myeloma samples, making it an important marker and potential target in the development of targeted biologics.

Daratumumab (trade name Darzalex®) received FDA approval for the treatment of multiple myeloma in 2015. Daratumumab is a monoclonal antibody that binds CD38 on multiple myeloma cells and induces cell death indirectly. Approval was supported by a Phase II pivotal trial in fourth line myeloma patients and subsequent randomized studies in earlier lines of myeloma therapy. A careful analysis of this study's results reveals that CD38 expression persists after patients have progressed on daratumumab and that the myeloma cells of patients who relapsed after daratumumab treatment showed an increase in cell surface receptors (CD55 and CD59) that inhibit daratumumab's ability to recruit an immune response to the myeloma cells (Nijhof *et al.*, 2016). Persistence of a surface marker that is central to disease strongly suggests that a different modality targeting that surface marker and that is not cross-resistant to antibody therapy may provide substantial clinical benefit in myeloma.

Despite cell specific expression, an ADC approach to CD38 has not been developed, likely because CD38 does not efficiently internalize, thereby limiting the amount of drug that could be delivered to myeloma cells. Because SLTA can force its own internalization and enzymatically inhibit ribosome function thereby killing the cell, Molecular theorized that the engineering of a potent and specific ETB targeted to CD38 could overcome the lack of internalization seen with CD38.

Molecular was developing MT-4019, an ETB that specifically targets CD38. Upon signing the collaboration agreement with Takeda in September 2018, TAK-169, an ETB that was jointly discovered with Takeda became the lead CD38 ETB. The compound was evaluated in many of the same preclinical assays as daratumumab. Daratumumab is an anti-cancer drug originally developed by Genmab. The mechanism of action of TAK-169 is wholly different than daratumumab, and Molecular believes that TAK-169 may be active in CD38+ myeloma patients that have failed treatment with an anti-CD38 antibody.

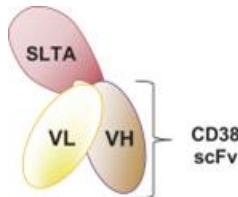
The proposed development plan for TAK-169 is modeled on that of daratumumab. After a robust response rate in its Phase I trial, daratumumab was granted Breakthrough Therapy Designation, and its expanded Phase II trial (N=106) was considered sufficient for registration. If similar efficacy is seen with TAK-169, Molecular believes it may be possible to pursue a similar accelerated approval strategy via a Phase II clinical trial.

Preclinical Data with TAK-169

TAK-169 Structure

TAK-169 utilizes Molecular's updated scaffold in which the fusion of the scFv to the SLTA has been optimized and in which the SLTA portion of the ETB has been de-immunized. TAK-169 has high affinity for the CD38 receptor and potent and specific cell-kill activity against CD38-expressing cells.

Figure 5. TAK-169 Drug Product



De-immunized SLTA scaffold

The host immune response to bacterial proteins used in the treatment of solid tumors has historically prevented prolonged dosing and limited the utility of immunotoxins as a class of molecules. There has been much greater success with immunotoxins in hematological malignancies, as patients tend to be immunosuppressed due both to the nature of their disease and the drugs used in treatment (Kreitman *et al.*, 2006). Multiple myeloma patients show a decreased immune response to bacterial proteins (Jacobson, *et al.*, 1986), and Molecular has further reduced the likelihood of high levels of neutralizing antibodies by using its proprietary de-immunized SLTA, as shown in Molecular's MT-4019 presentation at the 2017 AACR Annual Meeting. TAK-169 also utilizes Molecular's de-immunized SLTA scaffold.

Clinical and Regulatory Plan

Molecular has begun to pursue GMP manufacturing for MT-TAK-169. Molecular has substantial expertise with the GMP manufacture of ETBs based on its successful production of MT-3724. Molecular has a non-GMP facility in-house and has conducted seven GMP campaigns with MT-3724. From its experience with MT-3724, Molecular believes it can transfer expression of TAK-169 and complete manufacturing for GLP toxicity studies within six months. Based on expression and process improvements, TAK-169 is expected to have similar or better yields than MT-3724.

Molecular and Takeda initiated IND-enabling studies to fully characterize TAK-169 based on toxicology and pharmacology in 2018. Molecular and Takeda expect to initiate a Phase I clinical trial for TAK-169 in 2019. Molecular was awarded a \$15.2 million grant from CPRIT for the development of CD38 targeted ETBs.

Upcoming Presentations

TAK-169 AACR presentation. Molecular Templates plans to present on its CD38-targeted ETB, TAK-169 at the AACR Meeting in April 2019. TAK-169 has demonstrated potent cytotoxicity across a range of myeloma cell lines with a range of CD38 expression *in vitro* as well as in patient-derived samples including those with previous exposure to daratumumab. Furthermore, TAK-169 retains activity in the presence of excess approved, CD38 targeted therapeutic daratumumab. In xenograft models, complete regressions were observed using both a weekly and bi-weekly schedule of TAK-169. Tolerability studies in non-human primates demonstrate that repeat administration is tolerated at doses that are expected to be efficacious.

ETB Pipeline

Molecular has launched additional programs against the key targets HER2 and PD-L1. Molecular selected HER2 as a target because of its validated role in breast cancer. Targeting HER2 with different modalities (antibody, small molecule and ADC) has shown clinical benefit, and the target is known to persist after a given modality has failed. The clinical results seen with Kadcyla (an ADC to HER2) strongly suggests that a direct cell-kill approach to HER2 can provide significant benefit and be well tolerated in patients. Molecular believes that attacking HER2-expressing tumor cells with a differentiated mechanism of destruction may provide meaningful clinical benefits, even in patients whose disease has progressed on other HER2-targeted modalities. Molecular's lead HER2 ETB, MT-5111, has shown potent picomolar activity in Kadcyla insensitive HER2+ cell lines and has shown additive or synergistic benefit with Kadcyla *in vitro* in HER2+ cell lines.

PD-L1 is a focal point for immuno-oncology checkpoint antibodies; its expression on tumors is known to downregulate CD8 T-cell activity against tumor cells. In Molecular's ETB program targeting the PD-L1 receptor, Molecular has focused on targeting PD-L1 with a direct cell-kill approach rather than using it to induce an immune response. In addition, Molecular has integrated its Antigen Seeding Technology to the PD-L1 targeting ETB in order to induce targeted tumors to express CMV antigen in context with MHC-I on the tumor cell surface thereby redirecting an endogenous CMV-specific T-cell response to the tumor. Molecular believes that targeting PD-L1 expressing tumors via this dual mechanism of ribosome-inactivation and redirected immunity via CMV-specific T-cell response represents a novel mechanism of action against PD-L1 expressing tumors.

ETB Research & Development Partnerships

Takeda Pharmaceuticals

Takeda Collaboration and Individual Project Agreements

In October 2016, we entered into a collaboration and option agreement with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Ltd., or Takeda, to discover and develop CD38-targeting ETBs, which included MT-4019 for evaluation by Takeda (the “Takeda Collaboration Agreement”). Under the terms of the agreement, we were 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. We granted Takeda an exclusive option to negotiate an exclusive worldwide license agreement to develop and commercialize any ETB that may result from this collaboration, including MT-4019. We were entitled to receive up to \$2.0 million in technology access fees and cost reimbursement associated with our performance and completion of our obligations under the agreement. To date, we have received \$2.0 million under this agreement.

In connection with the Takeda Collaboration Agreement, we entered into an Individual Project Agreement (the “Takeda Individual Project Agreement”) with Takeda in June 2018 that was subsequently amended in July 2018. Under the Takeda Individual Project Agreement, we are responsible to perform certain research and development services relating to Chemistry, Manufacturing, and Controls (“CMC”) work for three potential lead ETBs targeting CD38. In consideration of these services, we will receive up to \$2.2 million in compensation. During the year ended December 31, 2018, we have received approximately \$2.0 million under the Takeda Individual Project Agreement.

Takeda License Agreement

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

Pursuant to the License Agreement, we will initially co-develop with Takeda one or more of the Licensed Products up to and including Phase Ia clinical trials, with us having an option to continue to co-develop the Licensed Products following Phase Ia clinical trials. We may exercise our co-development option within a specified time period following completion of the Phase Ia clinical trials with no additional fee by providing written notice of exercise to Takeda, provided we have paid all co-development costs due pursuant to the License Agreement as of the date of such exercise. Pursuant to the terms of the License Agreement, Takeda will be responsible for all regulatory activities and commercialization of the Licensed Products. We have granted Takeda specified intellectual property licenses to enable Takeda to perform its obligations and exercise its rights under the License Agreement, including exclusive license grants to enable Takeda to conduct development, manufacturing, and commercialization activities pursuant to the terms of the License Agreement.

Pursuant to the License Agreement, Takeda made an upfront payment of \$30.0 million to us. In addition to the upfront fee, if we exercise our co-development option and fund our share of development costs, we may receive up to an additional \$307.5 million in milestone payments upon the achievement of certain development and regulatory milestone events and up to an additional \$325 million in milestone payments upon the achievement of certain sales milestone events. If we do not exercise our co-development option, we may receive up to an additional \$162.5 million in milestone payments upon the achievement of certain development and regulatory milestone events and up to an additional \$175 million in milestone payments upon the achievement of certain sales milestone events. We will also be entitled to receive tiered royalties, subject to certain reductions, as percentages of annual aggregate net sales, if any, of Licensed Products. The royalty percentages would range from low double-digits to low twenties if we exercise our option to co-develop, and from high-single digits to low teens if we do not exercise its option to co-develop.

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

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

Takeda Multi-Target Agreement

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

Under the Takeda Multi-Target Agreement, Takeda has an option during an option period to obtain an exclusive license under our intellectual property to develop, manufacture, commercialize and otherwise exploit ETBs against the designated targets. The option period for each target ends three months after the completion of the evaluation of such designated target. Under the Takeda Multi-Target Agreement, both parties have the right to terminate the agreement, with a specified notice period.

We received an upfront fee of \$1.0 million and an additional \$2 million following the designation of each of the two targets in December 2017. As of December 31, 2018, we have received \$5.0 million from Takeda pursuant to the Takeda Multi-Target Agreement.

We may also receive an additional \$25.0 million in aggregate through the exercise of the option to license ETBs. Additionally, we may also be entitled to receive clinical development milestone payments of up to approximately \$397.0 million, for achievement of development milestones and regulatory approval of collaboration products under the Takeda Multi-Target Agreement. We may also be entitled to receive commercial milestone payments of up to \$150.0 million, for achievement of pre-specified sales milestones related to net sales of all collaboration products under the Takeda Multi-Target Agreement. We are also entitled to tiered royalty payments of a mid-single to low-double digit percentage of net sales of any licensed ETBs, subject to certain reductions. Finally, we are entitled to receive up to \$10.0 million in certain contingency fees.

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

Other Research & Development Collaborations

Henry M. Jackson Foundation

In July 2014, Molecular entered into a non-exclusive license agreement with the Henry M. Jackson Foundation for certain biological materials for use in conjunction with the development of Molecular’s lead clinical stage ETB MT-3724. Under the terms of the agreement, Molecular is required to pay the Henry M. Jackson Foundation aggregate payments totaling \$110,000 with respect to this license, upon completion of certain clinical milestones.

CPRIT Grant Contract

On September 18, 2018, we entered into a Cancer Research Grant Contract (the “CPRIT Agreement”) with CPRIT, in connection with a grant of approximately \$15.2 million awarded by CPRIT to us in November 2016 to fund research of a cancer therapy involving an ETB that is targeting CD38 (MT-4019) (the “Award”). Pursuant to the CPRIT Agreement, we may also use such funds to develop a replacement CD38 targeting ETB, with or without a partner. The Award is contingent upon funds being available during the term of the Agreement and subject to CPRIT’s ability to perform its obligations under the Agreement as well as our progress towards achievement of specified milestones, among other contractual requirements. In November 2011, Private Molecular was awarded a \$10.6 million product development grant from CPRIT for its CD20-targeting ETB MT-3724.

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

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

The CPRIT Agreement will terminate, with certain obligations extending beyond termination, on the earlier of (a) May 31, 2019 or (b) the occurrence of any of the following events: (i) by mutual written consent of the parties, (ii) by CPRIT for an Event of Default (as defined in the CPRIT Agreement) by us, (iii) by CPRIT if allocated funds should become legally unavailable during the term of the CPRIT Agreement and CPRIT is unable to obtain additional funds or (iv) by us for convenience. CPRIT may approve a no cost extension for the CPRIT Agreement for a period not to exceed six months after the termination date if additional time is required to ensure adequate completion of the approved project, subject to the terms and conditions of the CPRIT Agreement.

Manufacturing

Molecular has built a GMP manufacturing facility located in Austin, TX to supply future clinical trial materials for internal and partnered ETB programs. Molecular relies in part on third-party contract manufacturing organizations, or CMOs, to manufacture and supply Molecular with GMP drug substance and drug product materials to support Molecular's clinical trials. The manufacturing processes for MT-3724, TAK-169 and other preclinical ETB candidates have been developed by Molecular's manufacturing staff. Once a process is developed and defined for an ETB, it is transferred to CMOs to scale-up and optimize for manufacturing that conforms to current GMP, or cGMP, standards. Molecular is building a GMP manufacturing facility located in Austin, TX to supply future clinical trial materials for internal and partnered ETB programs.

Molecular has established well-defined, cost efficient manufacturing under GMP, including bioanalytical, quality control and quality assurance, logistics, distribution and supply chain management. After manufacturing, Molecular's ETB candidates are tested and released by Molecular's analytical and quality systems staff in conjunction with some select contract research organizations, or CROs. The quality control organization performs a series of release assays designed to ensure that the product meets all applicable specifications. Molecular's quality assurance staff also reviews manufacturing and quality control records prior to batch release in an effort to assure conformance with cGMP as mandated by the FDA and foreign regulatory agencies.

Molecular's manufacturing staff is trained and routinely evaluated for conformance to rigorous manufacturing procedures and quality standards. This oversight is intended to ensure compliance with FDA and foreign regulations and to provide consistent ETB output. Molecular's quality control and quality assurance staff is similarly trained and evaluated as part of Molecular's effort to ensure consistency in the testing and release of the product, as well as consistency in materials, equipment and facilities.

For the purposes of internal research and support for Molecular's ongoing collaborations, Molecular has small scale manufacturing capabilities that are sufficient to manufacture drug materials for preclinical research.

Evofofamide

Overview

Evofofamide is a prodrug designed to be activated under hypoxic conditions commonly found in the tumor microenvironment. Within regions of tumor hypoxia, evofofamide releases bromo isophosphoramide mustard (Br-IPM), a potent DNA alkylating agent that kills tumor cells by forming DNA crosslinks. Once activated in hypoxic tissues, Br-IPM can also diffuse into surrounding oxygenated regions of the tumor and kill cells there via a "bystander effect". Because of its preferential activation in the targeted hypoxic regions of solid tumors, evofofamide may be less likely to produce broad systemic toxicity seen with untargeted cytotoxic chemotherapies.

Clinical Overview

The Company has a collaboration with the MD Anderson Cancer Center which presented preclinical data on evofofamide in combination with immune checkpoint inhibitor antibodies. The data highlighted the promise of evofofamide to improve the efficacy of this class of immuno-oncology therapeutics. Immune checkpoint inhibitors are potent anti-cancer therapies that unleash an immune system attack on cancer cells. Molecular Templates has initiated a clinical trial in various solid tumors evaluating evofofamide in combination with one or more checkpoint inhibitor antibodies.

Intellectual Property Portfolio

Molecular seeks to protect proprietary rights to its platform technologies through a combination of patents and patent applications, trade secrets and know-how. Molecular's platform technologies include ETBs directed to specific molecular targets, in which a Shiga toxin A subunit construct is linked to immunoglobulin domains directed to the molecular target, and their uses for treating cancer, killing cancer cells and selectively delivering payload molecules into target cells. Molecular's platform technologies also include various ETB scaffolds regardless of target, and the Shiga toxin components of ETBs, including improved Shiga toxin A subunit constructs having disruptions of B-cell epitopes and/or T-cell epitopes for reduced immunogenicity when used in ETB scaffolds.

To cover its proprietary technologies and its current pipeline of proprietary ETB products and related methods, such as methods of use, Molecular has filed patent applications representing 13 international patent families, together covering 102 pending regional and national applications worldwide, including 14 pending U.S. patent applications and 91 foreign patent applications currently pending in the regional European Patent Office and nine other jurisdictions outside of the U.S. and Europe (Australia, Canada, China, Hong Kong, Israel, India, Japan, Mexico, and South Korea). Patents have granted from four of these international patent families, including in Australia, Europe, and Japan.

Molecular's patent families covering ETBs and modified ETB scaffolds for the targeted killing of cancer cells or for the selective delivery of molecules into a target cell include 13 internationally filed patent families. Patent rights in these patent families, if granted, will expire without extension in 2034–2038. Molecular also has a patent family directed to the screening of large ETB libraries, in which patent rights, if granted, will expire without extension in 2035. With respect to its ETB pipeline, Molecular's lead compound which targets CD20, MT-3724, and pharmaceutical compositions and uses of MT-3724, are covered by three international patent families. Patent rights in these patent families, if granted, will expire without extension in 2034 and 2036. Molecular's current pipeline also includes ETBs which target CD38, HER2, and PD-L1, covered by numerous patent applications, including one international patent family from which patent rights, if granted, will expire without extension in 2036.

As of December 31, 2018, Molecular owned 99 U.S. and foreign patents and patent applications relating to hypoxia-activated prodrugs and their manufacture, formulation and use, including covering the investigational prodrug evofosfamide currently in clinical development for treating cancer. These include 11 issued U.S. patents expiring from 2024 to 2031 and 59 issued foreign patents expiring from 2024 to 2036 (in each case, without extension), as well as four pending U.S., one pending Patent Cooperation Treaty and 19 pending foreign national patent applications, which, if issued, would in each case expire from 2024 to 2037 (without extension).

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, such as MT-3724, TAK-169, and any future product candidates. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Drug Development

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations and biologics under the FDCA, the Public Health Service Act, or PHS, and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on Molecular. MT-3724, TAK-169 and any ETB product candidates must be approved by the FDA through either a New Drug Application, or NDA, or Biologics Licensing Application, BLA, process before they may be legally marketed in the United States. The process generally involves the following:

- Completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;
- Submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- Approval by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before a trial may be initiated at that site;
- Performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice requirements, or GCP, and other clinical trial-related requirements to establish the safety and efficacy of the investigational product for each proposed indication;
- A determination by the FDA within 60 days of its receipt of an NDA or BLA that the NDA or BLA is sufficiently complete to permit a substantial review, in which case the NDA or BLA is filed;
- Satisfactory completion of a FDA pre-approval inspection of the manufacturing facility or facilities where the drug or biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug or biologic's identity, strength, quality and purity;
- Potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA or BLA; and
- FDA review and approval of the NDA or BLA, including consideration of the views of an FDA advisory committee, if one was involved, prior to any commercial marketing or sale of the drug or biologic in the United States.

The preclinical testing, clinical trials and the approval process requires substantial time, effort and financial resources, and Molecular cannot be certain that any approvals for MT-3724, TAK-169 and any future product candidates will be granted on a timely basis, or at all. The data required to support an NDA or BLA are generated in two distinct developmental stages: preclinical and clinical. The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational new drug to humans and must become effective before human clinical trials may begin.

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB at each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Preclinical Studies and IND

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of effects on reproduction and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions and places the IND on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials

Clinical trials generally are conducted in three sequential phases, known as Phase I, Phase II and Phase III, which may overlap.

- Phase I clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.
- Phase II clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- Phase III clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase IV clinical trials as a condition of approval of an NDA or BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or in vitro testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies may perform additional animal studies and develop additional information about the chemistry and physical characteristics of the drug or

biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that MT-3724, TAK-169 and any future product candidates do not undergo unacceptable deterioration over their shelf life.

NDA/BLA and FDA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA or BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. In short, the NDA or BLA is a request for approval to market the drug or biologic for one or more specified indications and must contain proof of safety and efficacy for a drug or safety, purity and potency for a biologic. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA or BLA must be obtained before a drug or biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA or BLA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes annual prescription drug product program fees and an annual establishment fee on facilities used to manufacture prescription drugs and biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business (fewer than 500 employees). Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs and BLAs before it accepts them for filing, or it may refuse to file the application and request additional information. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its initial review of a new molecular-entity (NME) or non NME NDA or original BLA and respond to the applicant, and six months from the filing date of a NME NDA or original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs or BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving an NDA or BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The Complete Response Letter may require additional clinical data, including additional pivotal Phase III clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than Molecular interpret the same data.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria. Specifically, new drugs and biologics are eligible for fast track designation if they are intended to treat a serious or life threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast track status any time before receiving NDA or BLA approval, but ideally no later than the pre-NDA or pre-BLA meeting.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biologic designated for priority review in an effort to facilitate the review. A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product.

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, an NDA or BLA or supplement to a NDA or BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act, or FDASIA, amended the FDCA to require that a sponsor who is planning to submit a marketing application

for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase II meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase III or Phase II/III study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

Post-marketing Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, and complying with promotion and advertising requirements, which include restrictions on promoting approved drugs for unapproved uses or patient populations (known as “off-label use”). Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require additional data from preclinical studies or clinical trials.

The FDA may also place other conditions on approvals including the requirement for REMS to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing. FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. Molecular rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of Molecular's products in accordance with cGMPs. These manufacturers must comply with cGMPs that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including recall.

Companion Diagnostics and Complementary Diagnostics

Molecular believes that the success of Molecular's product candidates may depend, in part, on the development and commercialization of either a companion diagnostic or complementary diagnostic. Companion diagnostics and complementary diagnostics can identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics and complementary diagnostics are regulated as medical devices by the FDA. The level of risk combined with available controls to mitigate risk determines whether a companion diagnostic device requires Premarket Approval Application, or PMA, approval or is cleared through the 510(k) premarket notification process. For a novel therapeutic product for which a companion diagnostic device is essential for the safe and effective use of the product, the companion diagnostic device should be developed and approved or 510(k)-cleared contemporaneously with the therapeutic. The use of the companion diagnostic device will be stipulated in the labeling of the therapeutic product.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval may also be subject to regulation by other regulatory authorities in the United States in addition to the FDA. Depending on the nature of the product, those authorities may include the CMS, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, OSHA, the Environmental Protection Agency and state and local governments.

For example, in the United States, sales and marketing must comply with state and federal fraud and abuse laws. These laws include the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, the Patient Protection and Affordable Care Act, or ACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes created by the Health Insurance Portability and Accountability Act of 1996, or HIPAA. A person or entity no longer needs to have actual knowledge of the 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.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against Molecular for violation of these laws, even if Molecular successfully defend against it, could cause Molecular to incur significant legal expenses and divert Molecular's management's attention from the operation of Molecular's business. Prohibitions or restrictions on sales or withdrawal of future products marketed by Molecular could materially affect Molecular's business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact Molecular's business in the future by requiring, for example: (i) changes to Molecular's manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of Molecular's products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of Molecular's business.

U.S. Patent-term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of MT-3724, TAK-169 and any future product candidates, some of Molecular's U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, Molecular may apply for restoration of patent term for Molecular's currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of a NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for a NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the ACA. This amendment to the PHSAA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Complexities associated with the larger, and often more complex, structure of biological products as compared to small molecule drugs, as well as the processes by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Whether a subsequent application, if approved, warrants exclusivity as the “first licensure” of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods. This six-month exclusivity, which attaches to both the twelve-year and four-year exclusivity periods for reference biologics, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued “Written Request” for such a trial. Furthermore, a biological product seeking licensure as biosimilar to or interchangeable with a reference product indicated for a rare disease or condition and granted seven years of orphan drug exclusivity may not be licensed by the FDA for the protected orphan indication until after the expiration of the seven-year orphan drug exclusivity period or the 12-year reference product exclusivity, whichever is later.

European Union Drug Development

In the European Union, Molecular’s future products also may be subject to extensive regulatory requirements. As in the United States, drugs, which are referred to as medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated, a clinical trial application must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred. The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency.

European Union Drug Review and Approval

In the European Economic Area, or EEA, which is comprised of the 27 Member States of the European Union (including Norway and excluding Croatia), Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

European Union New Chemical Entity Exclusivity

In the European Union, new chemical entities, sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies.

European Union Orphan Designation and Exclusivity

In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the European Union community (or where it is unlikely that the development of the medicine would generate sufficient return to justify the investment) and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or, if a method exists, the product would be a significant benefit to those affected).

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Rest of the World Regulation

For other countries outside of the European Union and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If Molecular fail to comply with applicable foreign regulatory requirements, Molecular may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Reimbursement

Sales of Molecular's products will depend, in part, on the extent to which Molecular's products will be covered by third-party payors, such as government health programs, commercial insurance and managed care organizations. In the United States no uniform policy of coverage and reimbursement for drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of Molecular's products will be made on a payor-by-payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require Molecular to provide scientific and clinical support for the use of Molecular's products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Congress and President Trump have expressed their intention to repeal or replace the ACA. If that is done, many if not all of the provisions of the ACA may no longer apply to prescription drugs.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which Molecular receive marketing approval. However, any negotiated prices for Molecular's products covered by a Part D prescription drug plan likely will be lower than the prices Molecular might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

As noted above, the marketability of any products for which Molecular receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. An increasing emphasis on cost containment measures in the United States has increased and Molecular expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which Molecular receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of Molecular's products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Competition

Molecular competes directly with companies that focus on oncology as well as companies dedicating their resources to novel forms of cancer therapies. Molecular also faces competition from academic research institutions, governmental agencies and various other public and private research institutions. With the proliferation of new drugs and therapies into oncology, Molecular expects to face increasingly intense competition as new technologies become available. Any ETB candidates that Molecular successfully develops and commercializes will compete with existing therapies and new therapies that may become available in the future.

Many of Molecular's competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than Molecular does. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of Molecular's competitors. Smaller or early-stage companies also may prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with Molecular in recruiting and retaining top qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, Molecular's programs.

The key competitive factors affecting the success of all of Molecular's ETB candidates, if approved, are likely to be their efficacy, safety, dosing convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Molecular's commercial opportunity could be reduced or eliminated if its competitors develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe effects than any products that Molecular may develop. Molecular's competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than Molecular may obtain approval for its products, which could result in Molecular's competitors establishing a strong market position before Molecular is able to enter the market. Even if Molecular's ETB candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then.

In addition to currently marketed therapies, there are also a number of products in late-stage clinical development directed to the same biological targets as Molecular's programs, including antibodies, antibody drug conjugates and bi-specific antibodies.

- Approved antibody-based products targeting CD20 include rituximab (Genentech/Roche), ofatumumab (Novartis), obinutuzumab (Genentech/Roche) and ibritumomab tiuxetan (Spectrum Pharmaceuticals).
- Antibody-based products, including bi-specific antibodies, and antibody targeting T-cell approaches targeting CD20 in development include veltuzumab (Immunomedics), ocaratuzumab (Mentrik Biotech), REGN1979 (Regeneron Pharmaceuticals), RG7828 (Genentech/Roche), XmAb13676 (Novartis/Xencor) and CD3-CD20 Duobody (Genmab), ATTCK20 (Unum Therapeutics).
- The approved antibody-based product targeting CD38 is daratumumab (Janssen/Genmab).
- Antibody-based products, including bi-specific antibodies, targeting CD38 in development include MOR02 (Morphosys), isatuximab (Sanofi) and XmAb13551 (Amgen/Xencor).
- Approved antibody-based products, including antibody drug conjugates, targeting HER2 include trastuzumab, pertuzumab, and trastuzumab emtansine (all from Genentech/Roche) and DS-8201 (Daiichi Sankyo).
- Antibody-based products, including bi-specific antibodies, targeting HER2 in development include margetuximab (Macrogenics), MEDI4276 (AstraZeneca), MM-111 (Merrimack Pharmaceuticals), FS102 (Bristol-Myers Squibb/F-star) and MCLA-128 (Merus).
- Approved antibody-based products targeting PD-L1 include atezolizumab (Genentech/Roche) and avelumab (Merck KGaA/Pfizer).
- Antibody-based products targeting PD-L1 in development include durvalumab (AstraZeneca), LY3300054 (Lilly) and BMS-936559 (Bristol-Myers Squibb).

Employees

As of December 31, 2018, Molecular had 68 full-time employees. 20 of Molecular's employees have Ph.D., PharmD or M.D. degrees, and 16 of Molecular's employees are engaged in research and development activities. None of Molecular's employees are subject to a collective bargaining agreement. Molecular believes that Molecular has good relations with Molecular's employees.

Corporate Information

On August 1, 2017, we completed our business combination with Molecular Templates OpCo, Inc., or what was then known as "Molecular Templates, Inc." ("Private Molecular"; formerly D5 Pharma Inc., a Delaware corporation incorporated on February 19, 2009), 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, now "Molecular Templates OpCo, Inc." (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.

Immediately after the Merger, there were approximately 18,164,843 shares of our common stock outstanding. Immediately after the Merger, the former Private Molecular stockholders, warrant holders and option holders owned approximately 65.6% of our fully-diluted common stock, with the Threshold's stockholders and warrant holders immediately prior to the Merger, whose warrants and shares of the common stock remain outstanding after the Merger, owning approximately 34.4% of our fully-diluted common stock.

Molecular and Molecular Templates OpCo, Inc. each have a principal executive office at 9301 Amberglen Boulevard, Suite 100, Austin, Texas 78729 and telephone number (512) 869-1555.

Available Information

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Exchange Act. The SEC maintains an Internet site that contains reports, proxy information and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is <http://www.sec.gov>. The materials are also available at the SEC's Public Reference Room, located at 100 F Street, Washington, D.C. 20549. The public may obtain information through the public reference room by calling the SEC at 1-800-SEC-0330.

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports on the day of filing with the SEC on our website at <http://www.mtem.com> or by contacting the Investor Relations Department at our corporate offices by calling (512) 869-1555. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this annual report on Form 10-K.

ITEM 1A. RISK FACTORS

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

Risks Related to Our Financial Condition and Capital Requirements

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

We are a clinical development-stage biopharmaceutical company with a limited operating history. We have incurred net losses in each year since 2009, including net losses attributable to common shareholders of \$30.3 million for year ended December 31, 2018. As of December 31, 2018, we had an accumulated deficit of \$94.7 million.

As of December 31, 2018, we had cash, cash equivalents and marketable securities of \$98.0 million. In August 2017, we raised approximately \$60.0 million through private placements of our common stock and warrants to purchase our common stock. In September 2018, we completed an underwritten public offering of 9,430,000 shares of common stock at an offering price of \$5.50 per share, which included the exercise in full by the underwriters of their option to purchase up to 1,230,000 additional shares of common stock. We received net proceeds of approximately \$48.1 million, after deducting underwriting discounts, commissions and estimated offering related transaction costs. We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to the Development of Our Product Candidates

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

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

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

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

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

- capacity of manufacturing facilities;
- contamination of drug candidates in the manufacturing process;
- natural or other disasters, including hurricanes, earthquakes, volcanoes or fires;
- labor disputes or shortages, including the effects of health emergencies or natural disasters;
- compliance with regulatory requirements;
- changes in forecasts of future demand;
- timing and actual number of production runs and production success rates and yields;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Identifying and 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 II combination study of MT-3724 with GEMOX includes patients with non-Hodgkin's lymphoma. The estimated incidence of non-Hodgkin's lymphoma in the United States is 74,680 new cases and approximately 19,910 deaths were attributable to non-Hodgkin's B-cell lymphomas in 2018. We may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical trials in a timely manner because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, and the willingness of physicians to participate in our planned clinical trials. If patients are unwilling to participate in our clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of our product candidates may be delayed.

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

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

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

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

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

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

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

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

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

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

ETB therapy remains a novel technology, with no ETB therapy product approved to date in the United States or elsewhere worldwide. Public perception may be influenced by claims that ETB therapy is unsafe, and ETB therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians who specialize in the treatment of the diseases targeted by our product candidates prescribing treatments that involve the use of one or more of our approved product candidates in lieu of, or in addition to, existing treatments with which they 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 in ETB clinical trials for our competitors' products, even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

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

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

Moreover, clinical data is often susceptible to varying interpretations and analyses. We do not know whether any Phase I, Phase II, Phase III or other clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety with respect to the proposed indication for use sufficient to receive regulatory approval or market our 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, we may forego or delay pursuit of opportunities with some programs or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or more profitable market opportunities. Our spending on current and future research and development programs and future product candidates for specific indications may not yield any commercially viable products. We may also enter into additional strategic collaboration agreements to develop and commercialize some of our programs and potential product candidates in indications with potentially large commercial markets. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaborations, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to current good manufacturing practices, or cGMP, regulations and corresponding foreign regulatory manufacturing requirements. As such, we and our CMOs will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any 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. In addition, if the FDA, EMA or a comparable foreign regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and record keeping for the products will be subject to extensive and ongoing regulatory requirements. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit for our products. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval.

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

- impose restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- impose fines or issue warning letters;

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

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

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Health Care and Education Reconciliation Act of 2010, which amended the Patient Protection and Affordable Care Act, or collectively the ACA, was passed. The ACA was intended to substantially change the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of specified branded prescription drugs, and promotes a new Medicare Part D coverage gap discount program.

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

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

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we will receive for any approved product. Any reduction in payments from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

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

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

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be subject to various federal and state fraud and abuse laws, including, the federal Anti-Kickback Statute, the federal False Claims Act, and physician 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;
- the Health Insurance Portability and Accountability Act of 1996, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the federal physician payment transparency requirements, sometimes referred to as the “Sunshine Act” under the ACA, which requires manufacturers of drugs, devices, biologics and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including governmental and private payors, to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

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

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

- require repayment of all or a portion of the grant proceeds, in certain cases with interest, in the event we violate certain covenants pertaining to various matters that include any potential relocation outside of the State of Texas, failure to achieve certain milestones or to comply with terms relating to use of grant proceeds, or failure to comply with certain laws;
- terminate agreements, in whole or in part, for any reason or no reason;
- reduce or modify the government’s obligations under such agreements without the consent of the other party;
- claim rights, including certain intellectual property rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose 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 2018 CPRIT Award, we are required to pay CPRIT a percentage of our revenues from sales of products directly funded by CPRIT, or received from our licensees or sub licensees, at a percentage in the low to mid-single digits until the aggregate amount of such payments equals 400% of the funds we receive from CPRIT, and thereafter at a rate of one-half percent.

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

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

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent our product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business rely, which could negatively impact our business.

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the US government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Intellectual Property

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

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

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

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

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

- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we or our current or future collaboration partners do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in major commercial markets; or
- we or our current or future collaboration partners may not develop additional proprietary technologies or products that are patentable.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technology without infringing the patent rights of third parties. We are currently not aware of U.S. or foreign patents or pending patent applications owned by third parties that cover our ETB product candidates or therapeutic uses of those ETB product candidates. In the future, we may identify such third-party U.S. and non-U.S. issued patents and pending applications. If we identify any such patents or pending applications, we may in the future pursue available proceedings in the United States 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 intellectual property rights necessary to develop our ETB technologies or to commercialize our product candidates and associated methods of use through acquisitions and in-licenses.

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

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

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

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

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

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

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

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

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

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

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

We are subject to data protection laws and regulations that address privacy and data security. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information.

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

Risks Related to Our Reliance on Third Parties

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

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

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

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

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

In addition, 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, because the number of qualified potential manufacturers is limited. Following BLA approval, a change in the manufacturing site could require additional approval from the FDA. This approval would require new testing and compliance inspections;
- our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- our future third-party manufacturers may not perform as contractually 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;
- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and some state agencies to ensure strict compliance with cGMPs and other U.S. and corresponding foreign requirements, and we do not have control over third-party manufacturers' compliance with these regulations and standards;
- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates; and
- our third-party manufacturers could breach or terminate their agreement with us.

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

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

In September 2018, we expanded our collaboration with Takeda, focused on the development collaboration of the parties regarding CD38 SLT-A fusion proteins, including MT-4019, by entering into the License Agreement. The primary objective of the strategic alliance is to advance novel therapies for indications associated with oncology, particularly multiple myeloma patients.

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

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

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

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

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

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

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

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

- collaborators often have significant discretion in determining the efforts and resources that they will apply to the collaboration, and may not commit sufficient resources to the development, marketing or commercialization of the product or products that are subject to the collaboration;
- collaborators may not perform their obligations as expected;
- any such collaboration may significantly limit our share of potential future profits from the associated program, and may require us to relinquish potentially valuable rights to our current product candidates, potential products or proprietary technologies or grant licenses on terms that are not favorable to us;
- collaborators may cease to devote resources to the development or commercialization of our product candidates if the collaborators view our product candidates as competitive with their own products or product candidates;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of product candidates, and might result in legal proceedings, which would be time consuming, distracting and expensive;
- collaborators may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from the collaboration;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- the collaborations may not result in us achieving revenues sufficient to justify such transactions; and
- collaborations may be terminated and, if terminated, may result in a need for us to raise additional capital to pursue further development or commercialization of the applicable product candidate.

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

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

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

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

Risks Related to Commercialization of Our Product Candidates

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

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

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

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

We may attempt to form strategic collaborations, create joint ventures or enter into licensing arrangements with third parties with respect to our programs in addition to those that we currently have that we believe will complement or augment our existing business. We may face significant competition in seeking appropriate strategic collaborators, and the negotiation process to secure appropriate terms is time consuming and complex. We may not be successful in our efforts to establish such a strategic collaboration for any product candidates and programs on terms that are acceptable 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 II combination study of MT-3724 with GEMOX is focused on non-Hodgkin's lymphoma. The estimated incidence of non-Hodgkin's B-cell lymphoma is 74,680 new cases and approximately 19,910 deaths were attributable to the disease in the United States in 2018, only a subset of which may benefit from treatment with MT-3724. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, while we believe that the data in our Phase II clinical trials for MT-3724 will be supportive of application to other indications, there can be no assurance that our clinical trials will successfully address any additional indications. 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 companies including the following have therapeutics marketed or in development that could compete directly or indirectly with ETBs: Genentech, Bayer, Takeda, AbbVie, Celgene, Seattle Genetics, Immunogen, Morphosys, Genmab, Bristol Myers Squibb, Novartis, Regeneron, Janssen, Xencor, Amgen, Macrogenics, Astra Zeneca, Lilly, Merck KGaA, Pfizer, Merus, Sanofi, Menterix Biotech, Merrimack Pharmaceuticals, Spectrum Pharmaceuticals, Unum Therapeutics, Daiichi Sankyo, Karyopharm, Mersana and F-Star. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than MT-3724 or any other product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive.

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

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

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

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

- the efficacy of the product as demonstrated in clinical trials and potential advantages over competing treatments;
- the prevalence and severity of the disease and any side effects;
- 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 United States Department of Health and Human Services, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel product candidates such as ours and what reimbursement codes our product candidates may receive if approved.

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

Moreover, increasing efforts by governmental and private payors in the United States and abroad to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our products. 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 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 class action litigation;
- failure by securities or industry analysts to publish research or reports about our business, or issuance of any adverse or misleading opinions by such analysts regarding our business 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;

- the trading volume of our common stock;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to ETB therapeutics generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with our potential products;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

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

Additionally, a decrease in our stock price may cause our common stock to no longer satisfy the continued listing standards of The Nasdaq Capital Market. If we are not able to maintain the requirements for listing on The Nasdaq Capital Market, we could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock. As of December 30, 2018, we had outstanding a total of approximately 36,736,012 shares of common stock.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline. As of December 31, 2018, we had outstanding a total of approximately 36,736,012 at shares of common stock. As a result of contractual arrangements entered into in connection with our September public offering, approximately 16.5 million shares of our common stock beneficially owned by our executive officers, directors and certain of our existing shareholders were subject to lock-up agreements until December 19, 2018 that prohibited, subject to certain exceptions, the offering, sale, contracting to sell, pledging or otherwise disposing of, directly or indirectly, any of our common stock or securities convertible into or exchangeable or exercisable for any of our common stock, entering into a transaction that would have the same effect, or entering into any swap, hedge or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock, whether any of these transactions are to be settled by delivery of our common stock or other securities, in cash or otherwise, or publicly disclosing the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement, without, in each case, the prior written consent of the representatives of the underwriters of the public offering, who may release any of the securities subject to these lock-up agreements at any time without notice. These shares can now be sold into the market and may cause the market price of our common stock to decline significantly.

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

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

Pursuant to our 2018 Equity Incentive Plan, or the 2018 Plan, we are authorized and have available to grant equity awards to our employees, directors and consultants for up to an aggregate of 3.4 million shares of our common stock reserved for issuance pursuant to the 2018 Plan as of December 31, 2018, which includes potential forfeitures and cancellations of outstanding stock options from the 2009 Equity Incentive Plan, 2014 Equity Incentive Plan and 2004 Equity Incentive Plan. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

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

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

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

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

Provisions of Delaware law, where we are incorporated, our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger or acquisition that our stockholders may consider favorable, including transactions in which 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 our board of directors to issue “blank check” preferred stock without any need for approval by stockholders;
- providing for a classified board of directors with staggered three-year terms;
- requiring supermajority stockholder votes to effect certain amendments to our amended and restated certificate of incorporation and amended and restated bylaws;
- eliminating the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of December 31, 2018, our directors, officers, and stockholders beneficially owning 5% or more of our shares or that may be affiliated with our board members, beneficially owned, in the aggregate, approximately 42% of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence almost all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would 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, LLC and its affiliates own approximately 24% of our shares, Longitude Capital Management Company, LLC and its affiliates own approximately 12% of our shares, Millennium Pharmaceuticals, Inc. owns approximately 8% of our shares BVF Partners, L.P. owns approximately 8% of our shares, Perceptive Advisors, LLC and its affiliates own approximately 6% of our shares. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire.

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

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. We do not have any control over these analysts. 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 and there can be no assurance that analysts will provide favorable coverage. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

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

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

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

Under Section 12b-2 of the Exchange Act, a "smaller reporting company" is a company that is not an investment company, an asset backed issuer, or a majority-owned subsidiary of a parent company. Effective September 10, 2018, the definition of a "smaller reporting company" was amended to include companies with a public float of less than \$250 million as of the last business day of its most recently completed second fiscal quarter or, if such public float is less than \$700 million, had annual revenues of less than \$100 million during the most recently completed fiscal year. Smaller reporting companies are permitted to provide simplified executive compensation disclosure in their filings; they are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal controls over financial reporting; and they have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. As of December 31, 2018, we qualify as a smaller reporting company. For as long as we continue to be a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of those respective classifications. Decreased disclosure in our SEC filings as a result of our having availed ourselves of scaled disclosure may make it harder for investors to analyze our results of operations and financial prospects.

Risks Related to Our Business Operations

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

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

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

As of December 31, 2018, we had 68 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, including a cybersecurity breach, 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. We maintain sensitive company data on our computer networks, including our intellectual property and proprietary business information. Our IT systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, cyber-attacks, computer viruses, breaches, unauthorized access, interruptions due to employee error or malfeasance or other disruptions, or damage from natural disasters, terrorism, war and telecommunication and electrical failures. Moreover, despite network security and back-up measures, some of our and our vendors’ servers are potentially vulnerable to physical or electronic break-ins, including cyber-attacks, computer viruses and similar disruptive problems. These events could lead to the unauthorized access, disclosure and use of non-public information including our intellectual property or proprietary business information. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. There can be no assurance that we will promptly detect any such disruption or security breach, if at all. If our computer systems are compromised, we could be subject to fines, damages, reputational harm, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business, in addition to possibly requiring substantial expenditures of resources to remedy. For example, the loss of data from completed clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce data and a cybersecurity breach could adversely affect our reputation and could result in other negative consequences, including disruption of our internal operations, increased cyber security protection costs, lost revenues or litigation. Despite precautionary measures to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

In October 2016, we entered into a facility lease agreement for 18,000 square feet of office and laboratory space in Austin, Texas, which serves as our corporate headquarters. The lease was initially set to expire in May 2022. In January 2017, Molecular entered into a first amendment to the lease to add an additional 4,000 square feet, consisting mostly of laboratory space. In March 2017, Molecular entered into a second amendment to the lease to add an additional 11,000 square feet of office and laboratory space. The term of Molecular's lease for the Austin, TX space expires August 2023. The lease has an option to renew for one additional five-year period at our discretion.

We also lease two properties for use as office space occupying approximately 12,000 square feet in the aggregate in Jersey City, New Jersey under leases expiring in September 2019, and December 2021, respectively.

We believe substantially all of our property and equipment is in good condition and that Molecular has sufficient capacity to meet its current operational needs.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Shares of Threshold Pharmaceuticals, Inc. common stock were historically listed on the Nasdaq Capital Market under the symbol “THLD.” After completion of the Merger on August 1, 2017, Threshold Pharmaceuticals, Inc was renamed “Molecular Templates, Inc.” and commenced trading on the Nasdaq Capital Market under the symbol “MTEM” on August 2, 2017.

There were approximately 51 holders of record of our common stock as of March 22, 2019. On March 22, 2019, the last reported sales price per share of our common stock was \$5.43 per share.

Unregistered Sales of Equity Securities

None.

Repurchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and have therefore omitted the information required by this Item 6.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties, including those set forth under the heading "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Our actual results and the timing of selected events discussed below could differ materially from those expressed in, or implied by, these forward-looking statements.

Overview

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

Business

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

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

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

Our initial approach to drug development in oncology involves the selection of lead compounds to validated targets in cancer. We have developed ETBs for various targets, including CD20, CD38, HER2, and PD-L1. CD20 is central to B cell malignancies and is clinically validated as a target for the treatment of lymphomas and autoimmune disease. CD38 has been validated as a meaningful clinical target in the treatment of multiple myeloma. PD-L1 is central to immune checkpoint pathways and is a target expressed in a variety of solid tumor cancers. Our lead compound, MT-3724, is an ETB that recognizes CD20, a B cell marker and is currently in Phase I study. The dose escalation portion of its first Phase I clinical trial has been completed for MT-3724 and was followed by the initiation of a Phase Ib expansion cohort, which was initiated in the fourth quarter of 2017. In the first quarter of 2019, we expect to start a Phase II monotherapy study with MT-3724, which has the potential to be a pivotal study. We expect to start enrolling patients in a Phase II combination study with MT-3724 and chemotherapy in earlier lines of diffuse large B-cell lymphoma (DLBCL) in the fourth quarter of 2018 and we expect to initiate a second Phase II combination study with MT-3724 and Revlimid® (lenalidomide) in earlier lines of DLBCL in the first quarter of 2019. We anticipate filing IND applications for TAK-169 in 2019, for our HER2 ETB in the first quarter of 2019, and for our PD-L1 ETB in the second half of 2019.

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

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

We are a clinical-stage company and have not generated revenue from product sales. Our ability to generate enough revenue 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 year ended December 31, 2018 and 2017, we incurred net losses of \$30.3 million and \$23.1 million, respectively. As of December 31, 2018, we had an accumulated deficit of \$94.7 million.

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

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

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

We expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the first half of 2021.

Collaboration Agreements

Takeda Pharmaceuticals

We recognize collaboration revenue over time as a customer obtains control of promised goods or services. For more information about our collaboration revenue, please see Note 4, "Research and Development Agreements" to our audited consolidated financial statements for the years ended December 31, 2018, included in this Annual Report on Form 10-K.

Takeda Collaboration and Individual Project Agreements

In October 2016, we entered into a collaboration and option agreement (the "Takeda Collaboration Agreement") with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Ltd. ("Takeda") to discover and develop CD38-targeting ETBs, which includes MT-4019 for evaluation by Takeda. Under the terms of the agreement, we are responsible for providing to Takeda (i) new ETBs generated using Takeda's proprietary antibodies targeting CD38 and (ii) MT-4019 for *in vitro* and *in vivo* pharmacological and anti-tumor efficacy evaluations. We granted Takeda an exclusive option to negotiate and obtain an exclusive worldwide license to develop and commercialize any ETB that may result from this collaboration, including MT-4019. We are entitled to receive up to \$2.0 million in technology access fees and cost reimbursement associated with our performance and completion of our obligations under the agreement. As of December 31, 2018, we have received \$2.0 million under the Takeda Collaboration Agreement.

In connection with the Takeda Collaboration Agreement, we entered into an Individual Project Agreement (the “Takeda Individual Project Agreement”) with Takeda in June 2018 that was subsequently amended in July 2018. Under the Takeda Individual Project Agreement, we are responsible to perform certain research and development services relating to Chemistry, Manufacturing, and Controls (“CMC”) work for three potential lead ETBs targeting CD38. In consideration of these services, we will receive up to \$2.2 million in compensation. During the year ended December 31, 2018, we have received approximately \$2.0 million under the Takeda Individual Project Agreement.

For more information about our collaboration agreements, please see Note 4, “Research and Development Agreements” to our audited consolidated financial statements for the years ended December 31, 2018, included in this Annual Report on Form 10-K.

Takeda Development and License Agreement

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

Pursuant to the License Agreement, we will initially co-develop with Takeda one or more of the Licensed Products up to and including Phase Ia clinical trials, with us having an option to continue to co-develop the Licensed Products following Phase Ia clinical trials. We may exercise our co-development option within a specified time period following completion of the Phase Ia clinical trials with no additional fee by providing written notice of exercise to Takeda, provided we have paid all co-development costs due pursuant to the License Agreement as of the date of such exercise. Pursuant to the terms of the License Agreement, Takeda will be responsible for all regulatory activities and commercialization of the Licensed Products. We have granted Takeda specified intellectual property licenses to enable Takeda to perform its obligations and exercise its rights under the License Agreement, including exclusive license grants to enable Takeda to conduct development, manufacturing, and commercialization activities pursuant to the terms of the License Agreement.

Pursuant to the License Agreement, Takeda made an upfront payment of \$30.0 million to us. In addition to the upfront fee, if we exercise our co-development option and fund our share of development costs, we may receive up to an additional \$307.5 million in milestone payments upon the achievement of certain development and regulatory milestone events and up to an additional \$325 million in milestone payments upon the achievement of certain sales milestone events. If we do not exercise our co-development option, we may receive up to an additional \$162.5 million in milestone payments upon the achievement of certain development and regulatory milestone events and up to an additional \$175 million in milestone payments upon the achievement of certain sales milestone events. We will also be entitled to receive tiered royalties, subject to certain reductions, as percentages of annual aggregate net sales, if any, of Licensed Products. The royalty percentages would range from low double-digits to low twenties if we exercise our option to co-develop, and from high-single digits to low teens if we do not exercise its option to co-develop.

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

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

For more information about our collaboration agreements, please see Note 4, “Research and Development Agreements” to our audited consolidated financial statements for the years ended December 31, 2018, included in this Annual Report on Form 10-K.

Takeda Multi-Target Agreement

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

Under the Takeda Multi-Target Agreement, Takeda has an option during an option period to obtain an exclusive license under our intellectual property to develop, manufacture, commercialize and otherwise exploit ETBs against the designated targets. The option period for each target ends three months after the completion of the evaluation of such designated target. Under the Takeda Multi-Target Agreement, both parties have the right to terminate the agreement, with a specified notice period.

We received an upfront fee of \$1.0 million and an additional \$2 million following the designation of each of the two targets in December 2017. As of December 31, 2018, we have received \$5.0 million from Takeda pursuant to the Takeda Multi-Target Agreement.

We may also receive an additional \$25.0 million in aggregate through the exercise of the option to license ETBs. Additionally, we may also be entitled to receive clinical development milestone payments of up to approximately \$397.0 million, for achievement of development milestones and regulatory approval of collaboration products under the Takeda Multi-Target Agreement. We may also be entitled to receive commercial milestone payments of up to \$150.0 million, for achievement of pre-specified sales milestones related to net sales of all collaboration products under the Takeda Multi-Target Agreement. We are also entitled to tiered royalty payments of a mid-single to low-double digit percentage of net sales of any licensed ETBs, subject to certain reductions. Finally, we are entitled to receive up to \$10.0 million in certain contingency fees.

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

For more information about our collaboration agreements, please see Note 4, “Research and Development Agreements” to our audited consolidated financial statements for the years ended December 31, 2018, included in this Annual Report on Form 10-K.

CPRIT Grant Contract

On September 18, 2018, we entered into a Cancer Research Grant Contract (the “CPRIT Agreement”) with CPRIT, in connection with a grant of approximately \$15.2 million awarded by CPRIT to us in November 2016 to fund research of a cancer therapy involving an ETB that is targeting CD38 (MT-4019) (the “Award”). Pursuant to the CPRIT Agreement, we may also use such funds to develop a replacement CD38 targeting ETB, with or without a partner. The Award is contingent upon funds being available during the term of the Agreement and subject to CPRIT’s ability to perform its obligations under the Agreement as well as our progress towards achievement of specified milestones, among other contractual requirements.

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

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

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

The CPRIT Agreement will terminate, with certain obligations extending beyond termination, on the earlier of (a) May 31, 2019 or (b) the occurrence of any of the following events: (i) by mutual written consent of the parties, (ii) by CPRIT for an Event of Default (as defined in the CPRIT Agreement) by us, (iii) by CPRIT if allocated funds should become legally unavailable during the term of the CPRIT Agreement and CPRIT is unable to obtain additional funds or (iv) by us for convenience. CPRIT may approve a no cost extension for the CPRIT Agreement for a period not to exceed six months after the termination date if additional time is required to ensure adequate completion of the approved project, subject to the terms and conditions of the CPRIT Agreement.

For more information about our collaboration agreements, please see Note 4, “Research and Development Agreements” to our audited consolidated financial statements for the years ended December 31, 2018, included in this Annual Report on Form 10-K.

Financial Operations Overview

Revenue

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

Grant revenue relates to our Cancer Prevention Research Institute of Texas, or CPRIT grants for MT-3724 and MT-4019. CPRIT grant funds for MT-3724 are provided to us in advance as conditional cost reimbursement where revenue is recognized as allowable costs are incurred. Amounts collected in excess of revenue recognized are recorded as deferred revenue. CPRIT grant funds for MT-4019 are provided to us in arrears as cost reimbursement where revenue is recognized as allowable costs are incurred. Revenue recognized in excess of amounts collected are recorded as unbilled revenue.

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

For more information about our revenue recognition policy, please see Note 1, “Summary of Significant Accounting Policies” to our audited consolidated financial statements for the years ended December 31, 2018, included in this Annual Report on Form 10-K.

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

Research and Development Expenses

Research and development expenses consist principally of:

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

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including the initiation and enrollment of patients in clinical trials and manufacture of drug materials for clinical trials. We expect research and development expenses to increase as we advance the clinical development of MT-3724 and further 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 related to general and administrative activities;
- professional fees for legal services related to the protection and maintenance of our intellectual property and regulatory compliance;
- cost of facilities, communication and office expenses;
- information technology services; and
- depreciation of long-lived assets.

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

Other Income (Expense)

Other income (expense) includes interest and other income, interest and other expense, loss on conversion of notes and change in fair value of warrant liabilities.

Results of Operations

Comparison for the Years Ended December 31, 2018 and 2017

The table below summarizes Molecular's results of operations for the years ended December 31, 2018 and 2017.

	Years ended December 31,	
	2018	2017
Research and development revenue - from related party	\$ 7,087	\$ 1,908
Research and development revenue - other	196	500
Grant revenue	6,002	987
Total revenue	13,285	3,395
Research and development expenses	30,202	9,487
General and administrative expenses	14,082	11,755
Total operating expenses	44,284	21,242
Loss from operations	30,999	17,847
Interest and other income, net	751	51
Interest and other expense, net	(990)	(853)
Change in fair value of warrant liabilities	951	128
Loss on conversion of notes	—	(4,619)
Net loss	\$ 30,287	\$ 23,140

Research and development revenue – from related party

Research and development revenue – from related party increased \$5.2 million during the year ended December 31, 2018 compared to the year ended December 31, 2017. Research and development revenues for the year ended December 31, 2018 and 2017 were comprised of research and development revenues from our collaboration with Takeda. The increase in research and development revenues from our collaboration with Takeda was primarily due to revenue recognized under the Takeda Development and License Agreement and the Takeda Individual Project Agreement.

Research and development revenue – other decreased \$0.3 million during the year ended December 31, 2018 compared to the year ended December 31, 2017. Research and development revenues for the year ended December 31, 2018 and 2017 were comprised of research and development revenues from our collaboration with an undisclosed company. All research and development services under this collaboration had been completed as of December 31, 2018.

For further information on our collaboration agreements refer to Note 4 “Research and Development Agreements” our audited consolidated financial statements for the years ended December 31, 2018, included in this Annual Report on Form 10-K.

Grant Revenue

Grant revenue increased \$5.0 million during the year ended December 31, 2018 as compared to the year ended December 31, 2017. The increase was primarily attributable to the CPRIT grant related to CD-38 targeting ETB MT-4019; and to CPRIT Phase II program expenses increasing during the year ended December 31, 2018.

Research and Development Expenses

The table below summarizes Molecular's research and development costs for the years ended December 31, 2018 and 2017.

Research and development expenses by cost type:

	Years ended December 31,	
	2018	2017
Employee compensation	\$ 8,128	\$ 2,903
Program costs	17,375	5,156
Laboratory costs	2,082	843
Other research and development costs	2,617	585
Total research and development expenses	\$ 30,202	\$ 9,487

Research and development expenses increased \$20.7 million during the year ended December 31, 2018 as compared to the year ended December 31, 2017. The increase was primarily due to costs related to increased outsourced program costs, along with increased payroll related costs due to increased headcount.

From a program perspective, all of our research and development expenses relate to the discovery and development of ETBs. From a program perspective, the increase in outsourced program costs during the year ended December 31, 2018 compared to the year ended December 31, 2017 is primarily due to increase in costs related to HER2 of \$4.2 million, CD-38 of \$1.6 million, PD-L1 of \$1.9 million and DLBCL of \$2.1 million.

The risks and uncertainties associated with our research and development projects are discussed more fully in the “Risk Factors” section in Part I, Item 1A of this Annual Report on Form 10-K. 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 Expenses

General and administrative expenses increased \$2.3 million during the year ended December 31, 2018 compared to the year ended December 31, 2017. The increase was primarily attributable to costs associated with being a publicly traded company, along with increased payroll related costs due to increased headcount.

Interest and Other Income

Interest and other increased \$700,000 during the year ended December 31, 2018, as compared to the year ended December 31, 2017, primarily due to higher yielding investments and higher cash, cash equivalents and marketable securities balances.

Interest and Other Expense

Interest and other expense increased \$137,000 during the year ended December 31, 2018, as compared to the year ended December 31, 2017, primarily due to interest expense associated with the Perceptive Credit Facility.

Change in fair value of warrant liability

The change in fair value of warrant liabilities relates to the revised fair value of the 2017 warrants categorized as liabilities. The decrease in the change in fair value of the warrant liabilities is primarily due to the decrease in the underlying stock price of our common stock as well the decrease in the expected term of the warrants as they are nearing expiration.

Loss on conversion of notes

The Loss on Conversion of Notes during the year ended December 31, 2017 was due to a loss recorded 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 \$94.7 million through December 31, 2018. We expect to incur substantial additional losses in the future as we expand our research and development activities. Based on our current research and development plans, we expect that our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements into first half of 2021.

Our financial statements as of December 31, 2018 have been prepared under the assumption that we will continue as a going concern for the next 12 months. To date, we have financed our operations through private placements of equity securities, a reverse merger, and upfront and milestone payments received from our collaborators under our research evaluation agreements, as well as funding from governmental bodies and bank and bridge loans. Since 2009, we raised gross proceeds of \$78.2 million from private placements of equity securities, including \$40.0 million from the Private Placement in August 2017 and \$20.0 million from the Takeda Financing in August 2017; as well as approximately \$52 million in gross proceeds from a public offering in September 2018. Since 2009, we have also received aggregate gross proceeds of \$39.7 million from our collaborators, received \$10.0 million in proceeds from related-party convertible promissory notes, received \$6.0 million in proceeds from bank loan from Silicon Valley Bank, or SVB, \$5.0 million in proceeds from the Perceptive Facility; and assumed \$15.2 million of cash balances of Threshold upon the closing of the Merger.

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

On February 27, 2018, we entered into the Perceptive Credit Facility, which allows for aggregate borrowings of up to \$10.0 million, subject to our achievement of certain milestones. We drew down an aggregate of \$5.0 million under the Perceptive Credit Facility through September 30, 2018. Payments for the first 24 months are interest only and are paid quarterly, commenced April 2018. After the second anniversary of the closing date of the Perceptive Credit Facility, principal payments of \$200,000 are due each calendar quarter, with a final payment of \$3.4 million due on February 27, 2022. The loan matures on February 27, 2022 and is secured by substantially all our assets.

On September 18, 2018, we entered into the CPRIT Agreement in connection with a grant of approximately \$15.2 million awarded by CPRIT to us in November 2016 to fund research of a cancer therapy involving a CD38 targeting ETB (MT-4019).

On December 21, 2018, we entered into a Controlled Equity OfferingSM Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, which provides that, upon the terms and subject to the conditions and limitations set forth in the Sales Agreement, we may elect to issue and sell shares of our common stock having an aggregate offering price of up to \$50.0 million from time to time through Cantor, acting as agent. To date, we have not sold any shares under the Sales Agreement and may choose to sell shares of our common stock having an aggregate offering price of up to \$50.0 million in the future.

As of December 31, 2018, we had cash, cash equivalents and marketable securities of \$98.0 million. As of December 31, 2017, we had cash and cash equivalents of \$58.9 million.

Cash Flows

Comparison of Years Ended December 31, 2018 and 2017

The table below summarizes Molecular's cash flows for the years ended December 31, 2018 and 2017.

(in thousands)	Years ended December 31,	
	2018	2017
Net cash used in operating activities	\$ (4,465)	\$ (14,264)
Net cash provided by / (used in) investing activities	(15,945)	9,715
Net cash provided by financing activities	49,221	61,743
Net increase in cash and cash equivalents	<u>\$ 28,811</u>	<u>\$ 57,194</u>

The decrease in net cash used in operating activities to \$4.5 million for the year ended December 31, 2018 from \$14.3 million for the year ended December 31, 2017 was primarily due to an increase in deferred revenue related to a \$30 million upfront payment received in October 2018, under the Takeda License Agreement, partially offset by an increase in operating cash disbursements as result of an increase in operating activities.

The increase in net cash used in investing activities to \$15.9 million for the year ended December 31, 2018 from net cash provided by investing activities of \$9.7 million for the December 31, 2017 was primarily due to purchase of marketable securities as well as increased leasehold improvements and increased purchases of equipment related to our GMP manufacturing facility build-out in our Austin, Texas facility.

The decrease in net cash provided by financing activities to \$49.2 million for the year ended December 31, 2018 from \$61.7 million for the year ended December 31, 2017 was primarily due to approximately \$48.1 million net proceeds from issuance of common stock in September 2018 compared to \$57.6 million in proceeds from issuance of common stock and warrants in August 2017.

Operating and Capital Expenditure Requirements

Other than for one year, we have not achieved profitability since our inception and had an accumulated deficit of \$94.7 million as of December 31, 2018. 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 initiate Phase II clinical trials of MT-3724;
- conduct the Phase I clinical trial of MT-4019, our second ETB candidate;
- continue the research and development of our other ETB candidates, including completing pre-clinical studies and commencing clinical trials;
- seek to enhance our technology platform using our antigen-seeding technology approach to immuno-oncology;
- seek regulatory approvals for any ETB candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our increased operations; and
- experience any delays or encounter any issues resulting from any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

We expect that our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements into first half of 2021. 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.

Controlled Equity OfferingSM Sales Agreement

On December 21, 2018, we entered into a Controlled Equity OfferingSM Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, which provides that, upon the terms and subject to the conditions and limitations set forth in the Sales Agreement, we may elect to issue and sell shares of our common stock having an aggregate offering price of up to \$50.0 million from time to time through Cantor, acting as agent.

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

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

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

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

Critical Accounting Policies and Use of Estimates

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.

Revenue Recognition

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

Grant revenue relates to the grants we have received from governmental bodies that are conditional cost reimbursement grants, and we recognize revenue as allowable costs are incurred. Amounts collected in excess of revenue recognized are recorded as deferred revenue.

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

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

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

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

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

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

We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation as each performance obligation is satisfied over time, with progress toward completion measured based on actual costs incurred relative to total estimated costs to be incurred over the life of the contract. Recorded revenue and costs are subject to revision as the contract progresses. Such revisions may result in increases or decreases to revenue and income and are reflected in the consolidated financial statements in the periods in which they are first identified. Estimating costs under our collaboration agreements is complex and involves significant judgment. Factors that must be considered in making estimates include labor productivity and availability, the nature and technical complexity of the work to be performed, potential performance delays, availability and timing of funding from the customer and progress toward completion. Adjustments to original estimates are often required as work progresses and additional information becomes known, even though the scope of the work required under the contract may not change. Any adjustment as a result of a change in estimates is made when facts develop, events become known, or an adjustment is otherwise warranted, such as in the case of contract change orders. We have procedures and processes in place to monitor the actual progress of a project against estimates and our estimates are updated if circumstances are warranted.

Performance obligations may include research and development services to be performed by us on behalf of the collaboration partner. Revenue is recognized on research and development efforts as the services are performed and presented on a gross basis, since we are the principal.

Under collaboration agreements, the timing of revenue recognition and contract billings may differ and result in contract assets and contract liabilities. Contract assets represent revenues recognized in excess of amounts billed under collaboration agreements and are transferred to accounts receivable when billed or billing rights become unconditional. Contract liabilities represent billings in excess of revenues recognized under collaboration agreements.

For further information regarding our revenue recognition, please see Note 1 "Summary of Significant Accounting Policies" to our audited consolidated financial statements for the year ended December 31, 2018, included in this Annual Report on Form 10-K.

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.

Income Taxes

For the years ended December 31, 2018 and 2017, we did not record an income tax provision due to net operating losses and the inability to record an income tax benefit. As of December 31, 2018, we had accumulated approximately \$95.0 million in federal net operating loss carryforwards to reduce future taxable income. If not utilized, our federal and state net operating loss carryforwards begin to expire in 2021 for federal tax purposes. Our net operating loss carryforwards are subject to certain limitations on annual utilization in case of changes in ownership, as defined by federal and state tax laws.

At December 31, 2018, we had federal research and development tax credits of approximately \$1.9 million, which expire in the year beginning 2022, and state research and development tax credits of approximately \$0.2 million, which have no expiration date.

Molecular has not recorded a benefit from our net operating loss or research credit carryforwards because we believe that it is uncertain that we will have sufficient income from future operations to realize the carryforwards prior to their expiration. Accordingly, we have established a valuation allowance against the deferred tax asset arising from the carryforwards.

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 2018 Equity Incentive Plan, 2014 Equity Incentive Plan, as amended, and our 2009 Stock Plan, as amended, 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 ("Summary of Significant Accounting Policies") to our audited financial statements for the year ended December 31, 2018, included in this Annual Report on Form 10-K.

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 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

**MOLECULAR TEMPLATES, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Molecular Templates, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Molecular Templates, Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Adoption of ASU 2014-09

As discussed in Note 1 and Note 4 to the consolidated financial statements, the Company changed its method of accounting for revenue recognition in 2018 due to the adoption of ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

Austin, Texas
March 29, 2019

MOLECULAR TEMPLATES, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 87,721	\$ 58,910
Marketable securities, current	10,234	—
Prepaid expenses	2,244	1,485
Accounts receivable from related party	240	—
Other current assets	4,424	19
Total current assets	104,863	60,414
Property and equipment, net	6,851	1,952
In-process research and development	26,623	26,623
Other assets	1,821	1,402
Total assets	\$ 140,158	\$ 90,391
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 780	\$ 2,517
Accrued liabilities	5,357	2,690
Current portion of long-term debt	—	2,400
Deferred revenue, current	26,231	2,765
Other current liabilities	141	70
Total current liabilities	32,509	10,442
Warrant liabilities	3	954
Deferred revenue, long-term	2,670	—
Long-term debt, net	3,254	1,078
Other liabilities	816	628
Total liabilities	39,252	13,102
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, \$0.001 par value:		
Authorized: 150,000,000 shares at December 31, 2018 and 2017; Issued and outstanding: 36,736,012 and 26,898,330 shares at December 31, 2018 and 2017, respectively.	37	27
Additional paid-in capital	195,573	141,733
Accumulated other comprehensive loss	—	—
Accumulated deficit	(94,704)	(64,471)
Total stockholders' equity	100,906	77,289
Total liabilities and stockholders' equity	\$ 140,158	\$ 90,391

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

MOLECULAR TEMPLATES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Years Ended December 31,	
	2018	2017
Research and development revenue - from related party	\$ 7,087	\$ 1,908
Research and development revenue - other	196	500
Grant revenue	<u>6,002</u>	<u>987</u>
Total revenue	13,285	3,395
Operating expenses:		
Research and development	30,202	9,487
General and administrative	<u>14,082</u>	<u>11,755</u>
Total operating expenses	<u>44,284</u>	<u>21,242</u>
Loss from operations	30,999	17,847
Interest and other income, net	751	51
Interest and other expense, net	(990)	(853)
Change in fair value of warrant liabilities	951	128
Loss on conversion of notes	<u>—</u>	<u>(4,619)</u>
Net loss	30,287	23,140
Deemed dividends on preferred stock	<u>—</u>	<u>958</u>
Net loss attributable to common shareholders	<u>\$ 30,287</u>	<u>\$ 24,098</u>
Net loss per share attributable to common shareholders:		
Basic and diluted	<u>\$ 1.02</u>	<u>\$ 2.11</u>
Weighted average number of shares used in net loss per share calculations:		
Basic and diluted	<u>29,601,692</u>	<u>11,400,881</u>
Other comprehensive loss:		
Unrealized gain (loss) on available-for-sale securities	<u>—</u>	<u>—</u>
Comprehensive loss	<u>\$ 30,287</u>	<u>\$ 24,098</u>

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

MOLECULAR TEMPLATES, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK and STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)		Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount					
Balances, December 31, 2016	9,116,405	\$ 25,871	214,641	\$ —	\$ 568	\$ —	\$ (40,373)	\$ (39,805)	
Issuance of common stock pursuant to stock plans	—	—	17,430	—	61	—	—	—	61
Deemed dividends on preferred stock	—	958	—	—	—	—	(958)	(958)	
Conversion of preferred stock to common stock in connection with merger	(9,116,405)	(26,829)	9,220,478	9	26,820	—	—	26,829	
Conversion of preferred stock warrants to common stock in connection with merger	—	—	12,653	—	87	—	—	87	
Conversion of redeemable convertible notes to common stock	—	—	2,208,716	2	15,103	—	—	15,105	
Issuance of common stock and assumption of options in connection with the merger	—	—	6,508,356	7	39,663	—	—	39,670	
Issuance of common stock to Takeda and certain other investors, net of issuance costs of \$2.4 million	—	—	8,716,056	9	57,639	—	—	57,648	
Stock-based compensation	—	—	—	—	1,792	—	—	1,792	
Change in unrealized gain (loss) on marketable securities	—	—	—	—	—	—	—	—	
Net income	—	—	—	—	—	—	(23,140)	(23,140)	
Balances, December 31, 2017	—	—	26,898,330	27	141,733	—	(64,471)	77,289	
Issuance of common stock pursuant to stock plans	—	—	407,682	1	282	—	—	283	
Issuance of warrant to purchase common stock in relation to term loan facility	—	—	—	—	1,522	—	—	1,522	
Issuance of common stock in a public offering, net of issuance costs of \$3.8 million	—	—	9,430,000	9	48,044	—	—	48,053	
Stock-based compensation	—	—	—	—	3,992	—	—	3,992	
Cumulative-effect adjustment upon adoption of new accounting standards	—	—	—	—	—	—	54	54	
Net loss	—	—	—	—	—	—	(30,287)	(30,287)	
Balances, December 31, 2018	—	\$ —	36,736,012	\$ 37	\$ 195,573	\$ —	\$ (94,704)	\$ 100,906	

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

MOLECULAR TEMPLATES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ 30,287	\$ 23,140
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	974	155
Stock-based compensation expense	3,992	1,792
Amortization of debt discount and accretion related to long term debt	318	342
Change in common stock warrant fair value	(951)	(128)
Accretion of asset retirement obligations	39	—
Capitalized interest	(125)	—
Loss on extinguishment of debt	115	4,619
Loss on disposal of equipment	35	2
Changes in operating assets and liabilities:		
Prepaid expenses	(825)	(410)
Accounts receivable from related party	(240)	0
Other current assets	(4,351)	(12)
Other assets	(450)	(81)
Accounts payable	(1,736)	1,209
Accrued liabilities	2,667	155
Other current liabilities	88	20
Other liabilities	136	318
Deferred revenue	26,136	895
Net cash used in operating activities	(4,465)	(14,264)
Cash flows from investing activities:		
Cash received from merger transaction	—	11,216
Purchases of property and equipment	(5,722)	(1,101)
Purchases of marketable securities	(10,223)	—
Increase in other assets	—	(400)
Net cash provided by (used in) investing activities	(15,945)	9,715
Cash flows from financing activities:		
Payments of capital lease obligations	(47)	(43)
Proceeds from issuance of long-term debt	4,537	—
Repayment of long-term debt	(3,605)	(2,400)
Retirement of stock warrants	—	(208)
Proceeds from issuance of related party debt	—	2,685
Proceeds from stock option exercises	283	61
Proceeds from promissory note	—	4,000
Proceeds from issuance of common stock and warrants, net of offering expenses	48,053	57,648
Net cash provided by financing activities	49,221	61,743
Net increase in cash and cash equivalents	28,811	57,194
Cash and cash equivalents, beginning of period	58,910	1,716
Cash and cash equivalents, end of period	\$ 87,721	\$ 58,910
Supplemental Cash Flow Information		
Cash paid for interest	\$ 629	\$ 250
Non-Cash Investing and Financing Activities		
Deemed dividends on preferred stock	\$ —	\$ 958
Conversion of preferred stock	\$ —	\$ 26,829
Conversion of related party debt	\$ —	\$ 10,486
Conversion of warrant liability	\$ —	\$ 87
Capital lease additions to fixed assets	\$ —	\$ 291
Fixed asset additions in accounts payable	\$ —	\$ 382

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

MOLECULAR TEMPLATES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of the Business

Molecular Templates, Inc. (the “Company” or “Molecular”), is a clinical stage biopharmaceutical company formed in 2001, with a biologic therapeutic platform for the development of novel targeted therapeutics for cancer and other diseases, headquartered in Austin, Texas. The Company’s 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.” Threshold also assumed all of the stock options issued and outstanding under Private Molecular’s 2009 Stock Plan, as amended, and issued and outstanding warrants of Private Molecular, with such stock options and warrants representing, following the Merger, the right to purchase a number of shares of Common Stock equal to 7.7844 multiplied by the number of shares of Private Molecular’s common stock previously represented by such stock options and warrants, as applicable, after taking into account the Reverse Stock Split. Immediately after the Merger, the former Private Molecular stockholders, warrantholders and optionholders owned approximately 65.6% of the fully-diluted Common Stock, with Threshold’s stockholders and warrantholders immediately prior to the Merger, whose warrants and shares of Threshold’s common stock remained outstanding after the Merger, owning approximately 34.4% of the fully-diluted Common Stock, in each case, without giving effect to the issuance of shares of Common Stock in the concurrent financing and the Takeda Financing, and excluding, in each case, out-of-the-money securities. 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

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

Reverse Stock Split

On August 1, 2017, in connection with, and prior to the completion of, the Merger, Threshold effected a Reverse Stock Split through an amendment to its amended and restated certificate of incorporation as part of the Merger. As of the effective time of the reverse stock split, every eleven shares of the Company’s issued and outstanding common stock were converted into one issued and outstanding share of common stock, without any change in par value per share. The reverse stock split affected all shares of the Company’s common stock outstanding immediately prior to the effective time of the reverse stock split, as well as the number of shares of common stock available for issuance under the Company’s equity incentive plans. In addition, the reverse stock split effected a reduction in the number of shares of common stock issuable upon the exercise of stock options or warrants outstanding immediately prior to the effectiveness of the reverse stock split. All references to shares of common stock and per share data for all periods presented in the accompanying financial statements and notes thereto have been adjusted to reflect the reverse stock split on a retroactive basis.

Reclassifications

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.

Accounting Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America as defined by the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss applicable to common stockholders by the weighted average number of shares of Common Stock outstanding during the period without consideration of Common Stock equivalents. Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods, as the inclusion of all potential common shares outstanding is anti-dilutive.

Cash and Cash Equivalents

The Company considers temporary investments with original maturities of three months or less from date of purchase to be cash equivalents.

Marketable Securities

The Company classifies its marketable securities as “available-for-sale.” Such marketable securities are recorded at fair value and unrealized gains and losses are recorded as a separate component of stockholders’ equity until realized. Realized gains and losses on sale of all such securities are reported in net loss, computed using the specific identification cost method. The Company places its marketable securities primarily in U.S. government securities, money market funds, corporate debt securities, commercial paper and certificates of deposit.

The Company’s investments are subject to a periodic impairment review. The Company recognizes an impairment charge when a decline in the fair value of its investments below the cost basis is judged to be other-than-temporary. The Company considers various factors in determining whether to recognize an impairment charge, including the length of time and extent to which the fair value has been less than the Company’s cost basis, the financial condition and near-term prospects of the investee, and the Company’s intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in the market value.

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 marketable securities are with two major financial institutions in the United States.

The Company performs an ongoing credit evaluation of its strategic partners’ financial conditions and generally does not require collateral to secure accounts receivable from its strategic partners. The Company’s exposure to credit risk associated with non-payment will be affected principally by conditions or occurrences within Takeda Pharmaceutical Company Ltd. (“Takeda”). Approximately 53% and 56% of total revenues for the year ended December 31, 2018 and 2017, were derived from Takeda. See also Note 4, Research and Development Collaboration Agreements, regarding the collaboration agreements with Takeda.

Drug candidates developed by the Company may require approvals or clearances from the 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.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Major additions and improvements are capitalized while maintenance and repairs that do not improve or extend the useful life of the respective asset are expensed. Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the assets, which range from five to seven years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the assets.

Impairment of Long-Lived Assets

When events, circumstances and/or operating results indicate that the carrying values of long-lived assets might not be recoverable through future operations, the Company prepares projections of the undiscounted future cash flows expected to result from the use of the assets and their eventual disposition. If the projections indicate that the recorded amounts are not expected to be recoverable, such amounts are reduced to estimated fair value. Fair value is estimated based upon internal evaluation of each asset that includes quantitative analyses of net revenue and cash flows, review of recent sales of similar assets and market responses based upon discussions in connection with offers received from potential buyers. Certain factors used for these types of nonrecurring fair value measurements are considered Level 3 inputs. Management determined there was no impairment during the years ended December 31, 2018 and 2017.

Revenue Recognition

The Company's revenue has consisted principally of research and development revenue and grant revenue.

Grant revenue relates to the grants the Company has received from governmental bodies that are conditional cost reimbursement grants, and we recognize revenue as allowable costs are incurred. Amounts collected in excess of revenue recognized are recorded as deferred revenue.

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

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

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

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

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

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

The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation as each performance obligation is satisfied over time, with progress toward completion measured based on actual costs incurred relative to total estimated costs to be incurred over the life of the contract. Recorded revenue and costs are subject to revision as the contract progresses. Such revisions may result in increases or decreases to revenue and income and are reflected in the consolidated financial statements in the periods in which they are first identified. Estimating costs under the Company's collaboration agreements is complex and involves significant judgment. Factors that must be considered in making estimates include labor productivity and availability, the nature and technical complexity of the work to be performed, potential performance delays, availability and timing of funding from the customer and progress toward completion. Adjustments to original estimates are often required as work progresses and additional information becomes known, even though the scope of the work required under the contract may not change. Any adjustment as a result of a change in estimates is made when facts develop, events become known, or an adjustment is otherwise warranted, such as in the case of contract change orders. The Company has procedures and processes in place to monitor the actual progress of a project against estimates and the Company's estimates are updated if circumstances are warranted.

Performance obligations may include research and development services to be performed by the Company on behalf of the collaboration partner. Revenue is recognized on research and development efforts as the services are performed and presented on a gross basis, since the Company is the principal.

Under collaboration agreements, the timing of revenue recognition and contract billings may differ, and result in contract assets and contract liabilities. Contract assets represent revenues recognized in excess of amounts billed under collaboration agreements and are transferred to accounts receivable when billed or billing rights become unconditional. Contract liabilities represent billings in excess of revenues recognized under collaboration agreements.

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

Income Taxes

Income taxes are recorded in accordance with ASC 740, Accounting for Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. The Company determines its deferred tax assets and liabilities based on differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

ASC 740 clarifies the accounting for uncertainty in income taxes recognized in the financial statements and provides that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. This interpretation also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods and disclosure. The Company's policy for recording interest and penalties associated with uncertain tax positions is to record such items as a component of tax expense.

Stock-Based Compensation

The Company accounts for its stock-based compensation awards to employees, including grants of employee stock options, to be recognized in the statements of operations based on their grant date fair values. The Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. The Company recognizes stock-based compensation expense, equal to the grant date fair value of stock options over the requisite service period.

Warrants

In conjunction with certain financing transactions, the Company issued warrants to purchase the Company's common stock. The Company determines whether the warrants should be classified as a liability or equity. For warrants classified as liabilities, the Company estimates the fair value of the warrants at each reporting period using Level 3 inputs. The estimates in valuation models are based, in part, on subjective assumptions, including but not limited to stock price volatility, the expected life of the warrants, the risk-free interest rate and the fair value of the common stock underlying the warrants, and could differ materially in the future. The Company will continue to adjust the fair value of the warrant liability at the end of each reporting period for changes in fair value from the prior period until the earlier of the exercise or expiration of the applicable warrant. For warrants classified as equity, the Company records the value of the warrants in additional paid-in capital on the balance sheet. The Company will continue to evaluate the classification of the warrants on a quarterly basis, to determine whether the warrants continue to meet equity classification requirement.

Research and Development Costs

Research and development expenses consist of costs such as salaries and benefits, laboratory supplies, facility costs, consulting fees and fees paid to contract research organizations, clinical trial sites, laboratories, other clinical service providers and contract manufacturing organizations. Research and development costs are expensed as incurred.

In-process Research & Development

In-process research and development, or IPR&D, represents the fair value assigned to acquired 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.

Comprehensive loss

Comprehensive loss is comprised of the Company's net loss and other comprehensive income (loss). Unrealized gain (loss) on available-for-sale marketable securities represents the only component of other comprehensive income (loss).

Clinical Trial Accruals

The Company's preclinical and clinical trials are performed by third party contract research organizations (CROs) and/or clinical investigators, and clinical supplies are manufactured by contract manufacturing organizations (CMOs). Invoicing from these third parties may be monthly based upon services performed or based upon milestones achieved. The Company accrues these expenses based upon its assessment of the status of each clinical trial and the work completed, and upon information obtained from the CROs and CMOs. The Company's estimates are dependent upon the timeliness and accuracy of data provided by the CROs and CMOs regarding the status and cost of the studies, and may not match the actual services performed by the organizations. This could result in adjustments to the Company's research and development expenses in future periods. To date the Company has had no significant adjustments.

Bonus Accruals

The Company has bonus programs for eligible employees. Bonuses are determined based on various criteria, including the achievement of corporate, departmental and individual goals. Bonus accruals are estimated based on various factors, including target bonus percentages per level of employee and probability of achieving the goals upon which bonuses are based. The Company's management periodically reviews the progress made towards the goals under the bonus programs. As bonus accruals are dependent upon management's judgments of the likelihood of achieving the various goals, it is possible for bonus expense to vary significantly in future periods if changes occur in those management estimates.

Segments

The Company has one reportable segment and uses one measurement of results of operations to manage its business. All long-lived assets are maintained in the United States of America.

Recently Issued Accounting Pronouncements

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

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

In December 2017, the SEC issued Staff Accounting Bulletin ("SAB") 118 to address the application of GAAP in situations in which a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Cuts and Jobs Act (the "Tax Act"), which was signed into law on December 22, 2017. In March 2018, the FASB issued ASU No. 2018-05, "Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118 (SEC Update)", which amended ASC 740 to incorporate the requirements of SAB 118. The impact of the adoption of the standard did not have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, "Stock-based Compensation: Improvements to Nonemployee Share-based Payment Accounting", which amends the existing accounting standards for share-based payments to nonemployees. This ASU aligns much of the guidance on measuring and classifying nonemployee awards with that of awards to employees. Under the new guidance, the measurement of nonemployee equity awards is fixed on the grant date. This ASU becomes effective in the first quarter of fiscal year 2019 and early adoption is permitted. Entities will apply the ASU by recognizing a cumulative-effect adjustment to retained earnings as of the beginning of the annual period of adoption. The Company early adopted the standard in the fourth quarter of 2018 and it did not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases (Topic 842)* (ASU 2016-02), that amends the guidance for the accounting and disclosure of leases. This new standard requires that lessees recognize operating and finance lease liabilities and corresponding right-of-use assets on the balance sheet and to provide enhanced disclosures surrounding the amount, timing, and uncertainty of cash flows arising from leasing arrangements. The Company is adopting the new standard effective January 1, 2019 on a modified-retrospective basis and will not restate comparative periods. We will elect the package of practical expedients permitted under the transition guidance, which allows us to carryforward our historical lease classification, our assessment on whether a contract is or contains a lease, and our initial direct costs for any leases that exist prior to adoption of the new standard. We will also elect to combine lease and non-lease components and to keep leases with an initial term of 12 months or less off the balance sheet and recognize the associated lease payments in the consolidated statements of income on a straight-line basis over the lease term. The Company does not expect to elect the practical expedient pertaining to the use of hindsight. The Company expects that the adoption of this standard will have a material effect on the Company's financial statements. While the Company continues to assess all the effects of adoption, the Company currently believes that the most significant impact will be reflected in: (i) the recognition of new ROU assets and lease liabilities on the Company's balance sheet for its operating leases of real estate and (ii) the requirement to provide significant new disclosures regarding the Company's leasing activities. The adoption of new standard will have a material impact on the Company's consolidated balance sheet as of January 1, 2019, as we will recognize the right-of-use assets and liabilities for our operating leases. We expect to record lease liabilities of approximately \$4.7 million based on the present value of the remaining minimum rental payments using discount rates as of the effective date. We also expect to record corresponding right-of-use assets of approximately \$4.2 million, based on the operating lease liabilities adjusted for unamortized deferred rent and lease incentives. The Company, however, does not expect a material impact to its consolidated statements of operations and consolidated statements of cash flow.

In May 2017, the FASB issued a new accounting standard update on stock compensation and the 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. The standard is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. The Company early adopted the standard in the first quarter of 2018 and it did not have a material impact on the Company's consolidated financial statements.

NOTE 2—NET LOSS PER COMMON SHARE

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

	Years Ended December 31,	
	2018	2017
Numerator:		
Net loss attributable to common shareholders	\$ 30,287	\$ 24,098
Denominator:		
Weighted-average number of common shares outstanding - basic and diluted	<u>29,601,692</u>	<u>11,400,881</u>
Net loss per share:		
Basic and diluted	<u>\$ 1.02</u>	<u>\$ 2.11</u>

In August 2017, in conjunction with the Merger, all of the Private Molecular common stock was exchanged for the Company's Common Stock at an exchange ratio of 7.7844, before giving effect to the 11:1 reverse stock split as a result of the Merger. Share amounts in the table above reflect this conversion.

The following outstanding warrants and options were split adjusted, and 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):

	Years Ended December 31,	
	2018	2017
Shares issuable upon exercise of warrants	3,522	3,332
Shares issuable upon exercise of stock options	4,003	2,769

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 a Reverse Stock Split and changed its name from Threshold Pharmaceuticals, Inc. to Molecular Templates, Inc. Under the terms of the Merger, at the effective time of the Merger, the Company issued shares of its common stock to Private Molecular stockholders, at an exchange ratio of 7.7844 shares of common stock (the “Exchange Ratio”), before 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 2009 Stock Plan (the “2009 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, then 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, then 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 remain issued and outstanding. However, for accounting purposes, Threshold equity awards are 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 all were vested and exercisable at a weighted average exercise price of \$33.62 per share, after giving effect to the Reverse Stock Split. As all assumed options were fully vested at the time of the Merger, no further stock-based compensation expense will be recognized.

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):

	August 1, 2017
Number of share of the combined company owned by Threshold stockholders	6,508 (1)
Multiplied by the price per share of Threshold common stock	\$ 5.94 (2)
Purchase price before options	\$ 38,658
Threshold options assumed	1,006 (3)
Settlement of preexisting bridge note with Threshold	(4,010) (4)
Total purchase price	<u><u>\$ 35,654</u></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 from 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 Private Molecular is considered to be the acquirer for accounting purposes, the pre-Merger vested stock options granted by Threshold under the 2014 Equity Incentive Plan are deemed to have been exchanged for equity awards of the Company and as such the portion of the acquisition date fair value of these equity awards attributable to pre-Merger service to Threshold were accounted for as a component of the consideration transferred.
4. Represent the bridge loan at the date of merger between Threshold and Molecular. Since the receivable on Threshold's balance sheet was settled as part of the merger, it is deemed to be a reduction in the purchase price.

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

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

	August 1, 2017
Cash and cash equivalents	\$ 11,216
Prepaid expenses and other current assets	945
In-process research and development (IPR&D)	26,623
Accounts payable, accrued expenses	(2,009)
Warrant liability	(1,121)
Net assets acquired	<u><u>\$ 35,654</u></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 Company completed the final allocation of the purchase price, which was based on the finalization of the valuation of the fair value of assets acquired and liabilities assumed and is included in these consolidated financial statements.

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.

Transaction Costs

Transaction costs associated with the Merger of approximately \$2.0 million are included in general and administrative expense for the year ended December 31, 2017.

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 as a reduction to purchase consideration.

Stock-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. Options to purchase 963,681 shares of common stock were assumed as a result of the Merger. As all assumed options were vested at the time of the Merger, no additional stock-based compensation will be recognized related to these assumed 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 13, Equity Incentive Plans and 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 \$320,000 of operating expenses attributable to the former Threshold business activities for the period of August 1, 2017 to December 31, 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).

	Unaudited Year ended December 31, 2017
Revenue	\$ 6,395
Net loss	\$(15,599)

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, 2017. 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 \$5.4 million for the year ended December 31, 2017.
- Elimination of the loss on conversion of notes of \$4.6 million for the year ended December 31, 2017.
- 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 year ended December 31, 2017.

- Elimination of severance payments of \$2.9 million related to former Threshold executives, in connection with the Merger for the year ended December 31, 2017.
- Elimination of interest expense of \$0.3 million for the year ended December 31, 2017, related to the Threshold bridge loan to Private Molecular that was paid down with the Merger.
- Elimination of the change in the fair value of the Threshold warrant liabilities of \$0.1 million of loss for the year ended December 31, 2017.

NOTE 4 — RESEARCH AND DEVELOPMENT AGREEMENTS

Disaggregated Research and Development Revenue

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

	Twelve Months Ended December 31,	
	2018	2017
Japan	\$ 7,087	\$ 1,908
United States	196	500
Total Research and Development Revenue	\$ 7,283	\$ 2,408

Impact of Adoption of ASC 606

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

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

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

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

Contract Assets and Liabilities

Changes in the Company's contract assets and liabilities under Topic 606 were as follows (in thousands):

	December 31, 2018	December 31, 2017(1)
Contract Assets		
Unbilled revenue	\$ —	\$ —
Contract Liabilities		
Deferred revenue	\$ 28,901	\$ 1,092

- (1) December 31, 2017 balances prior to the impact related to the modified retrospective adoption of ASC 606. During the year ended December 31, 2018, the Company recorded \$982,000 in research and development revenue that was previously included in deferred revenue at December 31, 2017. The main reason for the increase in deferred revenue during the year ended December 31, 2018, is the Takeda Development and License Agreement entered into during September 2018, and the increased consideration under the Takeda Individual Project Agreement.

Related Party Collaboration Agreements - 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 promised goods and services under the Takeda Collaboration Agreement were the background IP license, as well as the research and development services. The Company determined that there was one performance obligation, since the background IP and manufacturing were not distinct from the research and development services. Revenues are recognized over the period that the research and development services occur. The Company also concluded that, since the option for the exclusive license is deemed to be at fair value that the option does not provide the customer with a material right and should be accounted for if and when the option is exercised. All research and development services were performed as of December 31, 2018.

During the years ended December 31, 2018 and 2017, the Company recorded collaboration revenue from Takeda of \$92,000 and \$1.9 million under the Takeda Collaboration Agreement, respectively. This revenue is deemed to be revenue from a related party (as discussed further in Note 8 “Related Party Transactions”)

Takeda Individual Project Agreement

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

During the year ended December 31, 2018, the Company recognized research and development revenue from Takeda of \$2.2 million under the Takeda Individual Project Agreement. No revenue was recognized during the year ended December 31, 2017 since the agreement was not in place.

Takeda Development and License Agreement

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

Pursuant the Takeda Development and License Agreement Takeda made an upfront payment of \$30.0 million to the Company in October 2018.

The Takeda Development and License Agreement also provides for development costs to be shared equally between the Company and Takeda during the Early Stage Development Period. The Company has an option to opt into co-development after the Early Stage Development, that would make the Company eligible to potentially receive higher milestone payments and a higher royalty percentage.

In addition to the upfront fee, if the Company exercises its co-development option and funds its share of development costs, it is eligible to receive pre-clinical and clinical development milestone payments of up to \$307.5 million, upon the achievement of certain development milestones and regulatory approvals; and sales milestone payments of up to \$325.0 million, upon the achievement of certain sales milestone events. If the Company does not exercise its co-development option, it is eligible to receive development milestone payments of up to \$162.5 million upon the achievement of certain development milestones and regulatory approvals; and sales milestone payments of up to \$175.0 million upon the achievement of certain sales milestone events. The Company will also be entitled to receive tiered royalties, subject to certain reductions, as percentages of annual aggregate net sales, if any, of Licensed Products. The royalty percentages would range from low double-digits to low twenties if the Company exercises its option to co-develop, and from high-single digits to low teens if the Company does not exercise its option to co-develop.

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

The total transaction price of \$29.3 million, consisting of the (1) \$30.0 million upfront payment, (2) a \$10.0 million development milestone payment that is deemed probable of being achieved, (3) minus \$10.7 million in expected co-share payment payable to Takeda during Early Stage Development. The expected co-share payment is considered variable consideration, and the Company applied a constraint using the expected value method. Significant judgement was involved in determining transaction consideration, including the determination of the variable consideration, including the constraint on consideration.

The Company determined that the initial \$10.0 million potential development milestone payment under the Development and License Agreement is probable of being achieved. Therefore, this payment was included in the transaction consideration. As of December 31, 2018, the other potential development milestones and sales milestones are not currently deemed probable of being achieved, as they are dependent on factors outside the Company's control. Therefore, these future development milestones and sales-based milestone payments have been fully constrained and are not included in the transaction price as of December 31, 2018.

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

The Company recognized revenue of \$3.9 million during the year ended December 31, 2018, related to the Takeda Development and License Agreement. During the year ended December 31, 2017, the Company recorded no research and development revenue under the Development Agreement, since the agreement was not in place. As of December 31, 2018, deferred revenue related to the performance obligation was \$24.8 million.

Takeda Multi-Target Agreement

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

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

Molecular received an upfront fee of \$1.0 million and an additional \$2 million following the designation of each of the two targets in December 2017. As of December 31, 2018, the Company has received \$5.0 million from Takeda pursuant to the Takeda Multi-Target Agreement.

The Company may also receive an additional \$25.0 million in aggregate through the exercise of the option to license ETBs. Additionally, the Company may also be entitled to receive clinical development milestone payments of up to approximately \$397.0 million, for achievement of development milestones and regulatory approval of collaboration products under the Takeda Multi-Target Agreement. The Company may also be entitled to receive commercial milestone payments of up to \$150.0 million, for achievement of pre-specified sales milestones related to net sales of all collaboration products under the Takeda Multi-Target Agreement. The Company is also entitled to tiered royalty payments of a mid-single to low-double digit percentage of net sales of any licensed ETBs, subject to certain reductions. Finally, the Company is entitled to receive up to \$10.0 million in certain contingency fees.

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

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

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

In connection with the execution of the Takeda Multi-Target Agreement, Takeda also entered into a stock purchase agreement with the Company (“Takeda Stock Purchase Agreement”), pursuant to which Takeda purchased approximately \$20.0 million of shares of the Company’s common stock following the reverse-merger in the third quarter of 2017. See Note 12, Stockholders’ Equity, for further details. Since the Takeda Stock Purchase Agreement was dependent on contingent events, the Company determined that the transaction was constrained, and not a performance obligation under the Takeda Multi-Target Agreement. The Company accounted for the stock purchase agreement in August 2017, once the constraints were removed, and recorded the \$20.0 million in equity upon the settlement of the stock purchase transaction.

During the year ended December 31, 2018, the Company recorded \$901,000, in research and development revenue under the Multi-Target Takeda Agreement. During the year ended December 31, 2017 the Company recorded no collaboration revenue under the Multi-Target Takeda Agreement, since no services had been performed under the project. As of December 31, 2018, deferred revenue related to the performance obligation was \$4.1 million.

Other Collaboration Agreements

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

The customer also exercised an option under the Other Collaboration Agreement in November 2017, for the manufacture of additional quantities of ETB molecules, for additional consideration of \$250,000, upon delivery and acceptance of the additional materials.

The Company determined that at the inception of the agreement, the promised goods and services under the Other Collaboration Agreement were, the research and development services, and manufacturing. The Company determined that there was one performance obligation, since the manufacturing was not distinct from the research and development services. Revenues are recognized over the period that the research and development services occur using an input method to measure progress towards satisfaction of the performance obligation. The option for additional ETB molecules was determined to be at fair value and was accounted for once the option was exercised. All research and development services were performed as of December 31, 2018.

During the years ended December 31, 2018 and 2017, the Company recorded \$196,000 and \$500,000 in research and development revenue under the Other Collaboration Agreement, respectively.

Grant Agreements

The Company receives funds from a state grant funding program, which is a conditional cost reimbursement grant and revenue is recognized as allowable costs are paid.

In November 2011, Private Molecular was awarded a \$10.6 million product development grant from Cancer Prevention Research Institute of Texas, or CPRIT for its CD20-targeting ETB MT-3724. To date, Molecular has received \$9.5 million in grant funds.

On September 18, 2018, the Company entered into a Cancer Research Grant Contract (the “CPRIT Agreement”) with CPRIT, in connection with a grant of approximately \$15.2 million awarded by CPRIT to the Company to fund research of a cancer therapy involving a CD38 targeting ETB. Pursuant to the CPRIT Agreement, the Company may also use such funds to develop a replacement CD38 targeting ETB, with or without a partner.

The Company recognized approximately \$6.0 million and \$987,000 in grant revenue under these awards during the years ended December 31, 2018 and 2017, respectively. Amounts collected in excess of revenue recognized are recorded as deferred revenue. Amounts submitted for reimbursement in excess of amounts received are recorded as receivables in other current assets. As of December 31, 2018, we had \$4.1 million recorded in other current assets.

NOTE 5—MARKETABLE SECURITIES AND FAIR VALUE MEASUREMENTS

The Company accounts for its marketable securities in accordance with ASC 820 “*Fair Value Measurements and Disclosures*. ” ASC 820 defines fair value, establishes a framework for measuring fair value in 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 multiple 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 available-for-sale marketable securities) at fair value on a recurring basis as of December 31, 2018 and 2017:

(in thousands)	Fair Value as of December 31, 2018	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	\$ 82,843	\$ 82,843	\$ —	\$ —
Commercial paper	12,825	—	12,825	—
Total	<u><u>\$ 95,668</u></u>	<u><u>\$ 82,843</u></u>	<u><u>\$ 12,825</u></u>	<u><u>\$ —</u></u>

Amounts included in:

Cash and cash equivalents	\$ 85,434
Marketable securities, current	10,234
Total	<u><u>\$ 95,668</u></u>

(in thousands)	Fair Value as of December 31, 2017	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	\$ 51,751	\$ 51,751	\$ —	\$ —
Commercial paper	—	—	—	—
Total	<u><u>\$ 51,751</u></u>	<u><u>\$ 51,751</u></u>	<u><u>\$ —</u></u>	<u><u>\$ —</u></u>

Amounts included in:

Cash and cash equivalents	51,751
Marketable securities, current	—
Total	<u><u>\$ 51,751</u></u>

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

As of December 31, 2018 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value	Maturity Dates
					Level 1 Level 2 Level 3
Cash equivalents - money market funds and commercial paper	<u><u>\$ 85,434</u></u>	<u><u>\$ —</u></u>	<u><u>\$ —</u></u>	<u><u>\$ 85,434</u></u>	1/2019 - 9/2019
Marketable securities, current - commercial paper	<u><u>10,234</u></u>	<u><u>—</u></u>	<u><u>—</u></u>	<u><u>10,234</u></u>	<u><u>10,234</u></u>

As of December 31, 2017 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value	Maturity Dates
					Level 1 Level 2 Level 3
Cash equivalents - money market funds	<u><u>\$ 51,751</u></u>	<u><u>\$ —</u></u>	<u><u>\$ —</u></u>	<u><u>\$ 51,751</u></u>	<u><u>51,751</u></u>

There were no realized gains or losses in years ending December 31, 2018 and 2017.

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

(in thousands)	Fair Value as of December 31, 2018	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
2017 warrants	\$ 3	\$ —	\$ —	\$ 3

(in thousands)	Fair Value as of December 31, 2017	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
2017 warrants	\$ 954	\$ —	\$ —	\$ 954

The Company determined the fair value of the liability associated with its 2017 Warrants to purchase in aggregate 377,273 shares of outstanding common stock using a Black-Scholes Model. See detailed discussion in Note 12, "Stockholders' Equity."

As of December 31, 2018 and 2017 the fair value of the long-term debt approximated it's carrying value of \$3.3 million and \$3.5 million, respectively, because it is carried at market observable interest rates, which are considered Level 2.

NOTE 6—PROPERTY AND EQUIPMENT

Property and equipment comprise the following (in thousands):

	December 31,	
	2018	2017
Laboratory equipment	\$ 4,676	\$ 1,691
Leasehold improvements	3,274	512
Furniture and fixtures	89	85
Computer and equipment	145	76
	8,184	2,364
Less: Accumulated depreciation	(1,333)	(412)
Total property and equipment, net	\$ 6,851	\$ 1,952

Depreciation expense was \$958,000 and \$155,000 for the years ended December 31, 2018 and 2017, respectively.

NOTE 7—BALANCE SHEET COMPONENTS

Accrued liabilities comprise the following (in thousands):

	December 31,	
	2018	2017
Accrued liabilities:		
General and administrative	297	\$ 374
Clinical trial related costs	598	702
Non-clinical research and manufacturing operations	2,644	435
Payroll related	1,787	1,149
Other accrued expenses	31	30
Total accrued liabilities	\$ 5,357	\$ 2,690

Deferred revenue was comprised of the following:

	December 31,	
	2018	2017
Deferred revenue		
Grant agreements	\$ —	\$ 1,673
Research and development agreements	28,901	1,092
Total deferred revenue	\$ 28,901	\$ 2,765

NOTE 8—RELATED PARTY TRANSACTIONS

Convertible Notes

As of December 31, 2017, the Company had received an aggregate of approximately \$10.0 million from stockholders under secured convertible promissory notes (the "Notes"). All of the Notes were issued in 2017 and 2016 and had the same terms. The Notes were subordinate to the long-term debt due to Silicon Valley Bank (See Note 9, 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 and no Notes remain outstanding at December 31, 2017. The principal of \$10.0 million and accrued interest \$486,900 was converted to 3,121,098 shares, which converted to 2,208,716 post-split shares in the merged entity. As a result, the Company recorded a loss on conversion of notes of \$4.6 million during the year ended December 31, 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, the Takeda Multi-Target Agreement and the Takeda Development and License Agreement. Refer to Note 12. Stockholders' Equity, for more detail about the Takeda Stock Purchase Agreement. Jonathan Lanfear, a director of the Company, is the Vice President and Global Head of Oncology and Neuroscience Business Development for Takeda.

Private Placement

Immediately following the Private Placement in 2017 described in Note 12 below, Longitude Venture Partner III, L.P. ("Longitude") and CDK Associates, L.L.C. ("CDK") became related parties, with Longitude and CDK beneficially owning 15.3% and 5.55% of the Company, respectively, following investments of \$20.0 million and \$7.0 million, respectively. Scott Morenstein, a director of the Company is a Managing Director of Caxton Alternative Management LP, the investment manager of CDK. David Hirsch, a director of the Company, is a member of Longitude Capital Partners III, LLC, the general partner of Longitude. Furthermore, Kevin Lalande, a director of the Company is affiliated with Sante Health Ventures I, L.P. and Sante Heath Ventures Annex Fund, L.P., which are stockholders of the Company and were investors in the Concurrent Financing.

Threshold Promissory Note

The Company received \$4.0 million in the aggregate from Threshold during 2017 in the form on 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.

Public Offering

Following the Public Offering described in Note 12, "Stockholders' Equity" below, BVF Partners L.P. ("BVF") and Perceptive Advisors LLC ("Perceptive") owned 7.6% and 5.9% of the Company, following investments of \$15.3 million and \$11.9 million, respectively.

Neither BVF nor Perceptive is affiliated with any director or executive officer of the Company. Longitude Venture Partners III, L.P. and CDK, current stockholders of the Company, purchased 365,000 and 545,454 shares of common stock, respectively, in the Public Offering at the public offering price. Following the Public Offering, Longitude and CDK beneficially owned 12.33% and 4.96% of the Company, respectively. Scott Morenstein, a director of the Company is a Managing Director of Caxton Alternative Management LP, the investment manager of CDK. David Hirsch, a director of the Company, is a member of Longitude Capital Partners III, LLC, the general partner of Longitude.

NOTE 9 — BORROWING ARRANGEMENTS

SVB Loan Agreement

In April 2014, the Company entered into a loan and security agreement (the "Loan 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 48,874 shares of the Company's common stock at an exercise price of \$3.07 per share under the amended loan and security agreement; and (4) a final fee of \$375,000 due at the loan maturity date in addition to the principal and interest payments.

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

As of December 31, 2017, the Company had received \$6 million in the aggregate from this Growth Capital Loan. The Company was 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 December 31, 2017. Interest only payments were made monthly and beginning November 1, 2016, the Company paid the first of thirty consecutive equal monthly payments of principal plus interest.

The Company paid down the Growth Capital Loan on February 27, 2018, from the proceeds of the Perceptive Credit Facility, discussed below. Until the termination of the Growth Capital Loan on February 27, 2018, the Company paid \$3.2 million in principal, \$375,000 in a final fee, and \$42,000 in interest during the year ended December 31, 2018 and \$2.4 million in principal and \$237,000 in interest during the year ended December 31, 2017.

As of December 31, 2018 the Growth Capital Loan had been repaid, and the balance was zero. As of December 31, 2017, the Growth Capital Loan balance was \$3.5 million.

Perceptive Credit Facility

On February 27, 2018, the Company entered into a term loan facility with Perceptive Credit Holdings II, LP (“Perceptive”) in the amount of \$10.0 million (the “Perceptive Credit Facility”). The Perceptive Credit Facility consists of a \$5.0 million term loan, which was drawn on the effective date of the Perceptive Credit Facility, and an additional \$5.0 million term loan that can be drawn down at a future date. The Company used a portion of the proceeds from the Perceptive Credit Facility to pay off the existing debt facility with SVB. Borrowings under the Perceptive Credit Facility are secured by all of the property and assets of the Company. The principal on the facility accrues interest at an annual rate equal to a three-month LIBOR plus the Applicable Margin. The Applicable Margin is 11.00%. Upon the occurrence, and during the continuance, of an event of default, the Applicable Margin, defined above, will be increased by 4.00% per annum. The interest rate at December 31, 2018 was 13.8%. Payments for the first 24 months are interest only and are paid quarterly. After the second anniversary of the closing date of the Perceptive Credit Facility, principal payments of \$200,000 are due each calendar quarter, with a final payment of \$3.4 million due on February 27, 2022. This term loan facility matures on February 27, 2022 and includes both financial and non-financial covenants, including a minimum cash balance requirement. The Company is required to pay an exit fee of \$100,000 on a pro rata basis on the maturity date or the earlier date of repayment of the term loans in full. The exit fee is being accreted to interest expense over the term of the Perceptive Credit Facility using the effective interest method.

For the year ended December 31, 2018, the Company recorded \$569,000 of interest expense and \$292,000 of amortization of debt discount related to the Perceptive Credit Facility. For the year ended December 31, 2017, the Company did not incur any interest expense related to the Perceptive Credit Facility, since the facility was not in place at that time.

In connection with the Perceptive Credit Facility, on February 27, 2018 the Company issued Perceptive a warrant to purchase 190,000 shares of the Company’s common stock. The warrant is exercisable for a period of seven years from the date of issuance at an exercise price per share of \$9.5792, subject to certain adjustments as specified in the Warrant. See Note 12, “Stockholders’ Equity” for further discussion of the warrant. The fair value of the warrant of \$1.5 million was recorded as a debt discount, which is being amortized to interest expense over the term of the Perceptive Credit Facility using the effective interest method.

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

Future required principal payments on the Perceptive Credit facility were as follows as of December 31, 2018 (in thousands):

Year Ending December 31,		
2019	\$	—
2020		800
2021		800
2022		3,500
2023		—
Total		5,100
Debt discount and deferred finance costs		(1,846)
Total	\$	3,254

NOTE 10—COMMITMENTS AND CONTINGENCIES

Commitments

The Company is obligated under operating lease agreements covering the Company’s office facilities in Austin, Texas and Jersey City, New Jersey, respectively. Facilities expense under the operating leases was approximately \$1.5 million and \$625,000 thousand for the years ended December 31, 2018 and 2017, respectively.

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

Year Ending December 31,		
2019	\$	1,266
2020		1,193
2021		1,222
2022		1,247
2023		499
Total	\$	5,427

The Company leases laboratory equipment under non-cancelable capital lease agreements. As of December 31, 2018 and 2017, laboratory equipment under capital leases included in property and equipment totaled approximately \$99,000 and \$162,000, respectively, net of accumulated amortization of approximately \$108,000 and \$75,000, respectively. Future minimum capital lease payments consisted of the following at December 31, 2018 (in thousands):

Year Ending December 31,		
2019	\$	33
2020		21
Total future minimum capital lease payments		54
Less amount representing interest		(4)
Total capital lease obligations		50
Current portion of lease obligations		(33)
Capital lease obligations, non-current portion	\$	17

Contingencies

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

NOTE 11 — REDEEMABLE CONVERTIBLE PREFERRED STOCK

On August 1, 2017, the Company's preferred stock was converted to common shares as a result of the Merger. The outstanding 9,116,405 shares of preferred stock, along with preferred dividends converted to 3,912,892, were converted to 13,029,297 shares of common stock. These common shares were converted upon merger to 9,220,478 shares of the merged entity. Refer to Footnote 3: Merger with Private Molecular, for further details on the Merger.

The following table presents changes in the preferred stock during the year ended December 31, 2017 (in thousands):

	Series A Preferred	Series B Preferred	Series C Preferred	Total
Balance at December 31, 2016	\$ 3,889	\$ 5,480	\$ 16,502	\$ 25,871
Deemed dividends on preferred stock	119	178	661	958
Conversion to common stock in merger	(4,008)	(5,658)	(17,163)	(26,829)
Balance at December 31, 2017	\$ —	\$ —	\$ —	\$ —

NOTE 12—STOCKHOLDERS' EQUITY

Equity Financings and Related Warrants

Private Placement

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

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

Subsequent Private Placement

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 the Private Placement, Takeda purchased 2,922,993 shares of the Company common stock, at a price per share of \$6.8423, for an aggregate purchase price of \$20 million.

Public Offering

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

Common Stock Warrant Liability Valuation

As of December 31, 2018, the Company had warrants outstanding to purchase 3,521,735 shares of the Company’s common stock. The Company accounts for certain of its common stock warrants under guidance in ASC 480 that clarifies the determination of whether an instrument is classified as a liability or equity. The following table summarizes the Company’s outstanding warrants as of December 31, 2018 and 2017 and the warrant activity during the year ended December 31, 2018:

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

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

Due to change in control provisions outside of the Company's control in these warrant agreements, 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	37
Conversion of 2014 warrants to common stock	(87)
Warrant liability related to Merger on August 1, 2017	1,120
Change in fair value during the five months ended December 31, 2017	(165)
Balance at December 31, 2017	954
Change in fair value during the year ended December 31, 2018	(951)
Balance at December 31, 2018	<u><u>\$ 3</u></u>

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

	December 31, 2018	December 31, 2017
Risk-free interest rate	2.6 %	1.9 %
Expected life (in years)	1.1	2.1
Dividend yield	—	—
Volatility	77 %	103 %
Stock price at valuation date	\$ 4.04	\$ 10.02

During the year ended December 31, 2018 and 2017 the change in fair value of \$951,000 and \$128,000 of noncash income, respectively, related to the warrants was recorded as change in fair value of warrant liabilities in the Company's consolidated statement of operations and comprehensive loss.

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

In December 2017, the Company issued warrants to purchase 57,930 shares of the Company's common stock with an exercise price of \$6.84, the Wedbush Warrants as described above. The Wedbush Warrants are classified as equity and recorded in additional paid-in capital; and were valued at \$0.4 million using the Black-Scholes model. The Black-Scholes inputs used were: expected dividend rate of 0%, expected volatility of 108%, risk free interest rate of 2.3%, and expected term of 7.0 years. The Wedbush Warrants together with the Private Placement Warrants are combined as "2017 Private Placement Warrants" in the table above.

On February 28, 2018, in connection with the Perceptive Credit Facility, the Company issued warrants to purchase 190,000 shares of the Company's common stock with an exercise price of \$9.58 (the "2018 Warrants"). The 2018 Warrants are exercisable for a period of seven years from the date of issuance, subject to certain adjustments as specified in the Warrants. The 2018 Warrants were classified as equity and recorded in additional paid-in capital; and were valued at \$1.5 million using the Black-Scholes model. The Black-Scholes inputs used were: expected dividend rate of 0%, expected volatility of 105%, risk free interest rate of 2.8%, and expected term of 7.0 years. See Note 9, "Borrowing Arrangements", for further detail about the Perceptive Credit Facility.

NOTE 13—EQUITY INCENTIVE PLANS AND STOCK-BASED COMPENSATION

2014 Equity Incentive Plan

The terms of the 2014 Equity Incentive Plan (“2014 Plan”) provide for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, other stock awards, and performance awards that may be settled in cash, stock, or other property. Stock options may be granted under the 2014 Plan with an exercise price not less than 100% of the fair market value of the common stock on the date of grant. Stock options under the 2014 Plan may be granted with terms of up to ten years and generally vest over a period of four years, with the exception of grants to non-employee directors and consultants where the vesting period is or may be shorter. No additional awards have been or will be made after May 31, 2018 under the 2014 Plan.

2009 Equity Incentive Plan

The terms of the 2009 Stock Plan (the “2009 Plan”) provide for the issuance of incentive stock options, nonqualified stock options and restricted stock to employees, directors and consultants of the Company. In August 2017, the Company assumed the 2009 Stock Plan as part of the Merger. The Company has reserved a sufficient number of shares of common stock to permit exercise of options in accordance with the terms of the 2009 Plan. Options granted under the 2009 Plan generally vest according to a five-year vesting schedule, with 20% of the shares vesting on the one-year anniversary and equal monthly vesting installments thereafter. No additional awards have been or will be made after May 31, 2018 under the 2009 Plan.

2004 Equity Incentive Plan

The 2004 Equity Incentive Plan (“2004 Plan”) provided for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, stock awards and cash awards to employees and consultants. Stock options were granted under the 2004 Plan with an exercise price not less than 100% of the fair market value of the common stock on the date of grant. Stock options under the 2004 Plan were granted with terms of up to ten years and generally vested over a period of four years. The 2004 Plan expired pursuant to its terms on April 7, 2014. No additional awards have been or will be made after April 7, 2014 under the 2004 Plan.

2018 Equity Incentive Plan

In May 2018, the Company adopted the 2014 Equity Incentive Plan (“2018 Plan”). The terms of the 2018 Plan provide for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, other stock awards, and performance awards that may be settled in cash, stock, or other property. Stock options may be granted under the 2018 Plan with an exercise price not less than 100% of the fair market value of the common stock on the date of grant. Stock options under the 2018 Plan may be granted with terms of up to ten years and generally vest over a period of four years, with the exception of grants to non-employee directors and consultants where the vesting period is or may be shorter. The total number of shares of the Company’s common stock initially reserved for issuance under the 2018 Plan was equal to the sum of (i) 2,000,000 newly reserved shares, which included, as of April 30, 2018, 104,184 shares reserved and unallocated under the 2009 Stock Plan, as amended, and 322,290 shares reserved and unallocated under the 2014 Equity Incentive Plan, as amended, plus (ii) up to 2,885,121 additional shares that may be added to the 2018 Plan in connection with the forfeiture or expiration of awards outstanding under the 2014 Plan, the 2009 Plan and the 2004 Plan as of May 31, 2018. Additionally, the number of shares of common stock that may be issued under the 2018 Plan will automatically increase on each January 1, beginning with January 1, 2019, and continuing with January 1, 2028 by an amount equal to the lesser of (i) 4% of the number of outstanding shares of common stock on that date and (ii) an amount determined by the Company’s board of directors or compensation committee; provided, however, that in no event will the number of shares available for issuance under the 2018 Plan be increased to the extent such increase, in addition to any other increases proposed by the board of directors in the number of shares available for issuance under all other employee or director stock plan would result in the total number of shares then available for issuance under all employee and director stock plans exceeding 20% of the outstanding shares of the Company’s common stock on the first day of the applicable fiscal year. As of December 31, 2018, options to purchase 595,710 shares of common stock were available for future grants under the 2018 Plan.

2004 Employee Stock Purchase Plan

On January 1, 2017 an additional 9,091 shares were authorized for issuance under the 2004 Employee Stock Purchase Plan (“2004 Purchase Plan”) pursuant to the annual automatic increase to the authorized shares under the 2004 Purchase Plan. The 2004 Purchase Plan contains consecutive, overlapping 24 month offering periods. Each offering period includes four six-month purchase periods. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of the purchase period. For the year ended December 31, 2018, no shares were purchased by employees under the 2004 Purchase Plan. For the year ended December 31, 2017, employees had purchased 2,868 shares of common stock under the 2004 Purchase Plan at an average purchase price of \$2.80. At December 31, 2018, 18,917 shares were authorized and available for issuance under the 2004 Purchase Plan.

Threshold equity awards issued and outstanding at the time of the Merger pursuant to the 2004 Plan and the 2014 Plan remain issued and outstanding. However, for accounting purposes, Threshold equity awards are assumed to have been exchanged for equity awards of Private Molecular, the accounting acquirer.

The following table summarizes information about stock option activity assuming Threshold equity award plans were assumed by Private Molecular for years ended December 31, 2018 and 2017:

	<u>Outstanding Options Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value of December 31, 2018 (in millions):</u>
Balances, December 31, 2016	941,684	\$ 0.92	5.7	\$ 0.9
Options assumed in merger (1)	963,681	\$ 33.62		
Options granted	1,116,627	8.30		
Options exercised	(17,473)	3.66		
Options canceled	(235,808)	35.48		
Balances, December 31, 2017	2,768,711	\$ 12.07	5.6	\$ 11.0
Options granted	1,844,787	6.98		
Options exercised	(407,682)	0.70		
Options canceled	(202,817)	20.83		
Balances, December 31, 2018	<u>4,002,999</u>	\$ 10.43	6.4	\$ 1.5
Vested and expected to vest December 31, 2018	4,002,999	\$ 10.43	6.4	\$ 1.5
Exercisable at December 31, 2018	1,607,856	\$ 15.19	3.7	\$ 1.5

(1) Private Molecular, as an accounting acquirer assumed stock options covering an aggregate of 963,681 shares of common stock.

At December 31, 2018, stock options outstanding and exercisable by exercise price were as follows:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$ 0.42–1.27	469,797	4.74	\$ 1.05	469,797	\$ 1.05	
\$ 1.85–6.05	423,710	4.78	\$ 5.22	243,127	\$ 5.44	
\$ 6.31–6.31	1,389,634	8.53	\$ 6.31	60,313	\$ 6.31	
\$ 7.14–9.28	459,209	4.94	\$ 7.71	134,911	\$ 7.67	
\$ 9.40–18.04	947,539	7.31	\$ 10.91	386,598	\$ 12.37	
\$ 18.59–79.42	313,110	0.69	\$ 52.42	313,110	\$ 52.42	
\$ 0.42–79.42	<u>4,002,999</u>	6.37	\$ 10.43	<u>1,607,856</u>	\$ 15.19	

The total intrinsic value of stock options exercised during the years ended December 31, 2018 and 2017 were \$2.6 million and \$78,000, respectively, determined at the date of the option exercise. Cash received from stock option exercises were \$283,000 and \$61,000 for the years ended December 31, 2018 and 2017, 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 its current loss position.

Stock-based Compensation

The Company recognizes stock-based compensation in accordance with ASC 718, “*Compensation—Stock Compensation*.” Under this guidance, stock-based compensation cost is based on the recognition of the grant date fair value estimated in accordance with the provisions of ASC 815 over the service period, which is generally the vesting period. The Company accounts for forfeitures as they occur. Stock-based compensation expense, which consists of the compensation cost for employee stock options and the value of options issued to non-employees for services rendered, was allocated to research and development and general and administrative in the consolidated statements of operations as follows (in thousands):

	Years Ended December 31,	
	2018	2017
Stock-based compensation expense:		
Research and development	\$ 1,192	\$ 340
General and administrative	2,800	1,452
	\$ 3,992	\$ 1,792

Employee Stock-based Compensation Expense

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 Company accounts for forfeitures as they occur. The fair value of employee stock options was estimated using the following weighted-average assumptions for the years ended December 31, 2018 and 2017:

	Years Ended December 31,	
	2018	2017
Employee Stock Options		
Risk-free interest rate	2.8 %	2.1 %
Expected life (in years)	6.03	6.07
Dividend yield	—	—
Volatility	107 %	110 %
Weighted-average fair value of stock options granted	\$ 5.79	\$ 6.94

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*”. 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 considers its historical volatility and its industry peers. 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.

The Company recognized \$4.0 million and \$1.8 million of stock-based compensation expense related to stock options granted under the Company’s equity compensation plans, for the years ended December 31, 2018 and 2017, respectively. Additionally, pursuant to the terms of the Merger Agreement in 2017, 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 during the year ended December 31, 2017.

As of December 31, 2018, the total unrecognized compensation cost related to unvested stock-based awards granted to employees under the Company’s equity compensation plans was approximately \$13.0 million. This cost will be recorded as compensation expense ratably over the remaining weighted average requisite service period of approximately 2.9 years.

NOTE 14—INCOME TAXES

The Tax Reform Act was enacted in December 2017. The Tax Act significantly changes U.S. tax law by, among other things, lowering U.S. corporate income tax rates, implementing a territorial tax system, and imposing a one-time transition tax on deemed repatriated earnings of foreign subsidiaries. The Tax Act reduces the U.S. corporate income tax rate from 35% to 21%, effective January 1, 2018.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. As a result of the reduction in the U.S. corporate income tax rate from 35% to 21% under the Tax Act, we revalued our ending net deferred tax assets and liabilities at December 31, 2017 and recognized a \$6.9 million tax expense that was offset by a change in valuation allowance.

The Tax Act provided for a one-time transition tax on the deemed repatriation of post-1986 undistributed foreign subsidiary earnings and profits (“E&P”). The Company currently has one foreign subsidiary that has not commenced operations. As a result, the international aspects of the Tax Act are not applicable. The Company applied the guidance in Staff Accounting Bulletin, or SAB, 118 when accounting for the enactment-date effects of the Tax Act in 2017 and throughout 2018. During 2018, the Company completed its 2017 income tax returns and the Company’s accounting for the enactment-date income tax effects of the Act with no adjustments to the provisional amounts at December 31, 2017.

For the years ended December 31, 2018 and 2017, the Company did not record an income tax provision due to net operating losses and the inability to record an income tax benefit.

A reconciliation of income taxes at the statutory federal income tax rate to net income taxes included in the accompanying statements of operations is as follows (in thousands):

	2018	2017
U.S. federal taxes (benefit) at statutory rate	\$ (6,361)	\$ (7,867)
State federal income tax benefit	(69)	(21)
Permanent differences	(24)	87
Research and development credits	(608)	(237)
Change in valuation allowance due to operations	2,758	4,766
Acquisition-related permanent differences	—	2,281
Expiring state carryovers and other	4,304	991
Change in valuation allowance due to Tax Act	—	(6,863)
U.S. Statutory Rate Change due to Tax Act	—	6,863
Total	<u>\$ —</u>	<u>\$ —</u>

The tax effects of temporary differences that give rise to significant components of the net deferred tax assets are as follows (in thousands):

	December 31,	
	2018	2017
Deferred tax assets		
Net operating loss carryforward	\$ 19,941	\$ 13,797
Research and development credits	2,049	5,060
Deferred stock compensation	4,547	4,058
Deferred revenue	210	581
Other	404	254
Total deferred tax assets	<u>27,151</u>	<u>23,750</u>
Total deferred tax liabilities		
Depreciable and amortizable assets	(925)	(282)
R&D intangible assets	(5,591)	(5,591)
Total deferred tax liabilities	<u>(6,516)</u>	<u>(5,873)</u>
Less: Valuation allowance	(20,635)	(17,877)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

At December 31, 2018, the Company had federal net operating loss carryforwards of approximately \$95.0 million available to offset future taxable income. The Company's federal net operating loss carryforwards will begin to expire in 2021 if not used before such time to offset future taxable income or tax liabilities. For federal and state income tax purposes, a portion of the Company's net operating loss carryforward is subject to certain limitations on annual utilization in case of changes in ownership, as defined by federal and state tax laws. The annual limitation may result in the expiration of the net operating loss before utilization.

At December 31, 2018, the Company had federal research and development tax credits of approximately \$1.9 million, which expire in the year beginning 2022, and state research and development tax credits of approximately \$0.2 million, which have no expiration date.

The Company has established a valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets. The valuation allowance increased by \$2.8 million from continuing operations.

The total amount of unrecognized benefits as of December 31, 2018 and 2017 was \$0 million and \$1.1 million, respectively. The reconciliation of unrecognized tax benefits at the beginning and end of the year is as follows:

(in thousands)	2018	2017
Gross unrecognized tax benefits at January 1,	\$ 1,143	\$ —
Gross increases (decreases) related to acquisitions	(1,143)	1,064
Gross increases related to current year tax positions	—	79
Gross unrecognized tax benefits at December 31,	<u><u>\$ —</u></u>	<u><u>\$ 1,143</u></u>

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2018 and 2017, the Company had no accrued interest or penalties due to the Company's net operating losses available to offset any tax adjustment. The Company currently has no federal or state tax examinations in progress nor has it had any federal or state tax examinations since its inception. As a result of the Company's net operating loss carryforwards, all of its tax years are subject to federal and state tax examination.

NOTE 15—EMPLOYEE BENEFIT PLAN

The Company sponsors a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code covering all full-time employees ("Molecular Templates 401(k) Plan"). The Molecular Templates 401(k) Plan is intended to qualify under Section 401 of the Internal Revenue Code. Participants meeting certain criteria, as defined in the plan document, are eligible for a matching contribution, in amounts determined at the discretion of the Company. Contributions to the Molecular Templates 401(k) Plan by the Company were \$146,000 and \$0 for the years ended December 31, 2018 and 2017, respectively.

NOTE 16—SUBSEQUENT EVENTS

On January 23, 2019 the Company entered into a facility lease agreement for an additional 57,000 square feet of office and laboratory space in Austin, Texas. The lease is estimated to commence in March 2019 and expire August 2028 with no option to renew. The lease will be recognized and measured in accordance with ASC 842 guidance. As such, the Company expects a significant lease liability and right-of-use asset to be recorded on its consolidated balance sheet upon adoption of ASC 842 in 2019.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. 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 December 31, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to its management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2018, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Inherent Limitations of Internal Controls

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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 10-K for the year ended December 31, 2017, Private Molecular and its independent registered public accounting firm identified a material weakness in Private Molecular’s internal control over financial reporting, in connection with the audits of Private Molecular’s consolidated financial statements for the years ended December 31, 2015 and 2016 and preparation of interim financial statements for the first quarter of 2017, Private Molecular and its independent registered public accounting firm identified a material weakness in Private Molecular’s internal control over financial reporting. This material weakness continued to be in place as of December 31, 2017.

A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity’s financial statements will not be prevented, or detected and corrected on a timely basis.

Prior to the completion of the Merger, Private Molecular was a private company and had limited accounting and financial reporting personnel and other resources with which to address its internal controls and procedures. Private Molecular’s lack of adequate accounting personnel resulted in the identification of a material weakness in its internal control over financial reporting, which continued through December 31, 2017. Specifically, Private Molecular did not timely and appropriately account for and disclose the impact of complex, non-routine transactions in accordance with GAAP.

This material weakness was remediated as of December 31, 2018.

Remediation of Material Weakness

We completed the remediation of the material weakness during 2018, with the addition of additional accounting and finance personnel and revision to our internal controls over financial reporting. For example, in November 2017, we hired a new Chief Financial Officer and a Senior Vice President, Finance and Corporate Controller, each with extensive accounting and public company experience. Additionally, we implemented more robust review, supervision and monitoring of the non-routine transactions and the financial reporting process. As a result of the implementation of the remediation plan and based on the evaluation of our disclosure controls and procedures as of December 31, 2018, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel 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 and includes those policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of management and directors of the Company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework (2013).

Based on our assessment, management believes that, as of December 31, 2018, our internal control over financial reporting is effective based on those criteria.

Changes in Internal Control 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 year ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Effective March 29, 2019, our Board of Directors approved amendments to our Amended and Restated Bylaws to implement majority voting in director elections. Under the newly adopted bylaw provisions, each director will be elected by the vote of the majority of the votes cast with respect to that director's election, except that in a contested election as defined in the Bylaws, directors will be elected by plurality vote. For purposes of these provisions, a majority of votes cast shall mean that the number of votes cast "for" a director's election exceeds the number of votes cast "against" that director's election, with "abstentions" and "broker non-votes" not counted as a vote cast either "for" or "against" that director's election.

If, in an election that is not a contested election, an incumbent director does not receive a majority of the votes cast, the newly adopted bylaw provisions require that such director submit an irrevocable resignation to the Nominating and Corporate Governance Committee of the Board. The committee will make a recommendation to the Board as to whether to accept or reject the resignation of such incumbent director, or whether other action should be taken. The Board will act on the resignation, taking into account the committee's recommendation, and publicly disclose (by filing an appropriate disclosure with the Securities and Exchange Commission) its decision regarding the resignation within 90 days following certification of the election results. The committee in making its recommendation and the Board of Directors in making its decision each may consider any factors and other information that they consider appropriate and relevant.

If the Board accepts a director's resignation pursuant to the newly adopted bylaw provisions, or if a nominee for director is not elected and the nominee is not an incumbent director, the Board may fill the resulting vacancy pursuant to Article II, Section 2 of the Bylaws.

Prior to these amendments, director elections were conducted by plurality vote in all cases.

The amendments also include certain minor clarifying and updating changes. This summary of the amendments to our Amended and Restated Bylaws is qualified in its entirety by reference to the full text of the Amended and Restated Bylaws, which is filed as Exhibit 3.4 to this Annual Report on Form 10-K and is incorporated into this Item 9B by reference.

PART III

The information required by Part III is omitted from this report because we will file a definitive proxy statement within 120 days after the end of our 2018 fiscal year pursuant to Regulation 14A for our 2019 Annual Meeting of Stockholders, or the 2019 Proxy Statement, will be filed pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended. If the 2019 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Management and Corporate Governance,” “Section 16(a) Beneficial Ownership Reporting Compliance,” and “Code of Business Conduct and Ethics” in the Company’s Proxy Statement for the 2019 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Executive Officer and Director Compensation” in the Company’s Proxy Statement for the 2019 Annual Meeting of Stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Security Ownership of Certain Beneficial Owners and Management,” and “Equity Compensation Plan Information” in the Company’s Proxy Statement for the 2019 Annual Meeting of Stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Certain Relationships and Related Person Transactions” and “Management and Corporate Governance” in the Company’s Proxy Statement for the 2019 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Independent Registered Public Accounting Firm” in the Company’s Proxy Statement for the 2019 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are being filed as part of this report:

- (1) The following financial statements of the Company and the report of Ernst & Young LLP are included in Part II, Item 8:

Reports of Independent Registered Public Accounting Firms
Consolidated Balance Sheets
Consolidated Statements of Operations and Comprehensive Loss
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
Consolidated Statements of Cash Flows
Notes to Consolidated Financial Statements

- (2) All financial statement supporting schedules are omitted because the information is inapplicable or presented in the Notes to Consolidated Financial Statements.

- (3) A list of exhibits filed with this report or incorporated herein by reference is found in the Exhibit Index immediately following the signature page of this Annual Report.

EXHIBIT NUMBER

DESCRIPTION

2.1^	Agreement and Plan of Merger and Reorganization, dated March 16, 2017, by and among the Company, Molecular Templates OpCo, Inc. and Trojan Merger Sub, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, as amended (File No. 001-32979), filed on March 17, 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 (File No. 001-32979) filed on March 6, 2014).
3.2	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 (File No. 001-32979) as filed with the SEC on August 1, 2017).
3.3	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 (File No. 001-32979) as filed with the SEC on August 7, 2017).
3.4*	Amended and Restated Bylaws of the Company.
4.1	Form of Warrant issued pursuant to the Company's prospectus supplement, dated February 11, 2015, and accompanying prospectus (incorporated by reference to Exhibit 4.9 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 3, 2015).
4.2	Form of Warrant issued pursuant to the Securities Purchase Agreement, dated August 1, 2017, among the Company and the investors named therein (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).
4.3	Form of Warrant issued to Wedbush Securities, dated December 1, 2017 (incorporated by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K (File No. 001-32979), as filed with the SEC on March 30, 2018).
4.4	Warrant to Purchase Common Stock issued to Perceptive Credit Holdings II, LP (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-32979) filed with the SEC on March 2, 2018).
4.5	Form of Senior Indenture (incorporated by reference to Exhibit 4.7 to the Company's registration statement on Form S-3 (File No. 333-228975), as filed with the SEC on December 21, 2018).
4.6	Form of Subordinated Indenture (incorporated by reference to Exhibit 4.8 to the Company's registration statement on Form S-3 (File No. 333-228975), as filed with the SEC on December 21, 2018).
10.1+	2004 Amended and Restated Equity Incentive Plan of the Company, as amended (incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 15, 2012).
10.2+	Amended and Restated 2004 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8 (File No. 333-164865) filed on February 11, 2010).
10.3*	Amended and Restated Non-Employee Director Compensation Policy, adopted by the Board of Directors of the Company on June 14, 2018.
10.4	2014 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on October 13, 2017).

- 10.5+ [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 \(File No. 001-32979\) as filed with the SEC on August 7, 2017\).](#)
- 10.6+ [Form of Notice of Grant of Stock Options and Option Agreement under the 2004 Equity Incentive Plan \(incorporated by reference to Exhibit 10.25 to the Company's Current Report on Form 8-K \(File No. 000-51136\) filed on March 17, 2006\).](#)
- 10.7+ [Form of Stock Option Grant Notice and Option Agreement for employees under the 2014 Equity Incentive Plan \(incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K \(File No. 001-32979\), as filed with the SEC on March 30, 2018\).](#)
- 10.8+ [Form of Stock Option Grant Notice and Option Agreement for non-employee directors under the 2014 Equity Incentive Plan \(incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K \(File No. 001-32979\), as filed with the SEC on March 30, 2018\).](#)
- 10.9+ [Amended and Restated Executive Employment Agreement, dated April 22, 2016, between Molecular Templates OpCo, Inc. and Eric E. Poma, Ph.D. \(incorporated by reference to Exhibit 10.43 to the Company's Registration Statement on Form S-4/A, as filed with the SEC on May 15, 2017\).](#)
- 10.10+ [Amended and Restated Executive Employment Agreement, dated April 22, 2016, between Molecular Templates OpCo, Inc. and Jason Kim \(incorporated by reference to Exhibit 10.44 to the Company's Registration Statement on Form S-4/A, as filed with the SEC on May 15, 2017\).](#)
- 10.11+ [Amended and Restated Executive Employment Agreement, dated November 3, 2017, by and between the Company and Adam D. Cutler \(incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K \(File No. 001-32979\), as filed with the SEC on March 30, 2018\).](#)
- 10.12 [Sales Agreement between the Company and Cowen and Company, LLC, dated November 2, 2015 \(incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q \(File No. 001-32979\), filed on November 2, 2015\).](#)
- 10.13 [Form of Company Support Agreement by and between Molecular Templates OpCo, Inc. and each of the parties named in each agreement therein \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as amended \(File No. 001-32979\), filed on March 17, 2017\).](#)
- 10.14 [Form of Molecular Templates OpCo, Inc. Support Agreement by and between the Company and each of the parties named in each agreement therein \(incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, as amended \(File No. 001-32979\), filed on March 17, 2017\).](#)
- 10.15 [Form of Company Lock-Up Agreement by and between the Company and each of the parties named in each agreement therein \(incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, as amended \(File No. 001-32979\), filed on March 17, 2017\).](#)
- 10.16 [Form of Molecular Templates OpCo, Inc. Lock-Up Agreement by and between the Company and each of the parties named in each agreement therein \(incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, as amended \(File No. 001-32979\), filed on March 17, 2017\).](#)
- 10.17 [Lease Agreement, dated as of October 1, 2016, by and between NW Austin Officer Partners LLC and Molecular Templates OpCo, Inc., as amended on January 30, 2017 \(incorporated by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017, as amended on June 27, 2017\).](#)
- 10.17.1 [Second Amendment to the Lease Agreement, dated October 1, 2016, by and between NW Austin Officer Partners LLC and Molecular Templates OpCo, Inc., dated March 29, 2017 \(incorporated by reference to Exhibit 10.17.1 to the Company's Annual Report on Form 10-K \(File No. 001-32979\), as filed with the SEC on March 30, 2018\).](#)
- 10.17.2 [Third Amendment to the Lease Agreement, dated October 1, 2016, by and between NW Austin Officer Partners LLC and Molecular Templates OpCo, Inc., dated June 27, 2017 \(incorporated by reference to Exhibit 10.17.2 to the Company's Annual Report on Form 10-K \(File No. 001-32979\), as filed with the SEC on March 30, 2018\).](#)
- 10.18 [Sublease, dated October 1, 2016, by and between Zimmer Holdings, Inc. and Molecular Templates OpCo, Inc. \(incorporated by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017, as amended on June 27, 2017\).](#)
- 10.19 [Lease, dated as of August 11, 2016, by and between Evergreen Shipping Agency \(America\) Corporation and Molecular Templates OpCo, Inc. \(incorporated by reference to Exhibit 10.30 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017, as amended on June 27, 2017\).](#)

- 10.20† [Research Collaboration and Option Agreement, dated as of October 31, 2016, by and between Takeda Pharmaceutical Company, Ltd. and Molecular Templates OpCo, Inc. \(incorporated by reference to Exhibit 10.31 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017, as amended on June 27, 2017\).](#)
- 10.21† [Non-Exclusive License Agreement, dated as of July 17, 2014, by and between the Henry M. Jackson Foundation for the Advancement of Military Medicine and Molecular Templates OpCo, Inc. \(incorporated by reference to Exhibit 10.32 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017, as amended on June 27, 2017\).](#)
- 10.22+ [Molecular Templates Amended and Restated 2009 Stock Plan, as amended through September 19, 2013 \(incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K \(File No. 001-32979\), as filed with the SEC on March 30, 2018\).](#)
- 10.23+ [Molecular Templates 2009 Stock Plan Form of Option Agreement \(incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K \(File No. 001-32979\), as filed with the SEC on March 30, 2018\).](#)
- 10.24 [Equity Commitment Letter Agreement, dated as of March 16, 2017, among the Company, Molecular Templates OpCo, Inc., and Longitude Venture Partners III, L.P. \(incorporated by reference to Exhibit 10.35 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017, as amended on June 27, 2017\).](#)
- 10.25 [Note Purchase Agreement, dated as of March 16, 2017, by and between the Company and Molecular Templates OpCo, Inc. \(incorporated by reference to Exhibit 10.39 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017, as amended on June 27, 2017\).](#)
- 10.26 [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 \(File No. 001-32979\) as filed with the SEC on August 7, 2017\).](#)
- 10.27 [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 \(File No. 001-32979\) as filed with the SEC on August 7, 2017\).](#)
- 10.28 [Amended and Restated Loan and Security Agreement, dated as of April 30, 2015, by and between Molecular Templates OpCo, Inc. and Silicon Valley Bank \(incorporated by reference to Exhibit 10.42 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017, as amended on June 27, 2017\).](#)
- 10.29† [Multi-License Collaboration and License Agreement, dated as of June 23, 2017, by and between Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company, Ltd. and Molecular Templates OpCo, Inc. \(incorporated by reference to Exhibit 10.3 to the Company's Form 8-K \(File No. 001-32979\) as filed with the SEC on October 17, 2017\).](#)
- 10.30 [Stock Purchase Agreement, dated as of June 23, 2017, by and among Molecular Templates OpCo, Inc., the Company and Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Ltd. \(incorporated by reference to Exhibit 10.48 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017, as amended on June 27, 2017\).](#)
- 10.31† [Cancer Research Grant Contract, dated as of November 7, 2012, by and between the Cancer Prevention & Research Institute of Texas and Molecular Templates OpCo, Inc. \(incorporated by reference to Exhibit 10.33 to the Company's Current Report on Form 8-K \(File No. 001-32979\) filed with the SEC on June 22, 2018\).](#)
- 10.32+ [Molecular Templates, Inc. 2018 Equity Incentive Plan \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed \(File No. 001-32979\) with the Securities and Exchange Commission on June 1, 2018\).](#)
- 10.33+ [Form of Stock Option Grant Notice and Option Agreement for employees under the 2018 Equity Incentive Plan \(incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-4 \(File No. 333-225-826\), as filed with the SEC on June 22, 2018\).](#)
- 10.34+ [Form of Stock Option Grant Notice and Option Agreement for non-employee directors under the 2018 Equity Incentive Plan \(incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-4 \(File No. 333-225826\), as filed with the SEC on June 22, 2018\).](#)
- 10.35† [Development Collaboration and Exclusive License Agreement by and between Molecular Templates, Inc. and Millennium Pharmaceuticals, Inc., dated September 18, 2018 \(incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q \(File No. 001-32979\), as filed with the SEC on November 13, 2018\).](#)
- 10.36† [Cancer Research Grant Contract, dated September 18, 2018, by and between Molecular Templates, Inc. and the Cancer Prevention and Research Institute of Texas \(incorporated by reference to Exhibit 10.3 to the Company Quarterly Report on Form 10-Q/A \(File No. 001-32979\), as filed with the SEC on February 13, 2019\).](#)

10.37*	Sublease, dated as of January 23, 2019, by and between Molecular Templates, Inc. and State Farm Mutual Automobile Insurance Company.
10.38	Credit Agreement and Guaranty, dated as of February 27, 2018, among the Molecular Templates OpCo, Inc., a Delaware corporation, as borrower, Molecular Templates, Inc., a Delaware corporation, as guarantor, Perceptive Credit Holdings II, LP, as Lender, and certain of Lender's successors and assigns party thereto from time to time (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed with the SEC on March 2, 2018).
10.39	Registration Rights Agreement, dated February 27, 2018, by and between Molecular Templates, Inc. and Perceptive Credit Holdings II, LP (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File No. 001-32979) filed with the SEC on March 2, 2018).
10.40	Underwriting Agreement, dated September 20, 2018, among Molecular Templates, Inc. and Cowen and Company, LLC and Evercore Group L.L.C., as representatives of the several underwriters named therein (incorporated by reference to Exhibit 1.1 of Form 8-K (File No. 001-32979) filed with the SEC on September 24, 2018).
21.1*	Subsidiaries of the Company
23.1*	Consent of Ernst & Young LLP
31.1*	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act of 1934, as amended, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act of 1934, as amended, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	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

[^] The schedules and exhibits to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

^{*} Filed herewith.

^{**} 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 granted as to certain portions, which portions have been omitted and filed separately with the SEC.

⁺ Indicates a management contract or compensatory plan or arrangement.

ITEM 16. 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

March 29, 2019

By: /s/ ERIC E. POMA, PH.D.

Eric E. Poma, Ph.D.

Chief Executive Officer and Chief Scientific Officer

Pursuant to the requirements of the Securities and Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ Eric E. Poma, Ph.D.</u> Eric E. Poma, Ph.D.	Chief Executive Officer and Chief Scientific Officer (Principal Executive Officer)	March 29, 2019
<u>/s/ Adam Cutler</u> Adam Cutler	Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2019
<u>/s/ Harold E. Selick, Ph.D.</u> Harold E. Selick, Ph.D.	Director	March 29, 2019
<u>/s/ Jonathan Lanfear</u> Jonathan Lanfear	Director	March 29, 2019
<u>/s/ David R. Hoffmann</u> David R. Hoffmann	Director	March 29, 2019
<u>/s/ David Hirsch</u> David Hirsch	Director	March 29, 2019
<u>/s/ Kevin Lalande</u> Kevin Lalande	Director	March 29, 2019
<u>/s/ Scott Morenstein</u> Scott Morenstein	Director	March 29, 2019

AMENDED AND RESTATED BYLAWS**Adopted: March 29, 2019****AMENDED AND RESTATED BYLAWS****OF
MOLECULAR TEMPLATES, INC.
a Delaware corporation****ARTICLE I
STOCKHOLDERS**

1. Annual Meeting. An annual meeting of the stockholders, for the election of directors to succeed those whose terms expire and for the transaction of such other business as may properly come before the meeting, shall be held at such place, on such date and at such time as the Board of Directors shall each year fix, which date shall be within 13 months of the last annual meeting of stockholders.

2. Advance Notice; Purpose of Meeting. Nominations of persons for election to the Board and the proposal of business to be transacted by the stockholders may be made at an annual meeting of stockholders (a) pursuant to the notice given by the Corporation with respect to such meeting, (b) by or at the direction of the Board or (c) by any stockholder of record of the Corporation who was a stockholder of record at the time of the giving of the notice provided for in the following paragraph, who is entitled to vote at the meeting and who has complied with the notice procedures set forth in this section.

For nominations or other business to be properly brought before an annual meeting by a stockholder pursuant to clause (c) of the foregoing paragraph, (1) the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation, (2) such business must be a proper matter for stockholder action under the General Corporation Law of the State of Delaware, (3) if the stockholder, or the beneficial owner on whose behalf any such proposal or nomination is made, has provided the Corporation with a Solicitation Notice, as that term is defined in subclause (c)(iii) of this paragraph, such stockholder or beneficial owner must, in the case of a proposal, have delivered a proxy statement and form of proxy to holders of at least the percentage of the Corporation's voting shares required under applicable law to carry any such proposal, or, in the case of a nomination or nominations, have delivered a proxy statement and form of proxy to holders of a percentage of the Corporation's voting shares reasonably believed by such stockholder or beneficial holder to be sufficient to elect the nominee or nominees proposed to be nominated by such stockholder, and must, in either case, have included in such materials the Solicitation Notice and (4) if no Solicitation Notice relating thereto has been timely provided pursuant to this section, the stockholder or beneficial owner proposing such business or nomination must not have solicited a number of proxies sufficient to have required the delivery of such a Solicitation Notice under this section. To be timely, a stockholder's notice shall be

delivered to the Secretary at the principal executive offices of the Corporation not less 120 days, and not more than 150 days, prior to the first anniversary of the date on which the Corporation first mailed its proxy materials for the preceding year's annual meeting of stockholders; provided, however, that if the date of the annual meeting is advanced more than 30 days prior to or delayed by more than 60 days after the anniversary date of the preceding year's annual meeting, notice by the stockholder to be timely must be so delivered not later than the close of business on the later of (i) the 150th day prior to such annual meeting or (ii) the 10th day following the day on which public announcement of the date of such meeting is first made. Such stockholder's notice shall set forth (a) as to each person whom the stockholder proposes to nominate for election or reelection as a director, all information relating to such person as would be required to be disclosed in solicitations of proxies for the election of such nominees as directors pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (the "*Exchange Act*"), and such person's written consent to serving as a director if elected; (b) as to any other business that the stockholder proposes to bring before the meeting, a brief description of such business, the reasons for conducting such business at the meeting and any material interest in such business of such stockholder and the beneficial owner, if any, on whose behalf the proposal is made; and (c) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made (i) the name and address of such stockholder, as they appear on the Corporation's books, and of such beneficial owner, (ii) the class and number of shares of the Corporation that are owned beneficially and of record by such stockholder and such beneficial owner, and (iii) whether either such stockholder or beneficial owner intends to deliver a proxy statement and form of proxy to holders of, in the case of a proposal, at least the percentage of the Corporation's voting shares required under applicable law to carry the proposal or, in the case of a nomination or nominations, a sufficient number of holders of the Corporation's voting shares to elect such nominee or nominees (an affirmative statement of such intent, a "Solicitation Notice").

Notwithstanding anything in the second sentence of the second paragraph of this Section to the contrary, in the event that the number of directors to be elected to the Board is increased and there is no public announcement naming all of the nominees for director or specifying the size of the increased Board made by the Corporation at least 55 days prior to the first anniversary of the preceding year's annual meeting, a stockholder's notice required by this Bylaw shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business on the 10th day following the day on which such public announcement is first made by the Corporation.

Only persons nominated in accordance with the procedures set forth in this Section shall be eligible to serve as directors and only such business shall be conducted at an annual meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth in this Section.

The chairman of the meeting shall have the power and the duty to determine whether a nomination or any business proposed to be brought before the meeting has been made in accordance with the procedures set forth in these Bylaws and, if any proposed nomination or business is not in compliance with these Bylaws to declare that such defective proposed business

or nomination shall not be presented for stockholder action at the meeting and shall be disregarded.

For purposes of this Section, "*public announcement*" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or a comparable national news service or in a document publicly filed by the Corporation with the securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Exchange Act.

Notwithstanding the foregoing provisions of this Section, a stockholder shall also comply with all applicable requirements of the Exchange Act and the rules and regulations thereunder with respect to matters set forth in this Section. Nothing in this Section shall be deemed to affect any rights of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act.

3. Special Meetings; Notice. Special meetings of the stockholders, other than those required by statute, may be called at any time in accordance with the provisions of the Certificate of Incorporation only by the Chairman of the Board of Directors or the President or by the Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board of Directors. For purposes of these Bylaws, the term "Whole Board" shall mean the total number of authorized directors whether or not there exist any vacancies in previously authorized directorships. The Board of Directors may postpone or reschedule any previously scheduled special meeting.

Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to the Corporation's notice of meeting. Nominations of persons for election to the Board of Directors may be made at a special meeting of stockholders at which directors are to be elected pursuant to the Corporation's notice of meeting (a) by or at the direction of the Board of Directors or (b) by any stockholder of record of the Corporation who is a stockholder of record at the time of giving of notice provided for in this paragraph, who shall be entitled to vote at the meeting and who complies with the notice procedures set forth in Section 2 of this Article I. Nominations by stockholders of persons for election to the Board of Directors may be made at such a special meeting of stockholders if the stockholder's notice required by the second paragraph of Section 2 of this Article I shall be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business on the later of the 90th day prior to such special meeting or the 10th day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by the Board of Directors to be elected at such meeting.

Notwithstanding the foregoing provisions of this Section 3, a stockholder shall also comply with all applicable requirements of the Exchange Act and the rules and regulations thereunder with respect to matters set forth in this Section 3. Nothing in this Section 3 shall be deemed to affect any rights of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act.

4. Notice of Meetings. Notice of the place, date, and time of all meetings of the stockholders, and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting, shall be given, not less than 10 nor more than 60 days before the date on which the meeting is to be held, to each stockholder

entitled to vote at such meeting, except as otherwise provided herein or required by law (meaning, here and hereinafter, as required from time to time by the Delaware General Corporation Law or the Certificate of Incorporation of the Corporation).

When a meeting is adjourned to another time or place, notice need not be given of the adjourned meeting if the time and place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken; provided, however, that if the date of any adjourned meeting is more than 30 days after the date for which the meeting was originally noticed, or if a new record date is fixed for the adjourned meeting, notice of the place, if any, date, and time of the adjourned meeting and the means of communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such adjourned meeting, shall be given in conformity herewith. At any adjourned meeting, any business may be transacted which might have been transacted at the original meeting.

5. Quorum. At any meeting of the stockholders, the holders of a majority of all of the shares of stock entitled to vote at the meeting, present in person or by proxy when the meeting convenes, shall constitute a quorum for all purposes and for the entirety of the meeting, unless or except to the extent that the presence of a larger number may be required by law. Where a separate vote by a class or classes or series is required, a majority of the shares of such class or classes or series present in person or represented by proxy shall constitute a quorum entitled to take action with respect to that vote on that matter.

If a quorum shall fail to attend any meeting, the chairman of the meeting may adjourn the meeting to another place, date, or time.

6. Organization. Such person as the Board of Directors may have designated or, in the absence of such a person, the Chairman of the Board, or in his or her absence, the President of the Corporation or, in his or her absence, such person as may be chosen by the holders of a majority of the shares entitled to vote who are present, in person or by proxy, shall call to order any meeting of the stockholders and act as chairman of the meeting. In the absence of the Secretary of the Corporation, the secretary of the meeting shall be such person as the chairman of the meeting appoints.

7. Conduct of Business. The chairman of any meeting of stockholders shall determine the order of business and the procedure at the meeting, including such regulation of the manner of voting and the conduct of discussion as seem to him or her in order. The chairman of the meeting shall have the power to adjourn the meeting to another place, if any, date and time. The date and time of the opening and closing of the polls for each matter upon which the stockholders will vote at the meeting shall be announced at the meeting.

8. Proxies and Voting. At any meeting of the stockholders, every stockholder entitled to vote may vote in person or by proxy authorized by an instrument in writing or by a transmission permitted by law filed in accordance with the procedure established for the meeting. Any copy, facsimile telecommunication or other reliable reproduction of the writing or transmission created pursuant to this paragraph may be substituted or used in lieu of the original writing or

transmission for any and all purposes for which the original writing or transmission could be used, provided that such copy, facsimile telecommunication or other reproduction shall be a complete reproduction of the entire original writing or transmission.

The Corporation may, and to the extent required by law, shall, in advance of any meeting of stockholders, appoint one or more inspectors to act at the meeting and make a written report thereof. The Corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the person presiding at the meeting may, and to the extent required by law, shall, appoint one or more inspectors to act at the meeting. Each inspector, before entering upon the discharge of his duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of his ability. Every vote taken by ballots shall be counted by a duly appointed inspector or inspectors.

9. Stock List. A complete list of stockholders entitled to vote at any meeting of stockholders, arranged in alphabetical order for each class of stock and showing the address of each such stockholder and the number of shares registered in his or her name, shall be open to the examination of any such stockholder for a period of at least 10 days prior to the meeting in the manner provided by law.

The stock list shall also be open to the examination of any stockholder during the whole time of the meeting as provided by law. This list shall presumptively determine the identity of the stockholders entitled to vote at the meeting and the number of shares held by each of them.

ARTICLE II **BOARD OF DIRECTORS**

1. Number, Election and Term of Directors. Subject to the rights of the holders of any series of preferred stock to elect directors under specified circumstances, the number of directors shall be fixed from time to time exclusively by the Board of Directors pursuant to a resolution adopted by a majority of the Whole Board. Each director shall be elected in the manner set forth in these Bylaws and the Certificate of Incorporation and shall hold office until his successor shall have been elected and qualified, or until his death, or until he shall have resigned, or have been removed, as hereinafter provided in these Bylaws.

Each director shall be elected by the vote of the majority of the votes cast with respect to that director's election at any meeting for the election of directors at which a quorum is present, provided that if the number of nominees exceeds the number of directors to be elected at such meeting (a "contested election"), the directors shall be elected by the vote of a plurality of the votes cast. For purposes of this Section 1, "a majority of the votes cast" shall mean that the number of votes cast "for" a director's election exceeds the number of votes cast "against" that director's election (with "abstentions" and "broker non-votes" not counted as a vote cast either "for" or "against" that director's election).

If, in an election that is not a contested election, an incumbent director does not receive a majority of the votes cast, such director shall submit an irrevocable resignation to the Nominating and Corporate Governance Committee, or such other committee designated by the

Board of Directors pursuant to these Bylaws. Such committee shall make a recommendation to the Board of Directors as to whether to accept or reject the resignation of such incumbent director, or whether other action should be taken. The Board of Directors shall act on the resignation, taking into account the committee's recommendation, and publicly disclose (by filing an appropriate disclosure with the Securities and Exchange Commission) its decision regarding the resignation within ninety days following certification of the election results. The committee in making its recommendation and the Board of Directors in making its decision each may consider any factors and other information that they consider appropriate and relevant.

If the Board of Directors accepts a director's resignation pursuant to this Section 1, or if a nominee for director is not elected and the nominee is not an incumbent director, then the Board of Directors may fill the resulting vacancy pursuant to Section 2 of Article II of these Bylaws.

2. Newly Created Directorships and Vacancies. Any vacancies shall be filled in the manner specified in the Certificate of Incorporation. Subject to the rights of the holders of any series of preferred stock then outstanding, newly created directorships resulting from any increase in the authorized number of directors or any vacancies in the Board of Directors resulting from death, resignation, retirement, disqualification, removal from office or other cause shall, unless otherwise required by law or by resolution of the Board of Directors, be filled only by a majority vote of the directors then in office, though less than a quorum (and not by stockholders), and directors so chosen shall serve for a term expiring at the annual meeting of stockholders at which the term of office of the class to which they have been elected expires or until such director's successor shall have been duly elected and qualified. No decrease in the number of authorized directors shall shorten the term of any incumbent director.

3. Regular Meetings. Regular meetings of the Board of Directors shall be held at such place or places, on such date or dates, and at such time or times as shall have been established by the Board of Directors and publicized among all directors. A notice of each regular meeting shall not be required.

4. Special Meetings. Special meetings of the Board of Directors may be called by the Chairman of the Board, the President or by two or more directors then in office and shall be held at such place, on such date, and at such time as they or he or she shall fix. Notice of the place, date, and time of each such special meeting shall be given each director by whom it is not waived by mailing written notice not less than five days before the meeting or by telephone or by telegraphing or telexing or by facsimile transmission of the same not less than 24 hours before the meeting. Unless otherwise indicated in the notice thereof, any and all business may be transacted at a special meeting.

5. Quorum. At any meeting of the Board of Directors, a majority of the Whole Board shall constitute a quorum for all purposes. If a quorum shall fail to attend any meeting, a majority of those present may adjourn the meeting to another place, date, or time, without further notice or waiver thereof.

6. Participation in Meetings By Conference Telephone. Members of the Board of Directors, or of any committee thereof, may participate in a meeting of such Board or committee by means of conference telephone or similar communications equipment by means of which all persons

participating in the meeting can hear each other and such participation shall constitute presence in person at such meeting.

7. Conduct of Business. At any meeting of the Board of Directors, business shall be transacted in such order and manner as the Board may from time to time determine, and all matters shall be determined by the vote of a majority of the directors present, except as otherwise provided herein or required by law. Action may be taken by the Board of Directors without a meeting if all members thereof consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board of Directors. Such filing shall be made in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

8. Powers. The Board of Directors may, except as otherwise required by law, exercise all such powers and do all such acts and things as may be exercised or done by the Corporation, including, without limiting the generality of the foregoing, the unqualified power:

- (a) To declare dividends from time to time in accordance with Law;
- (b) To purchase or otherwise acquire any property, rights or privileges on such terms as it shall determine;
- (c) To authorize the creation, making and issuance, in such form as it may determine, of written obligations of every kind, negotiable or non-negotiable, secured or unsecured, and to do all things necessary in connection therewith;
- (d) To remove any officer of the Corporation with or without cause, and from time to time to devolve the powers and duties of any officer upon any other person for the time being;
- (e) To confer upon any officer of the Corporation the power to appoint, remove and suspend subordinate officers, employees and agents;
- (f) To adopt from time to time such stock option, stock purchase, bonus or other compensation plans for directors, officers, employees and agents of the Corporation and its subsidiaries as it may determine;
- (g) To adopt from time to time such insurance, retirement, and other benefit plans for directors, officers, employees and agents of the Corporation and its subsidiaries as it may determine; and
- (h) To adopt from time to time regulations, not inconsistent with these Bylaws, for the management of the Corporation's business and affairs.

9. Compensation of Directors. Unless otherwise restricted by the certificate of incorporation, the Board of Directors shall have the authority to fix the compensation of the directors. The directors may be paid their expenses, if any, of attendance at each meeting of the Board of Directors and may be paid a fixed sum for attendance at each meeting of the Board of Directors or paid a stated salary or paid other compensation as director. No such payment shall preclude any director from serving the Corporation in any other capacity and receiving compensation therefor. Members of special or standing committees may be allowed like compensation for attending committee meetings.

ARTICLE III COMMITTEES

1. Committees of the Board of Directors. The Board of Directors may from time to time designate committees of the Board, with such lawfully delegable powers and duties as it thereby confers to serve at the pleasure of the Board and shall, for those committees and any others provided for herein elect a director or directors to serve as the member or members, designating, if it desires, other directors as alternate members who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of any member of any committee and any alternate member in his or her place, the member or members of the committee present at the meeting and not disqualified from voting, whether or not he or she or they constitute a quorum, may by unanimous vote appoint another member of the Board of Directors to act at the meeting in the place of the absent or disqualified member.

2. Conduct of Business. Each committee may determine the procedural rules for meeting and conducting its business and shall act in accordance therewith, except as otherwise provided herein or required by law. Adequate provision shall be made for notice to members of all meetings; a majority of the members shall constitute a quorum unless the committee shall consist of one (1) or two (2) members, in which event one (1) member shall constitute a quorum; and all matters shall be determined by the affirmative vote of a majority of the members present. Action may be taken by any committee without a meeting if all members thereof consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission or transmissions are filed with the minutes of the proceedings of such committee. Such filing shall be made in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

ARTICLE IV **OFFICERS**

1. Titles. The officers of the Corporation shall be chosen by the Board of Directors and shall include a Chief Executive Officer or a President or both, a Chief Financial Officer, a Secretary and a Treasurer. The Board of Directors may also appoint other officers as are desired, including one or more Vice Presidents, Assistant Secretaries or Assistant Treasurers. Any number of offices may be held by the same person. All officers shall perform their duties and exercise their powers subject to the Board of Directors.

2. Election, Term of Office and Vacancies. The officers shall be elected annually by the Board of Directors at its regular meeting following the annual meeting of the stockholders, and each officer shall hold office until the next annual election of officers and until the officer's successor is elected and qualified, or until the officer's death, resignation or removal. Any officer may be removed at any time, with or without cause, by the Board of Directors.

Any vacancy occurring in any office may be filled by the Board of Directors.

3. Resignation. Any officer may resign at any time upon notice to the Corporation without prejudice to the rights, if any, of the Corporation under any contract to which the officer is a party. The resignation of an officer shall be effective when given unless the officer specifies a later time. The resignation shall be effective regardless of whether it is accepted by the Corporation.

4. Chief Executive Officer. The Board of Directors shall designate a Chief Executive Officer who may be the President or another person and may prescribe the duties and powers of the Chief Executive Officer. Subject to the provisions of these bylaws and to the direction of the Board of Directors, the Chief Executive Officer shall have the responsibility for the general management and control of the business and affairs of the Corporation and shall perform all duties and have all powers which are commonly incident to the office of chief executive or which are delegated to him or her by the Board of Directors. The Chief Executive Officer shall have power to sign all contracts and other instruments of the Corporation which are authorized.

5. President. The President shall perform the duties and exercise the powers of the Chief Executive Officer if the Corporation does not have a Chief Executive Officer or in the event of the absence or disability of the Chief Executive Officer. The President shall otherwise have such powers and duties which are delegated to him or her by the Board of Directors. He or she shall have power to sign all stock certificates, contracts and other instruments of the Corporation which are authorized. If the Board of Directors has not designated a person as the Chief Executive Officer or the Chief Executive Officer has resigned and not been replaced, the President shall be the Chief Executive Officer of the Corporation, in which case all references herein to the President shall be deemed to refer to the President and/or the Chief Executive Officer, as relevant.

6. Vice President. Each Vice President shall have such powers and duties as may be delegated to him or her by the Board of Directors. One Vice President or the Chief Financial Officer may be designated by the Board to perform the duties and exercise the powers of the President in the event of the President's absence or disability.

7. Chief Financial Officer; Treasurer and Assistant Treasurers. Unless the Board of Directors designates another Treasurer, the Chief Financial Officer will be the Treasurer of the Corporation. Unless otherwise determined by the Board of Directors or the Chief Executive Officer, the Chief Financial Officer or the Treasurer shall have custody of the corporate funds and securities, shall keep adequate and correct accounts of the Corporation's properties and business transactions, shall disburse such funds of the Corporation as may be ordered by the Board or the Chief Executive Officer (taking proper vouchers for such disbursements), and shall render to the Chief Executive Officer and the Board, at regular meetings of the Board or whenever the Board, an account of all transactions and the financial condition of the Corporation. At the request of the Treasurer, or in the Treasurer's absence or disability, any Assistant Treasurer may perform any of the duties of the Treasurer and when so acting, shall have all the powers of, and be subject to all the restrictions upon, the Treasurer.

8. Secretary and Assistant Secretaries. The Secretary shall issue all authorized notices for and shall keep minutes of all meetings of the stockholders and the Board of Directors. He or she shall have charge of the corporate books and shall perform such other duties as the Board of Directors may from time to time prescribe. At the request of the Secretary, or in the Secretary's absence or disability, any Assistant Secretary shall perform any of the duties of the Secretary and when so acting shall have all the powers of, and be subject to all the restrictions upon, the Secretary.

9. Other Officers. The other officers of the Corporation, if any, shall exercise such powers and perform such duties as the Board of Directors or the Chief Executive Officer shall prescribe.

10. *Compensation.* The Board of Directors shall fix the compensation of the Chief Executive Officer and may fix the compensation of other employees of the Corporation, including the other officers. If the Board does not fix the compensation of the other officers, the Chief Executive Officer shall fix such compensation.

11. *Actions with Respect to Securities of Other Corporations.* Unless otherwise directed by the Board of Directors, the Chairman of the Board, the President or any officer of the Corporation authorized by the Chairman of the Board or the President, shall have power to vote and otherwise act on behalf of the Corporation, in person or by proxy, at any meeting of stockholders of, or with respect to any action of stockholders of, any other corporation in which the Corporation may hold securities and otherwise shall have power to exercise any and all rights and powers which the Corporation may possess by reason of its ownership of securities in such other corporation.

12. *Delegation of Authority.* The Board of Directors may from time to time delegate the powers or duties of any officer to any other officers or agents, notwithstanding any provision hereof.

ARTICLE V **STOCK**

1. *Certificates of Stock.* Each stockholder shall be entitled to a certificate signed by, or in the name of the Corporation by, the Chairman or Vice Chairman or the President or a Vice President, and by the Secretary or an Assistant Secretary, or the Treasurer or an Assistant Treasurer, certifying the number of shares owned by him or her. Any or all of the signatures on the certificate may be by facsimile.

2. *Transfers of Stock.* Transfers of stock shall be made only upon the transfer books of the Corporation kept at an office of the Corporation or by transfer agents designated to transfer shares of the stock of the Corporation. Except where a certificate is issued in accordance with Section 4 of Article V of these Bylaws, an outstanding certificate for the number of shares involved shall be surrendered for cancellation before a new certificate is issued therefor.

3. *Record Date.* In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders, or to receive payment of any dividend or other distribution or allotment of any rights or to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may, except as otherwise required by law, fix a record date, which record date shall not precede the date on which the resolution fixing the record date is adopted and which record date shall not be more than 60 nor less than 10 days before the date of any meeting of stockholders, nor more than 60 days prior to the time for such other action as hereinbefore described; provided, however, that if no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held, and, for determining stockholders entitled to receive payment of any dividend or other distribution or allotment of rights or to exercise any rights of change, conversion or exchange of stock or for

any other purpose, the record date shall be at the close of business on the day on which the Board of Directors adopts a resolution relating thereto.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting.

4. Lost, Stolen or Destroyed Certificates. In the event of the loss, theft or destruction of any certificate of stock, another may be issued in its place pursuant to such regulations as the Board of Directors may establish concerning proof of such loss, theft or destruction and concerning the giving of a satisfactory bond or bonds of indemnity.

5. Regulations. The issue, transfer, conversion and registration of certificates of stock shall be governed by such other regulations as the Board of Directors may establish.

ARTICLE VI **NOTICES**

1. Notices. If mailed, notice to stockholders shall be deemed given when deposited in the mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the Corporation. Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders may be given by electronic transmission in the manner provided in Section 232 of the Delaware General Corporation Law.

2. Waivers. A written waiver of any notice, signed by a stockholder or director, or waiver by electronic transmission by such person, whether given before or after the time of the event for which notice is to be given, shall be deemed equivalent to the notice required to be given to such person. Neither the business nor the purpose of any meeting need be specified in such a waiver. Attendance at any meeting shall constitute waiver of notice except attendance for the sole purpose of objecting to the timeliness of notice.

ARTICLE VII **MISCELLANEOUS**

1. Facsimile Signatures. In addition to the provisions for use of facsimile signatures elsewhere specifically authorized in these Bylaws, facsimile signatures of any officer or officers of the Corporation may be used whenever and as authorized by the Board of Directors or a committee thereof.

2. Corporate Seal. The Board of Directors may provide a suitable seal, containing the name of the Corporation, which seal shall be in the charge of the Secretary. If and when so directed by the Board of Directors or a committee thereof, duplicates of the seal may be kept and used by the Treasurer or by an Assistant Secretary or Assistant Treasurer.

3. Reliance upon Books, Reports and Records. Each director, each member of any committee designated by the Board of Directors, and each officer of the Corporation shall, in the performance of his or her duties, be fully protected in relying in good faith upon the books of

account or other records of the Corporation and upon such information, opinions, reports or statements presented to the Corporation by any of its officers or employees, or committees of the Board of Directors so designated, or by any other person as to matters which such director or committee member reasonably believes are within such other person's professional or expert competence and who has been selected with reasonable care by or on behalf of the Corporation.

4. *Fiscal Year.* The fiscal year of the Corporation shall be as filed by the Board of Directors.

5. *Time Periods.* In applying any provision of these Bylaws which requires that an act be done or not be done a specified number of days prior to an event or that an act be done during a period of a specified number of days prior to an event, calendar days shall be used, the day of the doing of the act shall be excluded, and the day of the event shall be included.

ARTICLE VIII **INDEMNIFICATION OF DIRECTORS AND OFFICERS**

1. *Right to Indemnification.* Each person who was or is made a party or is threatened to be made a party to or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (hereinafter a "*proceeding*"), by reason of the fact that he or she is or was a director or an officer of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan (hereinafter an "*indemnitee*"), whether the basis of such proceeding is alleged action in an official capacity as a director, officer, employee or agent or in any other capacity while serving as a director, officer, employee or agent, shall be indemnified and held harmless by the Corporation to the fullest extent authorized by the Delaware General Corporation Law, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than such law permitted the Corporation to provide prior to such amendment), against all expense, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes or penalties and amounts paid in settlement) reasonably incurred or suffered by such indemnitee in connection therewith; provided, however, that, except as provided in Section 3 of this Article VIII with respect to proceedings to enforce rights to indemnification, the Corporation shall indemnify any such indemnitee in connection with a proceeding (or part thereof) initiated by such indemnitee only if such proceeding (or part thereof) was authorized by the Board of Directors of the Corporation.

2. *Right to Advancement of Expenses.* The right to indemnification conferred in Section 1 of this ARTICLE VIII shall include the right to be paid by the Corporation the expenses (including attorney's fees) incurred in defending any such proceeding in advance of its final disposition (hereinafter an "*advancement of expenses*"); provided, however, that, if the Delaware General Corporation Law requires, an advancement of expenses incurred by an indemnitee in his or her capacity as a director or officer (and not in any other capacity in which service was or is rendered by such indemnitee, including, without limitation, service to an employee benefit plan) shall be made only upon delivery to the Corporation of an undertaking (hereinafter an "*undertaking*"), by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal (hereinafter

a "final adjudication") that such indemnitee is not entitled to be indemnified for such expenses under this Section 2 or otherwise.

3. Right of Indemnitee to Bring Suit. If a claim under Section I or 2 of this Article VIII is not paid in full by the Corporation within 60 days after a written claim has been received by the Corporation, except in the case of a claim for an advancement of expenses, in which case the applicable period shall be 20 days, the indemnitee may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim. If successful in whole or in part in any such suit, or in a suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the indemnitee shall be entitled to be paid also the expense of prosecuting or defending such suit. In (i) any suit brought by the indemnitee to enforce a right to indemnification hereunder (but not in a suit brought by the indemnitee to enforce a right to an advancement of expenses) it shall be a defense that, and (ii) in any suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall be entitled to recover such expenses upon a final adjudication that, the indemnitee has not met any applicable standard for indemnification set forth in the Delaware General Corporation Law. Neither the failure of the Corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel, or its stockholders) to have made a determination prior to the commencement of such suit that indemnification of the indemnitee is proper in the circumstances because the indemnitee has met the applicable standard of conduct set forth in the Delaware General Corporation Law, nor an actual determination by the Corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel, or its stockholders) that the indemnitee has not met such applicable standard of conduct, shall create a presumption that the indemnitee has not met the applicable standard of conduct or, in the case of such a suit brought by the indemnitee, be a defense to such suit. In any suit brought by the indemnitee to enforce a right to indemnification or to an advancement of expenses hereunder, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the burden of proving that the indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article VIII or otherwise shall be on the Corporation.

4. Non-Exclusivity of Rights. The rights to indemnification and to the advancement of expenses conferred in this ARTICLE VIII shall not be exclusive of any other right which any person may have or hereafter acquire under any statute, the Corporation's Certificate of incorporation, Bylaws, agreement, vote of stockholders or disinterested directors or otherwise.

5. Insurance. The Corporation may maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise against any expense, liability or loss, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the Delaware General Corporation Law.

6. Indemnification of Employees and Agents of the Corporation. The Corporation may, to the extent authorized from time to time by the Board of Directors, grant rights to indemnification and to the advancement of expenses to any officer, employee or agent of the Corporation to the fullest extent of the provisions of this Article with respect to the indemnification and advancement of expenses of directors and officers of the Corporation.

7. Nature of Rights. The rights conferred upon indemnitees in this Article VIII shall be contract rights and such rights shall continue as to an indemnitee who has ceased to be a director, officer or trustee and shall inure to the benefit of the indemnitee's heirs, executors and administrators. Any amendment, alteration or repeal of this Article VIII that adversely affects any right of an indemnitee or its successors shall be prospective only and shall not limit or eliminate any such right with respect to any proceeding involving any occurrence or alleged occurrence of any action or omission to act that took place prior to such amendment or repeal.

ARTICLE IX AMENDMENTS

In furtherance and not in limitation of the powers conferred by law, the Board of Directors is expressly authorized to adopt, amend and repeal these Bylaws subject to the power of the holders of capital stock of the Corporation to adopt, amend or repeal the Bylaws; provided, however, that, with respect to the power of holders of capital stock to adopt, amend and repeal Bylaws of the Corporation, notwithstanding any other provision of these Bylaws or any provision of law which might otherwise permit a lesser vote or no vote, but in addition to any affirmative vote of the holders of any particular class or series of the capital stock of the Corporation required by law, these Bylaws or any preferred stock, the affirmative vote of the holders of at least 66 2/3% percent of the voting power of all of the then-outstanding shares entitled to vote generally in the election of directors, voting together as a single class, shall be required to adopt, amend or repeal any provision of these Bylaws.

ARTICLE X FORUM FOR ADJUDICATION OF DISPUTES

Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the Corporation, (b) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (c) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, the certificate of incorporation or the bylaws of the Corporation, or (d) any action asserting a claim governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the corporation shall be deemed to have notice of and consented to the provisions of this Article X.

MOLECULAR TEMPLATES, INC.
AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION
POLICY

ADOPTED BY THE BOARD OF DIRECTORS: OCTOBER 9, 2017
AMENDED EFFECTIVE AS OF MAY 31, 2018

Each member of the board of directors (the “*Board*”) of Molecular Templates, Inc. (the “*Company*”) who is not an employee of the Company or any parent or subsidiary of the Company (each, a “*Non-Employee Director*”) will be eligible to receive cash and equity compensation as set forth in this Molecular Templates, Inc. Non-Employee Director Compensation Policy (this “*Policy*”). The cash and equity compensation described in this Policy will be paid or granted, as applicable, automatically and without further action of the Board to each Non-Employee Director who is eligible to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Amended and Restated Policy became effective on October 9, 2017 (the “*Effective Date*”), was amended effective as of May 31, 2018 to reflect the adoption of the Company’s 2018 Equity Incentive Plan and will remain in effect until it is revised or rescinded by further action of the Board. Capitalized terms not explicitly defined in this Policy but defined in the 2018 Equity Incentive Plan (the “*2018 Plan*”) will have the same definitions as in the 2018 Plan.

1. CASH COMPENSATION.

(a) Annual Fees. Each Non-Employee Director will be eligible to receive the following annual fees for service as (i) a member of the Board and (ii) a member or chairperson of a committee of the Board (“*Committee*”) set forth below, as applicable, to be paid on a quarterly basis in the form of annual retainers:

Board or Committee	Type of Fee	Amount (Per Year)
Board	Retainer Fee	\$ 40,000
Chairman of Board	Retainer Fee	\$ 30,000
Audit Committee	Chair Retainer Fee	\$ 15,000
	Non-Chair Retainer Fee	\$ 7,500
Compensation Committee	Chair Retainer Fee	\$ 10,000
	Non-Chair Retainer Fee	\$ 5,000
Nominating and Governance Committee	Chair Retainer Fee	\$ 8,000
	Non-Chair Retainer Fee	\$ 4,000

(b) Expenses. Each Non-Employee Director will be entitled to reimbursement from the Company for all reasonable out-of-pocket expenses incurred by the Non-Employee Director in connection with his or her attendance at Board and Committee meetings.

To the extent that any taxable reimbursements are provided to a Non-Employee Director, they will be provided in accordance with Section 409A of the Internal Revenue Code of 1986, as amended, and the Treasury Regulations and other guidance thereunder and any state law of similar effect, including, but not limited to, the following provisions: (i) the amount of any such expenses eligible for reimbursement during the Non-Employee Director's taxable year may not affect the expenses eligible for reimbursement in any other taxable year; (ii) the reimbursement of an eligible expense must be made no later than the last day of the Non-Employee Director's taxable year that immediately follows the taxable year in which the expense was incurred; and (iii) the right to any reimbursement may not be subject to liquidation or exchange for another benefit.

2. EQUITY COMPENSATION.

The options described in this Policy will be granted under the 2018 Plan and will be subject to the terms and conditions of (i) this Policy, (ii) the 2018 Plan and (iii) the forms of option grant notices and option agreements approved by the Board for the grant of options to Non-Employee Directors.

(a) Initial Grants. Each individual who is elected or appointed for the first time after the Effective Date to be a Non-Employee Director automatically will be granted, on the date of such initial election or appointment, a nonstatutory stock option to purchase 25,000 shares of Common Stock (an "***Initial Option Grant***"); and each individual who is a Non-Employee Director on the Effective Date will receive an Initial Option Grant on the Effective Date.

(b) Annual Grants. On the date of each annual meeting of the Company's stockholders after the Effective Date, each individual who is then a Non-Employee Director and will be continuing as a Non-Employee Director following the date of such annual meeting automatically will be granted a nonstatutory stock option to purchase 15,000 shares of Common Stock (an "***Annual Option Grant***"), provided that such individual has served as a Non-Employee Director for at least six (6) months prior to the date of such annual meeting.

(c) Terms of Options.

(i) Exercise Price. The exercise price of each Initial Option Grant and Annual Option Grant will be equal to 100% of the Fair Market Value of the Common Stock subject to the option on the date the option is granted.

(ii) Vesting. Subject to Section 3 below, each Initial Option Grant and Annual Option Grant will vest and become exercisable as follows:

(A) Each Initial Option Grant will vest and become exercisable as to 50% of the shares of Common Stock subject to the option on each of the first and second anniversaries of the date of grant, rounded down to the nearest whole share, provided that the Non-Employee Director is an Employee, director or Consultant of the Company or an Affiliate through such dates.

(B) Each Annual Option Grant will vest and become exercisable on the first anniversary of the date of grant, provided that the Non-Employee Director is an Employee, director or Consultant of the Company or an Affiliate through such date.

3. CERTAIN TRANSACTIONS AND EVENTS.

(a) Corporate Transaction. The provisions of this Section 3(a) (and not Paragraph 25(b) of the 2018 Plan) will apply to all outstanding Initial Option Grants and Annual Option Grants in the event of a Corporate Transaction. In the event of a Corporate Transaction while a Participant remains a Non-Employee Director, the shares of Common Stock at the time subject to each outstanding Initial Option Grant and Annual Option Grant held by such Participant, but not otherwise vested, will automatically vest in full so that each such Initial Option Grant and Annual Option Grant will, immediately prior to the effective date of the Corporate Transaction, become exercisable for all the shares of Common Stock subject to such Initial Option Grant and Annual Option Grant as fully vested shares and may be exercised for any or all of those vested shares. Immediately following the consummation of the Corporate Transaction, each Initial Option Grant and Annual Option Grant will terminate and cease to be outstanding, except to the extent assumed by the successor corporation (or Affiliate thereof).

Each Initial Option Grant and Annual Option Grant which is assumed in connection with a Corporate Transaction will be appropriately adjusted, immediately after such Corporate Transaction, to apply to the number and class of securities which would have been issuable to the Participant in consummation of such Corporate Transaction had the Initial Option Grant or Annual Option Grant been exercised immediately prior to such Corporate Transaction. Appropriate adjustments will also be made to the exercise price payable per share under each outstanding Initial Option Grant and Annual Option Grant, provided that the aggregate exercise price payable for such securities will remain the same. To the extent the actual holders of the Common Stock receive cash consideration for their Common Stock in consummation of the Corporate Transaction, the successor corporation may, in connection with the assumption of the outstanding Initial Option Grants and Annual Option Grants, substitute one or more shares of its own common stock with a fair market value equivalent to the cash consideration paid per share of Common Stock in such Corporate Transaction.

(b) Change in Control. In the event of a Change in Control while a Participant remains a Non-Employee Director, the shares of Common Stock at the time subject to each outstanding Initial Option Grant and Annual Option Grant held by such Participant, but not otherwise vested, will automatically vest in full so that each such Initial Option Grant and Annual Option Grant will, immediately prior to the effective date of the Change in Control, become exercisable for all the shares of Common Stock subject to such Initial Option Grant and Annual Option Grant as fully vested shares and may be exercised for any or all of those vested shares. Each such Initial Option Grant and Annual Option Grant will remain exercisable for such fully vested shares until the expiration or sooner termination of the option term in connection with a Change in Control.

SUBLEASE AGREEMENT

THIS SUBLEASE AGREEMENT ("Sublease") is made this _____ day of January, 2019, by and between State Farm Mutual Automobile Insurance Company, an Illinois corporation (hereinafter referred to as "Sublandlord"), and Molecular Templates, Inc., a Delaware corporation (hereinafter referred to as "Subtenant").

RECITALS

- A. Sublandlord and Subtenant acknowledge the lease dated August 20, 2013 and any amendments (a copy of which is attached hereto as Exhibit "A") made by and between SFT INS (TX), LLC. as Landlord ("Landlord") and State Farm Mutual Automobile Insurance Company as Tenant ("Master Lease"). Subtenant represents it has read and is familiar with the terms of the Master Lease. Sublandlord acknowledges its continuing obligations under the Master Lease and that Subtenant has no obligations under the Master Lease.
- B. Sublandlord wishes to sublease to Subtenant and Subtenant wishes to sublease from Sublandlord the space containing approximately 57,085 rentable square feet ("Premises"), depicted in Exhibit "B" incorporated herein, located in the building (the "Building") commonly known as 8900 Amberglen Blvd., Austin, Texas, 78729 (the Building and the land on which the Building is located, collectively, the "Property"), and together, in common with other tenants, the common areas serving the Property, including the lobby area of the building, lunch room area on the first floor, shared access to common area break rooms located on the third floor, common corridors, exterior walk ways and roadways and parking facilities, pursuant to the terms and conditions below.

AGREEMENT

Sublandlord and Subtenant agree:

1. Sublease Term. The term of this Sublease ("Sublease Term") shall commence on the date (the "Sublease Commencement Date") which is the latest to occur of (1) the execution and delivery of this Sublease by the parties hereto (2) delivery of vacant possession of the Premises to Subtenant in the condition required by the terms of this Sublease together with the furnishings and equipment (collectively "FF&E") set forth on Exhibit "C" hereto, (3) receipt by Subtenant of the Consent (as defined in Section 34 hereof), and (4) receipt by Subtenant of the Recognition Agreement (as defined in Section 34 hereof), and shall expire on August 30, 2028 (the "Expiration Date"). Subtenant may elect to waive the delivery of the Recognition Agreement as a condition to Sublease Commencement Date. If the Recognition Agreement has not been received by the Subtenant within thirty (30) days following execution and delivery of the Sublease, Subtenant shall elect to (1) waive the delivery of the Recognition agreement as a condition to Sublease Commencement Date or (2) terminate the Sublease with no penalty.
2. Delivery of Premises. (a) If Sublandlord is unable to deliver possession of the Premises to Subtenant on the Sublease Commencement Date of the term hereof, Sublandlord shall not be subject to any liability for the failure to deliver possession on said date except as hereinafter provided, and such failure shall not affect the validity of this Sublease or the obligations of Subtenant hereunder or extend the term hereof, but the Rent reserved shall not commence to accrue until possession of the Premises is tendered to Subtenant. If Sublandlord cannot deliver possession of the Premises within ninety (90) days of the execution of this Sublease, unless said delays are caused by the Subtenant or by events described in Section 36, then Subtenant shall have the option to terminate this Sublease with no penalty and all amounts paid or deposited by Subtenant hereunder shall be promptly refunded or returned by Sublandlord.

(b) The Premises shall be delivered to Subtenant vacant and broom cleaned except that the FF&E shall be in the Premises on the Sublease Commencement Date. Sublandlord shall ensure that the Premises is delivered to Subtenant in compliance with all applicable laws on the Sublease Commencement Date and all building systems, including without limitation, plumbing, heating, electrical, air-conditioning, and equipment shall be in good working order.

3. Subtenant Allowance; Test Fit Allowance; Demising Work. (a) As an inducement for Subtenant to enter into this Sublease, Sublandlord shall provide Subtenant with a construction allowance in the amount of \$1,997,975.00. The allowance is intended to be applied to all costs incurred by Subtenant in connection with the build-out of the Premises for Subtenant's intended use (all such work and improvements collectively, "Subtenant's Work") including, but not limited to, space planning, architectural and engineering fees, actual construction material and labor, data and IT system design, equipment and cabling, and a supervision fee for Subtenant's construction manager(s). Subtenant may utilize up to \$171,255.00 of the allowance towards moving expenses and for furnishings, fixtures, equipment and lab equipment to be installed or used in the Premises. The allowance ("Sublandlord's Contribution") shall be payable (as hereinafter provided) against requisitions therefor accompanied by (i) a list specifying in reasonable detail the work performed for which such requisition is being submitted and the portion of the amount of such requisition allocated to each such item of work and (ii) waivers of mechanics liens for all work for which such installment of Sublandlord's Contribution has been requisitioned, from each contractor, sub-contractor, vendor and supplier of labor and material for whom such installment of Sublandlord's Contribution is being requisitioned. Sublandlord shall make the payments associated with each requisition within thirty (30) days of its receipt of the requisition and supporting documentation. Payments on account of Sublandlord's Contribution shall be payable more frequently than monthly. Any remaining portion of the Allowance not disbursed within twelve (12) months following the Sublease Commencement Date shall be forfeited

(b) In addition to Sublandlord's Contribution, Sublandlord, at Sublandlord's sole cost and expense, shall reimburse Subtenant for a test fit allowance ("Test-Fit Allowance") equal to \$5,708.50, outside of the Sublandlord's Contribution. The Test-Fit Allowance shall be paid to Subtenant within thirty (30) days of a requisition therefor.

(c) At the request of Sublandlord, Subtenant has agreed to construct the walls and associated points of ingress and egress for access and fire safety necessary to demise the Premises from the balance of the 3rd floor of the Building (such work, the "Demising Work"). Sublandlord and Subtenant agree that the estimate attached hereto as Exhibit "D" annexed hereto is a reasonable and fair estimate of the cost of the Demising Work. In consideration of Subtenant's agreement to perform the Demising Work at Sublandlord's request, Sublandlord shall pay to Subtenant the sum of \$115,532.00 (the "Demising Work Cost") which is sum reflected on Exhibit "D". Sublandlord shall pay the Demising Work Cost to Subtenant within ninety (90) days following the Commencement Date. Subject to Sublandlord's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed, Subtenant shall have the right to store materials necessary for the Demising Work outside of the Premises, provided that the storage does not unreasonably interfere with any other tenants. Subtenant shall not be obligated to perform the work during non-business hours. Sublandlord shall provide Subtenant with access to the adjoining space for purposes of the performance of the Demising Work during normal business hours.

4. Temporary Space. No later than March 1, 2019, Sublandlord shall provide Subtenant with temporary space ("Temporary Space") on a Wing on the 3rd floor. The exact location of the Temporary Space is outlined on "Exhibit J" annexed hereto. Subtenant shall have the right to use and occupy the Temporary Space from the date the Temporary Space is delivered to Subtenant until thirty (30) days following the substantial completion of Subtenant's Work (such period, the "Temporary Occupancy Period"). During the Temporary Occupancy Period, Subtenant shall have no obligation to pay any rent or other charge with respect to the Temporary Space except that Subtenant shall pay its pro-rata share of Operating Expenses (as hereinafter defined) based on the rentable square footage of the Temporary Space. Subtenant shall have no obligation to make any repairs or performance any maintenance with respect to the Temporary Space and the same shall be provided by Sublandlord as if the Temporary Space was the Premises demised hereunder. The Temporary Space shall be built out with offices and/or desk areas sufficient for Subtenant's normal business operations. Sublandlord shall provide Subtenant with reasonable access to the Temporary Space to inspect the same. All building systems and equipment servicing the Temporary Space shall be in proper working order on the delivery date. Sublandlord shall provide all Landlord Services to the Temporary Space during the Temporary Occupancy Period, including without limitation, heating, ventilation, air conditioning, electricity and janitorial services.
5. Generator. Subtenant shall have the right to use the area identified on Exhibit "E" attached hereto for the installation and maintenance of a backup generator to be installed by Subtenant, for Subtenant's exclusive use throughout the term of this Sublease. Sublandlord shall permit the use of such space at no additional cost or expense to Subtenant. Sublandlord shall provide Subtenant with access to and through such portions of the Building, including without limitation the basement, walls and roof, for the installation and maintenance of such equipment, wiring and conduits necessary to connect the generator to the Premises and the electrical supply of the Building. To the extent that the generator is not considered property of the Landlord upon installation pursuant to the terms of the Master Lease, Subtenant, at Subtenant's sole cost and expense, shall be responsible for the removal of the generator on or before the Expiration Date and any reasonable cost associated with the restoration needed to the area the generator was located. Notwithstanding the foregoing, in the event Subtenant enters into a direct lease with Landlord for occupancy of the Premises or another portion of the Building following the Expiration Date, Subtenant shall have no obligation to remove the generator.
6. Use. Subtenant will use and occupy the Premises during the Sublease Term for general office, laboratory use for research and development and storage purposes and in accordance with Section Article 4 of the Master Lease, and for no other purpose (provided that no laboratory classified as a BSL-3 or BSL-4 shall be permitted) and in all cases in accordance with Law, including any hazardous waste or medical waste rules and regulations promulgated by Sublandlord or any applicable governmental authority (collectively, the "Permitted Use"), Sublandlord acknowledges that it is not the intent of this Section 6 to prohibit Subtenant from using the Premises for the Permitted Use. Subtenant may operate its business according to prudent industry practices so long as the use or presence of Hazardous Materials is in accordance with applicable Hazardous Materials Law (as defined in Section 16). Subtenant agrees to deliver to Sublandlord prior to the Sublease Commencement Date a list identifying each type of Hazardous Materials (as defined in Section 16) to be brought upon, kept, used, stored, handled, treated, generated on, or released or disposed of from, the Premises and setting forth any and all governmental approvals or permits required in connection with the presence, use, storage, handling, treatment, generation, release or disposal of such Hazardous Materials on or from the Premises ("Hazardous Materials List"). Upon request of Sublandlord, Subtenant shall deliver to Sublandlord an updated Hazardous Materials List within thirty (30) days following Sublandlord's request, provided that Sublandlord shall not make such request more than once per calendar year during the Sublease Term (unless required by applicable legal requirements or in connection with a specific transaction involving the Premises). On request,

Subtenant shall deliver to Sublandlord true and correct copies of the permits, approvals, reports and material correspondence, and storage and management plans relating to the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials by Subtenant at the Premises, including plans relating to the installation of any storage tanks containing Hazardous Materials to be installed in or under the Premises (provided, said installation of tanks shall only be permitted after Sublandlord has given its written consent to do so, which consent shall be given in accordance with Section 6). At any time following Subtenant's receipt of a request from Sublandlord, Subtenant shall promptly complete a "hazardous substances questionnaire" (excluding confidential information, unless Sublandlord and Subtenant enter into a commercially reasonable non-disclosure agreement with respect to such confidential information) using the form then-provided by Sublandlord to the extent the same is reasonably satisfactory to Subtenant. Any handling, treatment, transportation, storage, disposal or use of Hazardous Materials by Subtenant in or about the Premises or the Property and Subtenant's use of the Premises shall comply with all applicable Hazardous Materials Law. Subtenant shall give written notice to Sublandlord as soon as reasonably practicable of (A) any communication received by Subtenant from any governmental authority concerning Hazardous Materials which relates to the Premises or the Property, and (B) any disposal, release or threat of release of Hazardous Materials on, under, from or about the Building or the Property of which Subtenant is aware.

7. Subtenant will, at Subtenant's sole cost and expense, comply with all applicable federal, state and local laws, ordinances, rules and regulations, court orders, governmental directives and governmental orders relating to, affecting, or arising out of Subtenant's specific use and specific manner of occupancy of the Premises as opposed to mere office use. Subtenant shall use commercially reasonable efforts to not create any nuisance, commit waste, or unreasonably interfere with or unreasonably disturb any other tenants or occupants of the Property. Sublandlord shall use commercially reasonable efforts to prevent and/or rectify any nuisance, waste or unreasonable interferences with or unreasonable disturbances of Subtenant by Sublandlord or any other tenants, subtenants or occupants of the Property. It is expressly acknowledged and agreed that the foregoing shall not prohibit Subtenant from installing and using the generator discussed in Section 5 nor Subtenant's use of the Premises for the permitted hereunder. Subtenant shall not in any manner deface or injure the exterior portion of the Building (excluding penetrations of the exterior and roof of the Building associated with the installation of the generator, Supplemental HVAC (as hereinafter defined) and roof exhaust stacks) or overload any floor of the Premises. Subtenant shall do nothing nor permit anything to be done to its knowledge that would cause the Master Lease to be breached or terminated. Subtenant shall do nothing that may cause Sublandlord's insurance premiums to increase, or cause Sublandlord's insurance to be canceled, after giving effect in such policies to Subtenant's use and occupancy of the Premises pursuant to the terms hereof, including the use of the Premises for laboratory purposes. If, solely as a result of Subtenant's acts (which acts shall be other than the mere use of the Premises for the uses permitted hereunder), the rate of insurance imposed on Sublandlord or on the Property or its contents increases then, Subtenant shall pay to Sublandlord the amount of such increase on demand.
8. Rent. Subtenant will pay Sublandlord rent in lawful money of the United States of America ("Base Rent") which shall be legal tender at the time of payment, in advance on the first day of each calendar month during said term, at the office of Sublandlord or at such other place as Sublandlord may from time to time so designate in writing, as follows:
 - (i) For the period commencing the Rent Commencement Date (as hereinafter defined) through and including the last day of the fourth calendar month following the Rent Commencement Date, all Base Rent payable hereunder shall be abated;
 - (ii) For the period from the fifth calendar month following the Rent Commencement Date through the day immediately preceding the first anniversary of the Rent Commencement Date, the sum of \$1,284,412.50 per annum payable in equal monthly installments of \$107,034.38 per month;

- (iii) For the period first anniversary of the Rent Commencement Date through the day immediately preceding the second anniversary of the Rent Commencement Date, the sum of \$1,327,226.25 per annum payable in equal monthly installments of \$110,602.19 per month;
- (iv) For the period from the second anniversary of the Rent Commencement Date through the day immediately preceding the third anniversary of the Rent Commencement Date, the sum of \$1,370,040.00 per annum payable in equal monthly installments of \$114,170.00 per month;
- (v) For the period from the third anniversary of the Rent Commencement Date through the day immediately preceding the fourth anniversary of the Rent Commencement Date, the sum of \$1,412,853.75 per annum payable in equal monthly installments of \$117,737.81 per month;
- (vi) For the period from the fourth anniversary of the Rent Commencement Date through the day immediately preceding the fifth anniversary of the Rent Commencement Date, the sum of \$1,455,667.50 per annum payable in equal monthly installments of \$121,305.63 per month;
- (vii) For the period from the fifth anniversary of the Rent Commencement Date through the day immediately preceding the sixth anniversary of the Rent Commencement date, the sum of \$1,498,481.25 per annum payable in equal monthly installments of \$124,873.44 per month;
- (viii) For the period from the sixth anniversary of the Rent Commencement Date through the day immediately preceding the seventh anniversary of the Rent Commencement Date, the sum of \$1,541,295.00 per annum payable in equal monthly installments of \$128,441.25 per month;
- (ix) For the period from the seventh anniversary of the Rent Commencement Date through the day immediately preceding the eighth anniversary of the Rent Commencement Date, the sum of \$1,584,108.75 per annum payable in equal monthly installments of \$132,009.06 per month;
- (x) For the period from the eighth anniversary of the Rent Commencement Date through the day immediately preceding the ninth anniversary of the Rent commencement date, the sum of \$1,626,922.50 per annum payable in equal monthly installments of \$135,576.88 per month; and
- (xi) For the period from the ninth anniversary of the Rent Commencement Date through the Expiration Date, the sum of \$1,669,736.25 per annum payable in equal monthly installments of \$139,144.69 per month.

For purposes of this Sublease, the Rent Commencement Date shall be the earlier to occur of (x) the date which is 151 days following the Sublease Commencement Date and (y) the date which is five (5) business days following the occurrence of the substantial completion of Subtenant's Work. For purposes herein, the phrase "substantial completion of Subtenant's Work" shall mean that, with the exception of minor or insubstantial details of construction, mechanical adjustments, finishing touches or decoration which do not materially interfere with Subtenant's use or occupancy of the Premises (collectively, "Punch-List Items"), Subtenant's Work shall have been completed in accordance with the approved plans and electrical, fire protection, plumbing and all other mechanical systems serving or affecting the Premises which are the responsibility of Sublandlord to maintain and repair shall then be in working order. Use of offices in the Premises by Subtenant's project management team shall not be deemed to be use or occupancy of the Premises for purposes of this provision. Rent shall be paid without deduction or set off. The installment of Rent payable for any portion, less than all, of a calendar month shall be a pro rata portion of the installment payable for a full calendar month.

9. Additional Rent.

9.01. If Operating Costs, as defined in Sections 9.03, for the Premises for any calendar year during the term of this Lease shall exceed Base Operating Costs, as defined in Section 9.01(a), Subtenant shall pay to Sublandlord as additional Rent an amount equal to Tenant's Proportionate Share, as defined in Section 9.02, of such excess a. For each calendar year during the term after the Base Year, Subtenant shall pay Subtenant's Proportionate Share of the increase in Operating Costs for such calendar year over those incurred during the Base Year (the "Base Operating Costs"). The Base Year shall be the calendar year 2019.

b. Commencing as of the second year of the Sublease Term through the remainder of the term and any extensions thereof, Subtenant shall pay to Sublandlord each month at the same time and in the same manner as monthly base rent one twelfth (1/12th) of Sublandlord's estimated Operating Costs payable by Subtenant for the then-current calendar year over and above said costs with respect to the Base Year. Such monthly amount may be adjusted by Sublandlord at any time on the basis of Sublandlord's experience and reasonably anticipated costs. Within one hundred twenty (120) days after the close of each calendar year, or as soon after such 120-day period as practicable, Sublandlord shall deliver to Subtenant a statement in reasonable detail of the actual amount of Operating Costs payable by Subtenant in accordance with this Article 9 for such calendar year. Sublandlord shall provide Subtenant with such additional information and substantiating documentation upon the request of Subtenant. The statement for the calendar year 2020 shall contain the calculation of the Operating Costs for the Base Year. Sublandlord's failure to provide such statement to Subtenant within the 120-day period shall not act as a waiver and shall not excuse Subtenant or Sublandlord from making the adjustments to reflect actual costs as provided herein. If on the basis of such statement Subtenant owes an amount that is less than the estimated payments for such calendar year previously made by Subtenant, Sublandlord shall credit such excess to Subtenant against future additional rent due under this Article 9 or refund such excess if no future additional rent is due within thirty (30) days of such determination. If on the basis of such statement Subtenant owes an amount that is more than the estimated payments for such calendar year previously made by Subtenant, Subtenant shall pay the deficiency to Sublandlord within thirty (30) days after delivery of the statement. The obligations of Sublandlord and Subtenant under this Section 9.01(b) with respect to the reconciliation between the estimated and actual amounts of Operating Costs payable by Subtenant for the last year of the term shall survive the termination of the Sublease for a period of twelve months. When the final determination is made of the actual amount of Operating Costs payable by Subtenant for the year in which this Sublease terminates, Subtenant shall pay any increase due over the estimated payments within thirty (30) days of such determination and, conversely, any overpayment made by Subtenant shall be reimbursed to Subtenant by Sublandlord within thirty (30) days of such determination.

9.02. "Subtenant's Proportionate Share" is a fraction, the numerator of which is the number of rentable square feet of the Premises as is set forth in the introductory section of this Sublease and the denominator of which is the number of rentable square feet of area in the Building. Landlord represents that the rentable square footage of the Building on the date hereof is 453,189. Subtenant's Proportionate Share may be adjusted from time to time if the area of the Premises or Building changes due to an increase or decrease in the rentable square footage. Subtenant's initial proportionate share is 12.596%.

9.03. "Operating Costs" means all reasonable and customary out of pocket costs, expenses, and obligations incurred Sublandlord in connection with the operation, repair or maintenance of the Property during or allocable to the term of this Sublease, including without limitation the following:

a. All real property taxes, assessments, license fees, excises, levies, charges or impositions and other similar governmental ad valorem or other charges levied on or attributable to the Building or its ownership or operation, and all taxes, charges, assessments or similar impositions imposed in lieu of the same. In all events, any taxes assessed on Subtenant's personal property, or any improvements, alterations or installations made by Subtenant, and any other tax or assessments arising out of the existence of this Sublease except income, estate, or inheritance taxes shall be paid by Subtenant ("Subtenant's Payment"). Subtenant shall, simultaneously with the payment of any sums required hereunder, reimburse Sublandlord for any excise, sales or transaction privilege tax imposed or levied by any governmental agency upon sublandlord as a result of any such Subtenant Payment. Operating Costs shall not include any taxes assessed on Sublandlord's personal property, or any improvement alterations or installations made by Sublandlord in connection with Sublandlord's use or occupancy of any portion of the Property for the operation of its business.

b. All utility charges paid or incurred by Sublandlord for lights, heat, air conditioning, power, water, sewer, drainage and waste disposal for the common areas of the Building and otherwise supplied to all tenantable areas of the Building.

c. All other costs paid or incurred by Sublandlord for operation, maintenance, replacement and repair including, without limiting the generality of the foregoing, the following: security, landscape maintenance, pest control, reasonable management fees (not to exceed three percent (3%) of the Base Rent payable in the appropriate calendar year), supplies, insurance, cost of service of independent contractors to provide any required service to all tenants of the Building, wages (including employment taxes and fringe benefits) of all employees (below the grade of building manager) performing services uniformly available to or performed for all building tenants, licenses and permits for the operation of the Property (as opposed to Sublandlord's operation of its business at the Property), equipment and tools, and professional fees which reduce or attempt to reduce Operating Costs (to the extent permitted in Section 9.04).

9.04. Operating Costs shall not include alterations performed for any tenant of the Building (including Subtenant) or contribution or allowance in lieu thereof, depreciation, interest on any payment made by Sublandlord, leasing fees or capital expenditures required to be capitalized under generally accepted real estate accounting practices. However, capital expenditures made to reduce the Operating Costs may be included and amortized over the useful life of the improvement involved provided such allocation does not exceed the reasonable estimate of annual cost savings. Operating Costs shall also exclude building compliance costs, reserves, costs related to hazardous materials, costs to correct original construction defects, costs related to casualty and costs related to Sublandlord's negligence. Operating Costs shall also not include:

(a) all rental payments under the Master Lease;

(b) the cost of any item for which Sublandlord is reimbursed by insurance or otherwise compensated, including reimbursement by any tenant;

- (c) all franchise, income, transfer, gains, occupancy, corporate, gross receipts or business taxes imposed on Sublandlord;
- (d) costs and expenses incurred by Sublandlord only by reason of Sublandlord's negligence, willful misconduct, or breach of Sublandlord's obligations under this Sublease;
- (e) interest, principal payments, and other costs of any indebtedness encumbering the Property;
- (f) legal fees, space-planner's fees, architectural fees, engineering fees, real estate commissions, and marketing and advertising expenses incurred in connection with the development, leasing and construction of the Building or any addition thereto;
- (g) costs of selling, financing, mortgaging, hypothecating, assigning or subleasing Sublandlord's interest in the Property;
- (h) Sublandlord's advertising, entertainment and promotional costs for the Property;
- (i) legal fees for disputes with tenants and legal and auditing fees, other than legal and auditing fees reasonably incurred in connection with the maintenance and operation of the Building or in connection with the preparation of statements required pursuant to additional rent or lease escalation provisions of this Sublease;
- (j) the incremental cost of furnishing services during any non-business hours, to any tenant, including Subtenant at such tenant's expense;
- (k) costs incurred in performing work or furnishing services for individual tenants (including Subtenant) at such tenant's expense and not furnished to all tenants; (l) any rent, penalties or interest payable under Master Lease;
- (m) costs incurred in connection with making any alteration or addition to the Property to increase the rentable square footage of the Building; and
- (n) costs of installing a specialty service such as messenger center, cafeteria or fitness club.

All references to "tenant" or "other tenant" shall be deemed to include Sublandlord in its capacity as a tenant of the Building.

9.05 By giving Sublandlord written notice within one hundred eighty (180) days after receipt of the year end statement of the adjustment to the Operating Costs for the prior calendar year, Subtenant may dispute in writing any specific item or items included in determining Operating Costs, and/or Subtenant shall have the right to audit and photocopy Sublandlord's records related to the calculation of Sublandlord's Operating Costs. Subtenant's right to audit and photocopy Sublandlord's records shall extend to the statement rendered with respect to the Base Year. Notwithstanding any dispute, Subtenant shall pay Sublandlord the sums required as set forth in Section 9.01. Subtenant agrees to maintain the confidentiality of all information provided by Sublandlord, and Sublandlord agrees to cooperate with Subtenant to resolve any audit concerns. After resolution of the dispute, Sublandlord and Subtenant agree that any required rental adjustments will be remitted to the other within thirty (30) days and the appropriate adjustment will be made to the monthly rental payment as required in Section 9.01.

9.06 In determining the amount of the Operating Costs for any calendar year, if less than 95% of the rentable square feet of the Building shall have been occupied by tenants at any time during such year, then the Operating Costs for such year, including the Base Year, shall be grossed up to reflect the Operating Costs estimated to be incurred if ninety-five percent (95%) of all such rentable square feet of the Building had been occupied throughout such calendar year.

10. Services. (a) Sublandlord shall furnish to the Premises, at Sublandlord's sole cost and expense, with the following services to the Premises throughout the Sublease Term:

- (i) on business days, daily cleaning services to the Premises, the common areas of the Building and the restrooms in a manner as provided by similar multi-tenant building in the Austin, Texas area. Supplemental cleaning needs for the lab space will be passed directly through to the Subtenant.
- (ii) electricity for lighting, office and laboratory equipment and machinery and the HVAC, and gas to the Premises throughout the Term; Supplemental HVAC shall be separately metered with the cost and maintenance the sole responsibility of Subtenant.
- (iii) hot and cold water to the Premises for Subtenant's use in the Premises and to the lavatories in or serving the Premises;
- (iv) heating, ventilation and air conditioning through the Building systems as seasonally required 8 am to 6 pm Monday through Friday and 8 am to 1 pm on Saturdays; and
- (v) security for the Building in a manner provided by similar multi-tenant buildings in the City of Austin, Texas.

(b) Failure by Sublandlord to any extent to furnish such services or any cessation thereof of Sublandlord shall not render Sublandlord liable in any respect for damages to either person or property, nor be construed as an eviction of Subtenant, nor cause an abatement of rent, nor relieve Subtenant from fulfillment of any convenient or agreement hereof. Should any of such services be interrupted, Sublandlord shall use reasonable diligence to restore same promptly, but Subtenant shall have no claim for rebate of rent or damages or eviction on account thereof, except as set forth herein.

(c) Notwithstanding any provision in this lease to the contrary, if any essential building services furnished by the Sublandlord (i.e. electricity, water, sewer, restroom facilities, elevator service or HVAC systems) are interrupted or diminished in any material way, and the occurrence of such event (or the restoration of such services) is not due to (i) the negligence of intentional misconduct of Subtenant, (ii) the failure or nonperformance by a public utility, (iii) the occurrence of fire or other event of casualty, (iv) the exercise of the power of eminent domain, or (v) the occurrence of a force majeure event, and if Subtenant's use and enjoyment of the Premises, or any material portion thereof, for the conduct of its business therein is materially and adversely affected as a result of such condition or the interruption or diminution in such essential building services, to the extent that the Premises, or a portion thereof, are untenable for the operation of Subtenant's business then currently conducted in such portion (the "Service Interruption") and Subtenant furnished written notice of the Service Interruption to Sublandlord as soon as practical following the occurrence thereof (the "Interruption Notice") and such Service Interruption continues for a period of three (3) consecutive business days following the Sublandlord's receipt of the Interruption Notice, Subtenant shall be entitled to an equitable abatement of Rent (Base Rent and Additional Rent) in proportion to those portions of the Premises rendered untenable, beginning on the fourth (4th) business day after Sublandlord's receipt of the Interruption Notice, until such services are restored or repairs completed.

(d) Subtenant shall have access to the Premises seven days per week, twenty-four hours per day. Subtenant shall make its own arrangements for telecommunications and internet service. Sublandlord shall permit Subtenant's service providers with access to the main connection point in the Building. Subtenant shall have the right to use such telecommunication wiring presently installed which services the Premises. In addition, Subtenant shall have the right to use riser and shaft space sufficient for the installation of any additional telecommunications cables and wiring. Subtenant shall also have the right to use such riser and shaft space for the installation of wiring to connect the generator to the Premises. Subtenant shall be responsible for independently securing their equipment where located. Subtenant shall be responsible for adding conduit where needed from phone room to sublease space and shall complete any work disruption to Sublandlords space. Subtenant shall remove the tele/data wiring associated with the Subtenant space at lease termination to meet the NEC requirements.

(e) Subtenant shall have the right to install a supplemental heating, ventilation and air conditioning system ("Supplemental HVAC") to exclusively serve all or part of the Premises. In the event it is reasonably necessary, Subtenant shall have the right to install and maintain throughout the Sublease Term equipment associated with the Supplemental HVAC outside of the Premises, including on the roof of the Building, in a location mutually and reasonably agreeable to Sublandlord and Subtenant and Subtenant shall have the right to use shaft and riser space and make such roof penetrations as reasonably necessary to connect such equipment with the Premises. Subtenant shall have structural engineer confirm that the Building can support the weight of the proposed unit and that it meets all applicable code and zoning requirements.

11. Repair and Maintenance. Throughout the Term, Sublandlord shall be responsible for the condition, operation, repair, replacement, maintenance and management of the Property, including the Building, the Premises and the Common Areas. Sublandlord shall, at its sole cost and expense, be responsible for (a) keeping all of the Building, and other improvements erected on the Property in good order and repair, reasonable wear and tear excepted, including without limitation, the roof and the Building heating, ventilation and air conditioning system and other electrical and mechanical systems; (b) subject to the terms of the Master Lease, making all necessary structural, non-structural, exterior and interior repairs and replacements to any Building or improvements erected on the Property; (c) maintaining the Exterior Areas (as defined in the Master Lease) in good condition and repair; and (d) paying all costs of operating the Property in the ordinary course of business. Sublandlord shall keep the Property in a neat and sanitary condition and shall not commit any nuisance or waste in, on or about the Property. Sublandlord's repairs shall be at least equal in quality and workmanship to the original work and Sublandlord shall make the repairs in accordance with all applicable laws. Sublandlord shall regularly and periodically sweep and clean the driveways and parking areas. Sublandlord shall be responsible for removal of snow, leaves and debris in the driveways and parking areas. Sublandlord shall, subject to Section 9, make any necessary (x) structural repairs or structural replacements to the Premises and (y) repairs or replacements to (i) any fire alarm and communication system in the Premises (unless installed by Subtenant), and (ii) any sprinkler system in the Premises (unless installed by Subtenant). Subtenant shall give Sublandlord prompt notice of any accident or needed repairs or replacements which are the responsibility of Sublandlord.

Subtenant shall be responsible for the maintenance, repair and replacement of the Supplemental HVAC. Subtenant shall have access to the roof for purposes of maintaining, repairing and replacing the Supplement HVAC equipment installed thereon twenty-four hours per day, seven days per week. Subtenant shall have the right to enter into and maintain such maintenance and service contracts as

Subtenant determines in connection with satisfying its obligations under this Section 11. Subtenant's repairs shall be at least equal in quality and workmanship to the original work, and Subtenant shall make the repairs in accordance with all Laws.

If, after the Sublease Commencement Date, any Governmental Authority requires any alteration to the Premises as a result of Subtenant's particular use of the Premises or as a result of any alteration to the Premises made by or on behalf of Subtenant (other than the Demising Work), Subtenant shall pay the cost of all such alterations or the cost of compliance, as the case may be. Sublandlord shall otherwise be required to comply with any requirement applicable to the Premises and/or the Building and pay the cost of all such alterations or the cost of compliance, as the case may be.

At the expiration or other termination of this Sublease, Subtenant will surrender peaceable possession of the Premises in good condition and repair, reasonable wear and tear excepted, and if terminated pursuant to Section 26 or Section 27 hereof, damage by casualty or condemnation excepted. Subtenant shall have no obligation to remove any permitted alterations or improvements made to the Premises. Notwithstanding the foregoing, prior to the Expiration Date, Subtenant shall remove the generator and all fixtures or improvements installed by Subtenant in connection with Subtenant's use of the Premises as a laboratory, but Subtenant shall have no obligation to remove any plumbing or electrical equipment installed within the walls, ceilings or floors of the Premises but the same shall be capped and concealed within the walls, floor or ceiling as the case may be. In addition, once the fixtures and improvements are removed from that portion of the Premises used by Subtenant as a laboratory, Subtenant shall restore such portion of the Premises used as a laboratory (but no other portion of the Premises) to substantially the same condition it was delivered to Subtenant on the Sublease Commencement Date, reasonable wear and tear and natural deterioration excepted, and except that Subtenant shall have no obligation to prepare walls for paint or otherwise paint any portion of the Premises. Subtenant shall remove the Supplemental HVAC and exhaust stacks installed on the roof of the Building and seal, in good and workmanlike manner, all roof penetrations associated therewith. In the event of a Subtenant Default, Sublandlord may, in its sole discretion, require Subtenant to remove any permitted alterations or improvements made to the Premises. Subtenant shall have the right to remove its moveable trade fixtures, demountable walls, audio visual equipment, laboratory equipment and other personal property from the Premises. Subtenant will promptly repair any damage to the Premises caused by such removal. All property of Subtenant not removed on or before the last day of the Term shall be deemed abandoned if not removed by Subtenant within thirty (30) days after written notice from Sublandlord.

12. **Alterations; Subtenant's Work.** (a) Subtenant shall not, except with Sublandlord's prior written consent, make or cause to be made any alterations, additions or improvements to the Premises. Sublandlord's consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, Subtenant shall have the right to make cosmetic and non-structural alterations to the Premises without the consent of Sublandlord. It is further understood and agreed by and between the parties hereto that if Subtenant installs furniture, fixtures, or other equipment with the written consent of Sublandlord, the furniture, fixtures, or other equipment may be, but is not obligated to be, detached and removed by Subtenant at the expiration of this Sublease. Subtenant agrees to repair any damages caused by the removal of any of its furniture, fixtures, or other equipment.

(b) Subtenant shall pay the cost and expense of all alterations. Prior to commencing any alterations, Subtenant shall procure or require its contractor to procure on its behalf and maintain in effect during the performance of any alterations: (a) if applicable due to the nature of the alterations, builder's "all risk" insurance in an amount at least equal to the replacement value of the alterations, and (b) commercially

reasonable liability insurance insuring against construction related risks. If requested by Sublandlord, Subtenant shall, before commencing alterations or delivering (or accepting delivery of) any materials to be used in connection with the alterations, deliver to Landlord proof of insurance required by this Subsection.

(c) Notwithstanding anything to the contrary set forth herein, Sublandlord hereby consents to the alterations and improvements to the Premises as depicted on the floor plan sketch attached hereto as Exhibit "G" subject, however, to Sublandlord's approval of Subtenant's final plans and specifications. Prior to the commencement of Subtenant's Work, Subtenant shall submit to Sublandlord plans and specifications ("Plans") for Subtenant's Work. Sublandlord shall have fifteen (15) business days from receipt of the Plans to review and comment or approve the Plans. If Sublandlord fails to provide details comments to the Plans or approve the Plans within said fifteen (15) business day period, Sublandlord's consent to the Plans and Subtenant's Work shall be deemed given. Plans for any work that meets the definition of Structural Alterations per the Master Lease must be provided to Sublandlord at least 45 days prior to starting work to enable Sublandlord to notify Landlord in accordance with the Master Lease. In no event may Sublandlord unreasonably withhold or condition its consent of the Plans in a manner which would prevent Subtenant's use of the Premises for laboratory provided such Plans are in compliance with applicable laws.

13. Liens. Subtenant shall keep the Premises free and clear of liens arising out of any work performed, materials furnished, or obligations incurred by Subtenant, including mechanics' liens.
14. Parking. Subtenant shall have the right to use not less than 285 parking spaces at the Building including eight (8) reserved parking spaces identified on Exhibit "H" attached hereto.
15. Signs. Subtenant will not place any signs or other advertising matter or material on the exterior or on the interior of the Premises (which can be seen from the exterior) or of the building without the prior written consent of the Sublandlord first had and obtained, which consent shall not be unreasonably withheld, conditioned or delayed. Any sign or symbol placed on the exterior of the Building or in the windows or doors of the Building so as to be visible from the street that is not reasonably satisfactory to Sublandlord, shall be removed immediately on demand by Sublandlord and if not so removed within ten (10) days will constitute breach of this Sublease. Subtenant will be permitted to list its name on the Building Directory at no charge during the Sublease Term. Subtenant shall also have the right to install its name and/or logo on exterior, road-side monument signage identified on Exhibit "I" hereto and in the entrance lobby of the Building, at no cost, except for initial installation and removal of sign at the end of the term.
16. Hazardous Materials. (a) Subtenant will not cause any Hazardous Materials (as hereinafter defined) to be brought upon or kept or used in the Property or Premises in a manner or for a purpose prohibited by any Hazardous Materials Law (as hereinafter defined). Subtenant, at its sole cost and expense, will comply with all Hazardous Materials Laws and prudent industry practice relating to the presence, treatment, storage, transportation, disposal, release or management of Hazardous Materials in, on or under the Premises or Property required for Subtenant's use of the Premises or Property. Subtenant will notify Sublandlord of any release of any Hazardous Materials, enforcement, clean-up, removal or other governmental or regulatory action instituted, completed or threatened under any Hazardous Materials Law, any loss or injury resulting from or claimed to result from Hazardous Materials, and deliver to Sublandlord any notices, warnings or asserted violation relating to the Premises or Subtenant's use of the Premises or common areas of the Property.

(b) Subtenant shall indemnify and hold the Sublandlord fully harmless against any and all claims or any expenses of any kind whatsoever (including consultants' fees, experts' fees, and reasonable attorneys' fees) arising or resulting, in whole or in part, directly or indirectly, from the presence, treatment, storage, transportation, disposal, release or management of Hazardous Materials in, on or under the Premises resulting from the Subtenant's use of the Premises.

(c) "Hazardous Materials" shall mean any of the following, in any amount other than small quantities of office cleaning and other office supplies as are customarily used by Tenant in the ordinary course of business; (a) any petroleum or petroleum product, asbestos in any form, urea formaldehyde and polychlorinated biphenyls; (b) any radioactive substance; (c) any toxic, infectious, reactive, corrosive, ignitable or flammable chemical or chemical compound; and (d) any chemicals, materials or substances, whether solid, liquid or gas, defined as or included in the definitions of "hazardous substances," "hazardous wastes", "Hazardous materials", "extremely hazardous wastes", "restricted hazardous wastes," "toxic substances," "toxic pollutants," "solid wastes," or words of similar import in any federal, state or local statute, law, ordinance or regulation now existing or existing on or after the Effective Date as the same may be interpreted by government offices and agencies.

(d) "Hazardous Materials Laws" means any federal, state or local statutes, laws, ordinances or regulations now existing or existing after the Sublease Commencement Date that control, classify, regulate, list or define Hazardous Materials.

17. Indemnification and Hold Harmless. Subtenant shall indemnify and save Sublandlord harmless from and against any and all liabilities, claims and costs (including reasonable attorney's fees, penalties and fines) for death, injury or damages to persons or property during the Sublease Term, arising from (a) any default by Subtenant in the performance of its obligations under this Sublease, or (b) the negligence, or intentional acts or omissions of Subtenant in or about the Property. This hold harmless and indemnity shall survive termination of this Sublease. Sublandlord shall indemnify and save Subtenant harmless from and against any and all liabilities, claims and costs (including reasonable attorney's fees, penalties and fines) for death, injury or damage to persons or property during the Sublease Term in or about the Property, arising from (a) any default by Sublandlord in the performance of its obligations under this Sublease or the Master Lease, or (b) the negligence or intentional acts or omissions of Sublandlord.
18. Subtenant Insurance Requirements. (a) Subtenant agrees to carry at its own expense throughout the Sublease Term, commercial general liability insurance insuring both Sublandlord and Subtenant against all claims, demands or actions arising out of or in connection with Subtenant's use or occupancy of the Premises, or by the condition of the Premises with minimum limits of \$3,000,000 each occurrence and \$5,000,000 general aggregate. Subtenant shall name Sublandlord as an additional insured.
(b) Subtenant agrees to carry property insurance at least as broad as the ISO Special Form in an amount not less than the full insurable replacement cost of all Subtenant's trade fixtures and other personal property within the Premises. Coverage shall include business income insurance covering at least six (6) months of Base Rent payable hereunder.
(c) Subtenant shall maintain statutory workers' compensation and employers' liability insurance covering all persons employed by the Subtenant on the Premises in the minimum amounts as required by state law.

- (d) Subtenant shall deliver a Certificate of Insurance to Sublandlord prior to the date of occupancy of the Premises and said insurance policy shall list and protect Sublandlord and Subtenant as their interests may appear and shall contain an endorsement stating that the insurer agrees to give no less than thirty (30) days prior written notice to Sublandlord in the event of modification or cancellation thereof. Subtenant shall be responsible for its own personal property insurance.
- (e) If Subtenant fails to maintain the insurance coverage required of it under this Section, and such failure continues for ten (10) business days following written notice thereof from Sublandlord to Subtenant, Sublandlord may procure and maintain the insurance on Subtenant's behalf and charge Subtenant for all related costs and expenses including without limitation, premium costs, brokerage costs/commissions as additional rent.
19. Right of First Refusal. Subtenant shall have a one (1) time Right of First Refusal on the each of the remaining two wings of the 3rd floor, collectively or individually. The terms and conditions for the Right of First Refusal shall be based on the same terms and conditions as the initial Sublease. Prior to the execution of a sublease or other agreement with a third party for the use or occupancy of either or both of said remaining wings, Sublandlord shall deliver written notice to Subtenant identifying the wing or wings available for sublease and the date for delivery of possession. The Right of First Refusal granted to Subtenant must be exercised by delivery of written notice to Sublandlord within five (5) business days of receipt of such notice by Subtenant. If Subtenant timely exercises its right to sublease such wing or wings, the parties shall execute an amendment to this Sublease incorporating such space. If such notice is for only one of the wings, Subtenant's Right of First Refusal shall remain in full force and effect for the other wing regardless of whether Subtenant exercised its right for the first wing offered. Sublandlord shall not grant any other present or future subtenant of the Property a right to first refusal or first offer with respect to either wing on the 3rd floor.
20. Financials. Subtenant shall not be required to provide Sublandlord a yearly balance sheet and income statement every 6 months on the condition that Subtenant's financial information is publicly available to Sublandlord.
21. Intentionally Omitted.
22. Waiver of Subrogation. Subtenant and Sublandlord each waives its right of recovery against the other and each releases the other from any claim arising out of loss, damage, destruction to the Property and other improvement on the Premises, or contents on, or in the Premises to the extent its respective property is covered by Subtenant's policy of insurance as required herein of Sublandlord's policy of insurance as required under the Master Lease, whether or not the loss, damage, or destruction may be attributable to Sublandlord's negligence, provided, however, the waiver or release shall not be applicable to any loss, damage, or destruction caused by Subtenant's negligence or intentional acts or omissions. Each party hereto agrees, if required by its insurance policy or policies, to give to each insurance company which has issued to it fire and other property insurance, written notice of the notice of the terms of said mutual waivers, and to have said insurance properly endorsed, if necessary, to prevent the invalidation of said insurance coverage by reason of said waivers.
23. Letter of Credit. Subtenant shall deliver to Sublandlord, within thirty (30) days after the execution of this Sublease, an irrevocable and unconditional Letter of Credit (herein, together with all replacements thereof, being called the "Letter of Credit") issued by a national bank or financial institution reasonably acceptable to Sublandlord. Sublandlord hereby approves of Silicon Valley Bank as the issuing bank.

The Letter of Credit shall be in the amount of \$3,000,000.00, provided, however, that (i) after the thirty-sixth (36th) full calendar month of the term of this Sublease, the Letter of Credit will be reduced to the amount of \$2,000,000.00, (ii) after the forty-eighth (48th) full calendar month of the term of this Sublease, the Letter of Credit will be reduced to the amount of \$1,000,000.00 and (iii) after the sixtieth (60th) full calendar month of the term of this Sublease, the Letter of Credit will be reduced to the amount of \$500,000.00. The reduction in the Letter of Credit may be effectuated by an amendment to the Letter of Credit or delivery of a replacement Letter of Credit. Sublandlord shall reasonably cooperate with Subtenant to effectuate the exchange of the Letter of Credit, if applicable.

The term of the Letter of Credit shall extend from the date of this Sublease through the last day of the Sublease Term (as may be extended). At Subtenant's option, the initial Letter of Credit may be for a term of not less than one (1) year, and, in such event, such Letter of Credit shall be extended by Subtenant for periods of not less than one (1) year each so that the Letter of Credit, as extended and replaced, remains continually in existence during the entire period required in this Section 23. Notwithstanding any provisions to the contrary herein, if such Letter of Credit is for a term shorter than the entire period required for the Letter of Credit in this Section 23 (i.e., the entire period commencing on the date of issuance of the Letter of Credit, and ending on the last day of the term of this Sublease, as may be extended) and Sublandlord shall not receive, at least thirty (30) days prior to the expiration date of such Letter of Credit, a replacement Letter of Credit in form and substance identical to said Letter of Credit so expiring and otherwise satisfying the obligations herein, Sublandlord may, without any further notice draw upon the entire amount of the Letter of Credit and hold the proceeds thereof as cash security. Subtenant shall thereafter provide a replacement Letter of Credit no later than ten (10) days following such draw. Notwithstanding the foregoing, failure of Subtenant to provide a replacement Letter of Credit for any expired Letter of Credit within said ten (10) day period shall be an Event of Default by Subtenant. Upon delivery of the same to Sublandlord, Sublandlord shall return the cash security deposit to Subtenant. Sublandlord shall only have the right to draw upon the Letter of Credit or the cash security deposit upon the default, beyond applicable periods of notice and grace, of Subtenant's obligations under this Sublease. The Letter of Credit or the cash security deposit, as applicable, shall be returned to Subtenant within thirty (30) days following the Expiration Date or sooner termination of this Sublease. Sublandlord shall assign the Letter of Credit or cash security to any assignee of its interest under the Master Lease.

The Letter of Credit shall be in form reasonably acceptable to Sublandlord, in its sole discretion, and shall provide that the only condition to a draw under the Letter of Credit shall be the presentation by Sublandlord of a sight draft certifying that Sublandlord is entitled to draw upon the Letter of Credit in accordance with the terms of the Sublease. The Letter of Credit shall provide that it is governed by the International Chamber of Commerce's International Standby Practices ("ISP98") except to the extent that the terms thereof are inconsistent with the provisions of the ISP98, in which case the terms of the Letter of Credit shall govern. The Letter of Credit shall provide that draw requests need not be presented as originals and may be submitted by courier or by facsimile, and it should include the issuing bank's address and facsimile number. The Letter of Credit shall be transferable and assignable multiple times by Sublandlord to Sublandlord's successor in interest in the Building. Sublandlord shall pay all reasonable costs and shall take all steps necessary for any such proposed transfer or assignment of the Letter of Credit, provided Subtenant fully cooperates with any such transfer or assignment, and Subtenant further acknowledges that the unlimited transferability of the Letter of Credit is a material provision of this Sublease. The Letter of Credit may be drawn in whole or in part by Sublandlord (at Sublandlord's option) from time to time (and more than one time for partial draws) upon the occurrence of any Event of Default by Subtenant under this Sublease, which default is not cured within any applicable notice and cure period (provided, however, that if the giving of any notice of default by Sublandlord is barred by applicable law, no such notice shall be required as a condition to Sublandlord's

draw under this Letter of Credit, and Sublandlord may draw upon the Letter of Credit notwithstanding that no such notice was given and no such cure period commenced), and without any further notice to Subtenant. Sublandlord may draw upon the Letter of Credit without proceeding against any person or exhausting any other remedies which Sublandlord may have and without resorting to any other security held by Sublandlord. Sublandlord may apply the proceeds of the Letter of Credit in any order or manner to any amounts owed by Subtenant under or pursuant to this Sublease. All amounts drawn by Sublandlord under the Letter of Credit and applied in accordance with this Sublease shall immediately become the property of Sublandlord and shall be retained by Sublandlord. To the extent any amounts in excess of those applied to sums due and owing by Subtenant are drawn by Sublandlord, the excess shall be held by Sublandlord as cash security hereunder. In no event shall any such application cure any event of default by Subtenant under this Sublease. Furthermore, in no event shall the Letter of Credit, or Sublandlord's right to draw upon the Letter of Credit, be affected or impaired by (A) the waiver, compromise, settlement, termination or other release of the performance or observance by any person liable or to become liable for the obligations under this Sublease; (B) the modification or amendment (whether material or otherwise) of any obligation, covenant or agreement set forth in this Sublease; (C) the voluntary or involuntary liquidation, dissolution, sale of all or substantially all of the assets, marshalling of assets and liabilities, receivership, conservatorship, insolvency, bankruptcy, assignment for the benefit of creditors, reorganization, arrangement, composition or readjustment of, or any similar proceeding affecting Subtenant, or any allegation or contest of the validity of this Sublease; or (D) the taking or the omission of any of the actions referred to in this Sublease. If all or any portion of the Letter of Credit is drawn upon and properly applied by Sublandlord, Subtenant shall, within fourteen (14) days after written demand therefor, reinstate the Letter of Credit for the full amount required pursuant to this Section 23. The failure of Subtenant to comply with the provisions of this Section 23 shall constitute an Event of Default under this Lease.

24. **Default by Subtenant.** (a) Each of the following occurrences shall be considered a "Default": (i) Subtenant's failure to pay any portion of Rent or Additional Rent within five (5) days of when due; and (ii) Subtenant's failure to comply with any term, provision, condition or covenant of this Sublease, if the failure is not cured within thirty (30) days after written notice to Subtenant of such failure. In the event a default in the nature of clause (ii) above cannot be remedied using commercially reasonable efforts within such thirty (30) day period, Subtenant shall not be in Default provided Subtenant commences commercially reasonable steps to remedy the Default within said thirty (30) day period and delivers written notice to Sublandlord of the same, and thereafter diligently prosecutes the same to completion.
 - (b) Upon a Subtenant Default, Sublandlord may choose: (a) re-enter the Premises and terminate this Sublease and hold Subtenant responsible for all damages resulting from the breach; or (b) re-enter the Premises, keep this Sublease intact, and attempt to relet the Premises on behalf of Subtenant as Subtenant's agent; or (c) choose not to re-enter but to hold Subtenant responsible for all terms of this Sublease. Upon re-entering the Premises, Sublandlord may relet the Premises or any part thereof for such term, on such conditions, and at such rental as Sublandlord may deem advisable with the right to make alterations and repairs to the Premises and no such re-entry shall be considered or construed to be forcible entry or detainer.
25. **Default by Sublandlord.** In the event that Sublandlord defaults in the performance or observance of any of Sublandlord's obligations under this Sublease, then Subtenant will give Sublandlord written notice of Sublandlord's default. Sublandlord shall remedy any default by Sublandlord hereunder within thirty (30) business days after the date of Subtenant's notice, this period will be extended for an additional reasonable time, provided that Sublandlord commences to cure such default within such thirty (30) day period and proceeds diligently thereafter to effect such cure as quickly as possible.

26. Eminent Domain. (a) If during the Sublease Term, a condemning authority takes the whole of the Premises or of the Property, this Sublease will terminate on the date that the condemning authority takes possession of the Premises. Subtenant shall receive a refund of all amounts paid on account hereunder with respect to the period from and after the taking.
- (b) If during the Sublease Term, a condemning authority takes only a portion of the Premises, this Sublease shall terminate as to the portion of the Premises taken as of the date that the condemning authority takes possession of that portion. Rent shall be equitably adjusted according to the remaining Premises. Notwithstanding the foregoing, if thirty percent or more of the Premises is taken, Subtenant shall have the right to terminate this Sublease and receive a refund of all amounts paid on account hereunder with respect to the period from and after the taking.
- (c) Sublandlord shall be entitled to receive and keep all damages awards or payments resulting from or paid on account of a taking, subject to the terms of the Master Lease; provided, however, that Subtenant may make a claim for a separate award for the value of Subtenant's moveable trade fixtures and equipment, for moving costs, and loss of good will and retain the proceeds thereof. Accordingly, Subtenant waives and assigns to Sublandlord any interest of Subtenant in any such damages, awards or payments except with respect to Subtenant's separate claim.
27. Casualty. (a) If during the term of this Sublease, the Premises or the Property are destroyed or damaged in whole or in part by fire or other casualty, then either party shall have the option to terminate this Sublease if: (i) less than twenty-four (24) months remain under the term of the Master Lease, and (ii) restoration of the Property cannot be completed in less than one hundred eighty (180) days after the date of the casualty, as reasonably determined by Sublandlord, upon delivering of written notice to the other party.
- (b) If this Sublease is not terminated in accordance with this Section following a casualty or fire, Sublandlord shall restore the damaged portions of the Premises substantially to the same condition as existed prior to the fire or casualty with all reasonable diligence and speed. Rent shall be abated on a reasonable basis, in proportion to the portion of the Premises, if any, which are rendered untenantable from the date of damage until the completion of Sublandlord's repairs, unless Subtenant caused such damage, in which case, Subtenant shall continue to pay Rent without abatement.
28. Assignments, and Subleases. Subtenant shall not assign this Sublease, or sell, or sublet the Premises, without Sublandlord's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. This Sublease shall not be assigned by operation of law. Any consent given by Sublandlord to any assignment of this Sublease, or Sublease of the Premises or any part of them, shall not bar Sublandlord from subsequently refusing to consent to any further assignment or sublease. Any attempt to sell, or sublet without the consent of Sublandlord shall be deemed as a default by Subtenant, and entitle Sublandlord to remedies described in Section 24. Notwithstanding the foregoing, over-the-counter stock market transactions shall not be deemed to be assignments under this Sublease.
29. Access. Subtenant shall allow Sublandlord or Landlord, and their agents, access at all reasonable times to the Premises upon reasonable prior notice for the purpose of inspecting or making repairs, additions, or alterations to the Premises. Subtenant shall have the right to require a representative of Subtenant to be present during any access by Sublandlord or Landlord.

30. Insolvency or Bankruptcy. If Subtenant becomes insolvent or involuntarily bankrupt, or it a receiver, assignee, or other liquidating office is appointed for the business of Subtenant, and Subtenant is otherwise in Default under this Sublease, then Sublandlord may terminate this Sublease at its option with notice.
31. Quiet Enjoyment. Sublandlord covenants that Subtenant shall, while Subtenant is not in default of the terms of this Sublease, peaceably and quietly hold and enjoy the Premises for the Sublease Term, without interference or hindrance from Sublandlord or person claiming by or through Sublandlord or other third parties.
32. Smoking. Smoking is strictly prohibited at all times in the Premises and the Building. Subtenant shall be responsible for ensuring that its employees, subcontractors, agents, officers, contractors, licensees, invitees, and guests, strictly adhere to this Smoking policy. The term "Smoking" means inhaling, exhaling, breathing, or carrying any lighted cigar, cigarette, or other tobacco product or similar lighted product, including any vaping materials, in any manner or in any form.
33. Surrender. (a) Except as otherwise provided in Section 11 hereof, upon expiration of the Sublease Term or earlier termination of this Sublease, Subtenant shall surrender the Premises without notice and will deliver to Sublandlord the Premises in its then "as is" condition. Notwithstanding the foregoing, in the event of a Subtenant Default, Sublandlord may, in its sole discretion, require Subtenant to remove any permitted alterations or improvements made to the Premises.

(b) At least three (3) months prior to the surrender of the Premises, Subtenant shall deliver to Sublandlord a narrative description of the actions proposed (or required by any governmental authority) to be taken by Subtenant in order to surrender the Premises (including any Alterations permitted to remain in the Premises pursuant to the terms hereof, including, without limitation, Section 11 at the expiration or earlier termination of the Term, consistent with Subtenant's obligations under in this Section (the "Surrender Plan"). Subtenant's Surrender Plan shall state that, (a) (i) all laboratory space, including floors, walls, ceilings, counters, piping, supply lines, waste lines and plumbing in or serving the Premises and all exhaust or other ductwork in or serving the Premises, and (ii) any applicable systems shared by laboratory space, including without limitation exhaust or other ductwork, in or serving the Premises have been de-commissioned to the extent required by, and in accordance with, applicable laws and in accordance with best industry practice; (b) the interior surfaces of the Premises (including floors, walls, ceilings, and counters), piping, supply lines, waste lines and plumbing, and all such exhaust or other ductwork in the Premises, may be reused by a subsequent Subtenant or disposed of in compliance with applicable laws without: (i) incurring special costs on account of uncompleted de-commissioning work; (ii) undertaking special procedures for demolition, disposal, investigation, assessment, cleaning or removal of such Hazardous Materials related to the former laboratory use areas of the Premises; or (iii) giving notice in connection with such Hazardous Materials; and (c) the Premises may be reoccupied for office or laboratory use, or demolished or renovated without: (i) incurring special costs on account of uncompleted de-commissioning work; (ii) undertaking special procedures for disposal, investigation, assessment, cleaning or removal of Hazardous Materials; or (iii) giving notice in connection with Hazardous Materials. Further, for purposes of clauses (b) and (c), "special costs" or "special procedures" shall mean costs or procedures, as the case may be, that would not be incurred but for the nature of the Hazardous Materials as Hazardous Materials instead of non-Hazardous Materials. The final report shall also include reasonable detail concerning the clean-up measures taken, the clean-up locations, the tests run and the analytic results applicable to the above.

- (c) Subtenant shall surrender the Leased Premises to Sublandlord free of Hazardous Materials (subject to the requirements of Sections 6 and 16) brought upon, kept, used, stored, handled, treated, generated in, or released or disposed of from, the Premises by any person claiming by, through or under Subtenant (collectively, "Subtenant Laboratory Operations") and released of all licenses, clearances or other authorization of any kind arising by, through or under Subtenant and required to enter into and restore the Premises issued by any governmental authority having jurisdiction over the use, storage, handling, treatment, generation, release, disposal, removal or remediation of Hazardous Materials, broom clean, ordinary wear and tear and casualty loss and condemnation excepted. Subtenant's Surrender Plan shall be accompanied by a current listing of (i) all Hazardous Materials licenses and permits held by or on behalf of Subtenant or any party claiming by, through or under with respect to the Premises, and (ii) all Hazardous Materials used, stored, handled, treated, generated, released or disposed of from the Premises, and shall be subject to the review and approval of Sublandlord's environmental consultant. In connection with the review and approval of the Surrender Plan, upon the request of Sublandlord, Subtenant shall deliver to Sublandlord or its consultant such additional non-proprietary information concerning Subtenant Laboratory Operations as Sublandlord shall reasonably request. On or before such surrender, Subtenant shall deliver to Sublandlord evidence that the approved Surrender Plan shall have been satisfactorily completed and Sublandlord shall have the right, subject to reimbursement at Subtenant's expense as set forth below, to cause Sublandlord's environmental consultant to inspect the Premises and perform such additional procedures as may be deemed reasonably necessary to confirm that the Premises are, as of the effective date of such surrender or early termination of the Lease, in compliance with Sections 6 and 16. Subtenant shall reimburse Sublandlord, within thirty (30) days of demand as additional rent, for the reasonable out-of-pocket expense incurred by Sublandlord for Sublandlord's environmental consultant to review and approve the Surrender Plan and to visit the Premises and verify satisfactory completion of the same. Sublandlord shall have the unrestricted right to deliver such Surrender Plan and any report by Sublandlord's environmental consultant with respect to the surrender of the Premises to third parties with a legitimate business reason to receive the same.
34. Master Lease. (a) Sublandlord shall comply with all its obligations under the Master Lease and keep the Master Lease in full force and effect throughout the term of this Sublease. Sublandlord represents that attached hereto as Exhibit "A" is a true and correct copy of the Master Lease and that the Master Lease is in full force and effect on the date hereof. Sublandlord shall not enter into any agreement with Landlord for the early termination of the Master Lease or the surrender of the property leased thereunder.
- (b) As a condition to the occurrence of the Sublease Commencement Date, Sublandlord shall obtain from the Landlord, (i) the written consent (the "Consent") of Landlord to the subletting of the Premises to Subtenant for the uses set forth herein and (ii) an agreement ("Recognition Agreement") substantially in the form attached hereto as "Exhibit K" and otherwise reasonably acceptable to Subtenant whereby Landlord agrees to recognize Subtenant as a tenant of the Property and this Sublease in the event of a termination of the Master Lease. Sublandlord shall submit a written request to Landlord for the Recognition Agreement together with the request for the Consent. In the event that Subtenant waives the delivery of the Recognition Agreement as a condition to the occurrence of the Sublease Commencement Date, Sublandlord shall use commercially reasonable and diligent efforts to obtain the Recognition Agreement following the Sublease Commencement Date.
- (c) If Subtenant waives Sublandlord's obligation to deliver the Recognition Agreement and the Master Lease is terminated for any reason, this Sublease, if not sooner terminated hereunder, will automatically terminate on the effective date of termination of the Master Lease, and Sublandlord will not be liable to Subtenant or any other person for loss, damage or expense resulting therefrom unless such termination was due to a default by Sublandlord under the Master Lease; provided, however, if the Master Lease

gives Sublandlord any right to terminate the Master Lease in the event of the partial or total damage, destruction, or condemnation, then the exercise of such right by Sublandlord will not constitute a default or breach by Sublandlord under this Sublease. If such termination will be due solely to the fault of Subtenant, Sublandlord will be entitled to recover from Subtenant and Subtenant will pay, in addition to all other sums to which Sublandlord may be entitled, all damages, losses, costs and expenses (including reasonable attorneys' fees) suffered or incurred by Sublandlord as a result of such termination.

35. Waiver of One Breach Not Waiver of Others. Waiver of one breach of a term, condition, or covenant of this Sublease by either party to this Sublease shall be limited to the particular instance and shall not be construed as a waiver of past or future breaches of this Sublease or other terms, conditions, or covenants.
36. Force Majeure. In the event Sublandlord or Subtenant is delayed, hindered or prevented from performing any act or thing required hereunder by reason of strikes, lockouts, labor troubles, casualties, governmental laws or regulations, riots, insurrection, war, acts of God, or other causes beyond the reasonable control of Sublandlord or Subtenant, neither party shall be liable for the delay, and the period for the performance by either party shall be extended for a period equivalent to the period of such delay. The foregoing shall be inapplicable to the payment of Rent by Subtenant.
37. Notices. The parties can be notified by certified or registered mail or overnight delivery service with verification of delivery as follows:

Sublandlord: State Farm Mutual Automobile Insurance Company
One State Farm Plaza, C-4
Bloomington, IL 61704
Attn: Lease Administration

Subtenant: Molecular Templates, Inc.

Prior to the Subtenant's occupancy of the Premises:

9301 Amberglen Blvd., Suite 100
Austin, TX 78729
Attention: Jack Higgins

With a copy to:

Molecular Templates, Inc.
Harborside 5
185 Hudson Street, Suite 1510
Jersey City, NJ 07311
Attention: General Counsel

Following Subtenant's occupancy of the Premises:

To Subtenant at the Premises
Attention: Jack Higgins

With a copy to:

Molecular Templates, Inc.
Harborside 5
185 Hudson Street, Suite 1510
Jersey City, NJ 07311
Attention: General Counsel

All notices shall be deemed delivered one (1) business day following deposit of the same with a recognized overnight courier service and three (3) business days after being deposited with the United States postal service, postage prepaid, if delivered by registered or certified mail

38. End of Term. Subtenant shall not remain in possession of the Premises upon the expiration of the Sublease Term.
39. Governing Law. This Sublease shall be governed by and construed in accordance with the laws of the State wherein the Premises, is located.
40. No Joint Venture. Nothing contained herein nor the acts of the parties shall be deemed or construed to create the relationship of principal and agent, partnership, joint venture, or similar relationship or arrangement, it being understood that the relationship between the parties is solely that of Sublandlord and Subtenant.
41. OFAC Certification/Anti-Money Laundering Laws. (a) Each party certifies that (i) it is not acting directly or indirectly for or on behalf of any person, group, entity, or nation named by any Executive Order or the United States Treasury Department, through its Office of Foreign Assets Control ("OFAC") or otherwise, as a terrorist, "Specially Designated Nation," "Blocked Person," or other banned or blocked person, entity, nation, or transaction pursuant to any law, order, rule or regulation that is enforced or administered by OFAC or another department of the United States government, and (ii) it is not engaged in this transaction (directly or indirectly) on behalf of, or instigating or facilitating this transaction (directly or indirectly) on behalf of, any such person, group, entity or nation. Sublandlord and Subtenant each shall indemnify, defend, and hold harmless the other party from and against any claims, damages, losses, risks, liabilities, and expenses (including reasonable attorneys' fees and costs) arising from or related to any breach of the foregoing certification.

(b) Subtenant shall from time to time, upon not less than twenty (20) business days' prior written request by Sublandlord, provide such information as is necessary or appropriate to comply with the anti-money laundering laws of any applicable jurisdiction, or to respond to requests for information concerning the identity of Subtenant, any person controlling or controlled by subtenant, or any person having a beneficial interest (either directly or indirectly) in Subtenant, from any governmental authority, self-regulatory organization or financial institution in connection with Sublandlord.
42. Broker. Sublandlord warrants and represents that Core Group ("Broker") is the sole exclusive agent representing the Subtenant in the negotiation of this sublease. Sublandlord will pay a market commission equal to four percent (4%) of the gross value of the sublease per a separate agreement. Sublandlord hereby indemnifies and holds Subtenant harmless with respect to the commission due Broker or any claim for a commission payable with respect to this Sublease made by any other third party.

43. Headings. The titles and headings of this Sublease are for convenience of reference only and shall not in any way be deemed a part of this Sublease for the purpose of construing or interpreting the meaning thereof, or for any other purpose.
44. Counterparts. This Sublease may be executed in counterparts each of which shall be deemed an original and all of which together shall constitute one instrument. The parties intend that electronic signatures constitute original signatures and a ".pdf" file of this sublease containing the signatures (original or electronic) of all parties is binding on the parties.
45. Entire Agreement. This Sublease contains the entire agreement and understanding between Sublandlord and Subtenant relating to the subleasing of the Premises and obligations of Sublandlord and Subtenant. This Sublease supersedes any and all prior or contemporaneous agreements and understandings between Sublandlord and Subtenant, and shall not be modified or amended unless both Sublandlord and Subtenant agree in writing. Sublandlord and Subtenant specifically agree that this instrument be interpreted as a sublease rather than an assignment.

[BALANCE OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the parties have executed this Sublease as of the day and year first above written.

SUBLANDLORD: State Farm Mutual Automobile Insurance Company

BY: Mike Buelow

TITLE: Assistant Vice President

DATE: 1/23/2019

SUBTEANT: MOLECULAR TEMPLATES, INC.

BY: /s/ Jason Kim

TITLE: President & COO

DATE: 1/11/2019

BY: /s/ Adam Cutler

TITLE: Chief Financial Officer

DATE: 1/11/2019

EXHIBIT A

[COPY OF MASTER LEASE]

EXHIBIT B

[FLOOR PLAN]

See Attached

EXHIBIT B

[FLOOR PLAN]

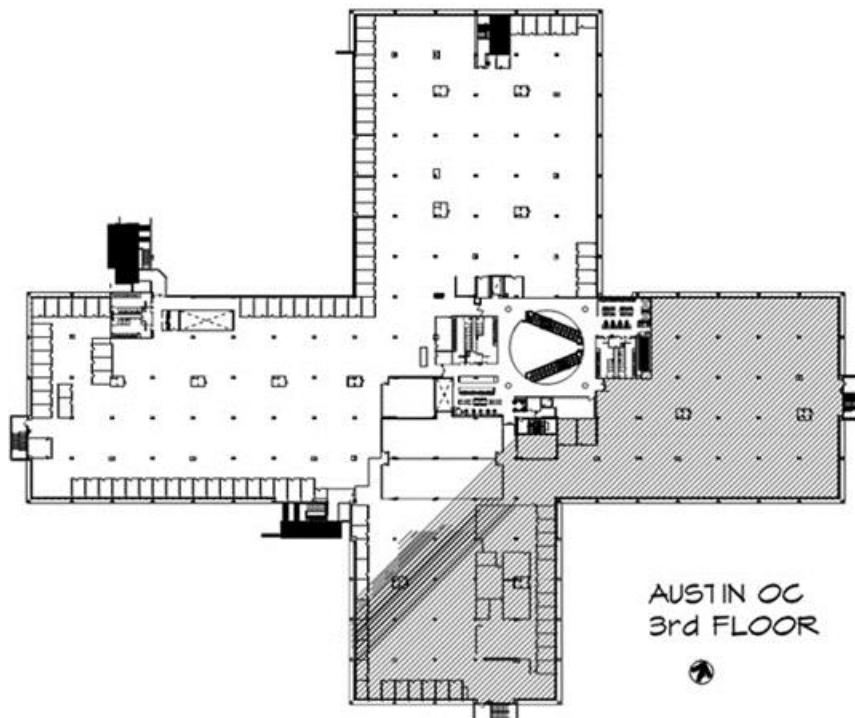


EXHIBIT 'X'

SUB- TENANT PREMISES

EXHIBIT C

[LIST OF FF&E TO BE DELIVERED WITH THE PREMISES]

EXHIBIT C

FF&E

Furniture and Fixtures which currently reside in and that Molecular Templates requests to remain within the Leased Premises:

1. All Moveable Office wall partitions which currently create the Cubicles shown below (note, the ones to be removed have been covered (blue), this will retain three of the cubicles rows).
 2. (6) Add Cubicles in the open area that was previously SF Legal support (upper left in drawing below)
 3. (53) Modesty Tables
 4. All Conference Tables and credenzas that are currently in conference rooms and add conference table(s) and credenza to large conference room by main entryway (akin to how it has been set
 - i. up in the past)
 5. (10) Teak Top Conference Tables
 6. (113) Leap Chairs (93 in office area, 22 in lab area)
 7. (50) Side Chairs
 8. (96) Conference Room Chairs
 9. (23) P Shape or U Shape Desks
 10. (52) Office Trash Cans
 11. (72) Cubicle Trash Cans
 12. (30) 2-3 Draw file cabinets (22 for lab area and 8 for office area modesty table desk setups)
 13. (68) 2-3 Draw file cabinets for cubicles (48 for center area desk configured cubicles, 20 for cubicles in SF Legal office area)
 14. (28) Book case or book shelves for offices
 15. (16) 4-5 Draw Vertical File Cabinet (8 in office area, 8 in legal area)
 16. (6) Tall storage cabinets
-

EXHIBIT D

[DEMISING WORK ESTIMATE]

EXHIBIT D

DEMISING WORK

**STATE FARM
INSURANCE DEMISING
WALL SPECIFICATIONS**

- All equipment and finishes to be new; any existing equipment and finishes to be reused must be in like-new working condition.
- Below are typical State Farm Design Guidelines. State Farm will need to approve final finish selections.
- New work shall meet or exceed all national, state, and local codes.

GENERAL

1. Demising walls: Walls between tenants to be floor to deck per code compliance and minimal 1 hour rated walls; typical drywall thickness 5/8" or 1/2" min., with Sound Batt Insulation floor to deck.
2. Interior Wall Finish: All walls (including existing walls) to be finished to match adjacent surfaces.
3. Interior Doors: Size to be a minimum of 3' x 7' x 1-3/8" wood solid core installed in steel jambs with keyed Lockset or Latchsets and door stop; keying to be specified by State Farm. All doors within area of the demising wall must be new.
4. Door Hardware: Hardware is typically provided by Contractor in compliance with building standards.
 - i. Security Hardware, and general Hardware, hinge finish, door stop, closer, etc. to match; to be reviewed for security type to be specified by State Farm.
5. Ceiling: 2' x 2' lay-in grid system; beveled edge tile; NRC of .90 for fiberglass; NRC of .75 for mineral tiles
6. Signage: At suite entry, elevator, building lobby as needed.
7. Exit Signs/Emergency Lighting/ Fire Sprinklers/Smoke Detectors, adjusted as required per code.
8. Demising Partitions: Must be built from floor to deck, per code.
9. Access and Security System: Rough-in (same as "Empty Conduit") for electric strikes, key readers, key pads, door contacts, intercom, key switch, panic button, etc.; include door closer and stockroom function lockset; prep door frame and provide VonDuprin 5100 electric strike
 - ii. (fail "secure"); make final rigid electrical connection (dedicated circuit) to system equipment; design and systems provided and installed by State Farm.
10. Mechanical: All full-height walls to deck shall have a transfer air duct installed to provide a path for return air back to the AHU as required depending on location. "Z" type configuration is preferred.
11. Life Safety: New exit signs installed at doors in demising wall as required by state and local code requirements. Fire Alarm strobes / horns adjusted at demising partitions as required by state and
 - iii. local code.
12. Lighting: Switching to be adjusted as required depending on affected lights around Demising partitions.
13. Fire Sprinklers (if required): Adjust as needed; to be centered in ceiling tile.

INTERIOR FINISHES GENERAL GUIDELINES:

1. All interior finish selections to be reviewed and approved by State Farm Corporate Interior Design
 2. Flooring, Carpet:
 - o Location: As required for replacement where demising wall is constructed. Product to match existing adjacent carpet tile in type, color, and pattern. State Farm to approve selection.
 3. Rubber Cove Base:
 - o Color to match existing adjacent cove base
 - o Manufacturers:
 - Johnsonite Traditional 4", Mannington Premium Edge 4", Roppe Pinnacle 4"
 4. Paint:
 - o Walls to receive primer and two coats of low VOC – eggshell finish
 - o Colors: To match existing adjacent wall surfaces. State Farm to approve selection.
 - o Interior door frames (if applicable) – Low VOC – Satin finish
 - o Manufacturers:
 - Sherwin Williams, Benjamin Moore, PPG
-

EXHIBIT E

[SITE PLAN IDENTIFYING LOCATION FOR GENERATOR]

See attached

EXHIBIT E - GENERATOR LOCATION

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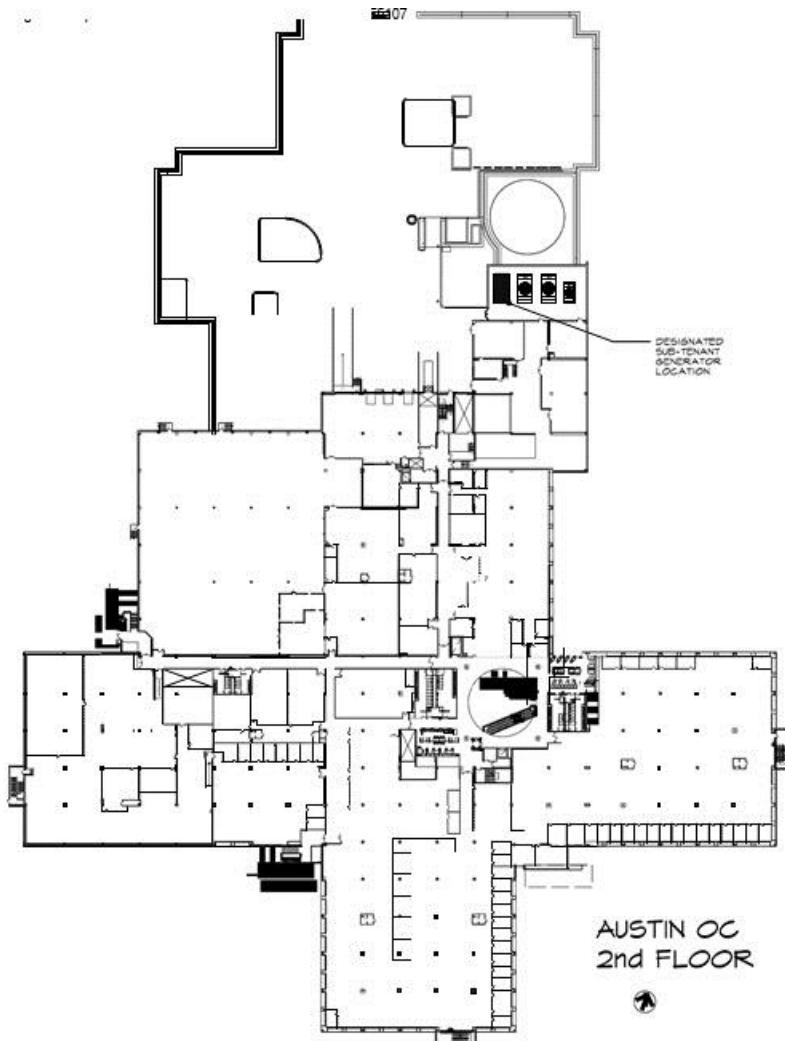


EXHIBIT 'x'
SUB- TENANT GENERATOR PLACEMENT

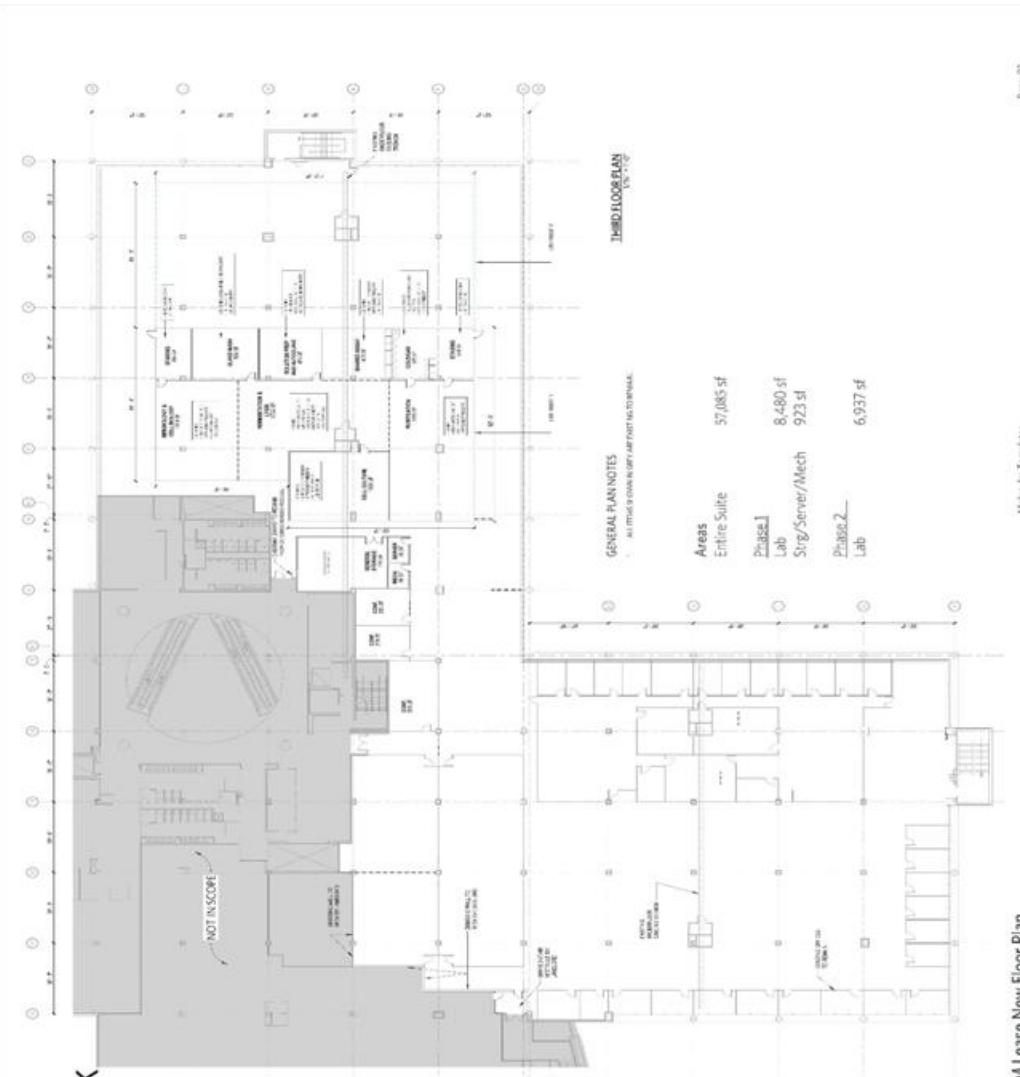
EXHIBIT F

INTENTIONALLY OMITTED

EXHIBIT G

[SUBTENANT'S WORK]

**EXHIBIT G -
SUBTENANT'S WORK**



MTEM Lease New Floor Plan
Module 260 Lab and Office

Studio8
Architecture & Interiors

Page 9
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EXHIBIT H

[PLAN IDENTIFYING LOCATION OF RESERVED PARKING SPACES]

See Attached

EXHIBIT H

PARKING

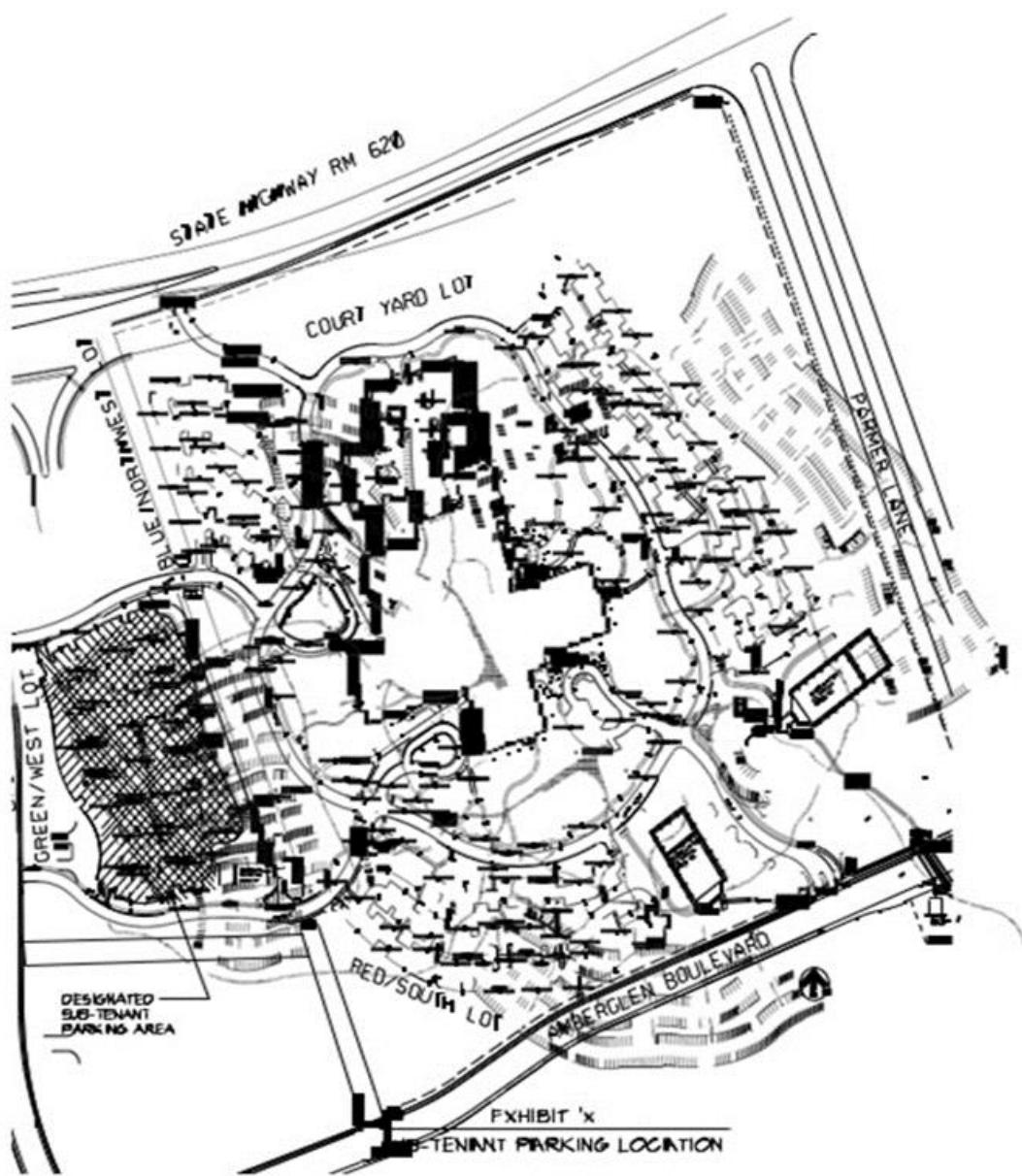


EXHIBIT 'X'

SUB-TENANT PARKING LOCATION

EXHIBIT I

[PLAN IDENTIFYING MONUMENT SIGN]

EXHIBIT I

PLAN IDENTIFYING MONUMENT SIGN

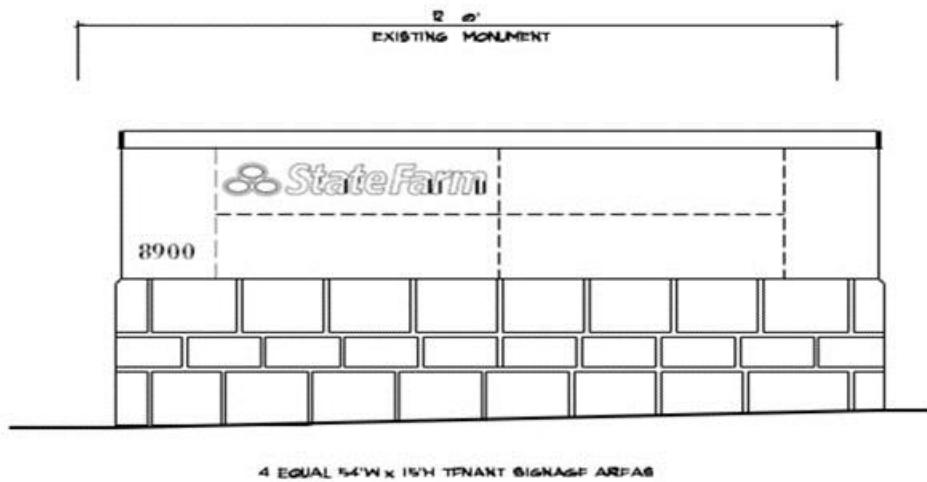


EXHIBIT 'X'
MONUMENT SIGNAGE

EXHIBIT J

[Temporary Space Floor Plan]

EXHIBIT J

TEMPORARY SPACE FLOOR PLAN

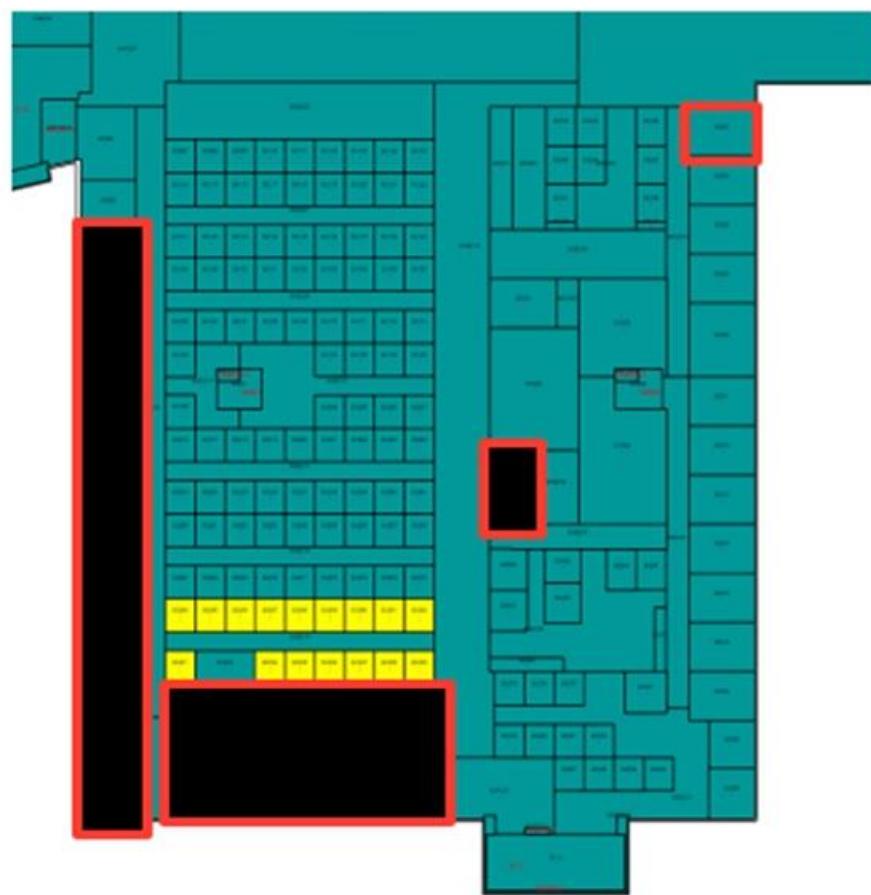


EXHIBIT K

[Form of Recognition Agreement]

SUBSIDIARIES OF MOLECULAR TEMPLATES, INC.

Subsidiary

Molecular Templates OpCo, Inc.
THLD Enterprises (UK), Limited

Jurisdiction

Delaware
United Kingdom

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- 1) Registration Statement (Form S-3 No. 333-228975) of Molecular Templates, Inc.,
- 2) Registration Statement (Form S-3 No. 333-225223) of Molecular Templates, Inc.,
- 3) Registration Statement (Form S-3 No. 333-220477) of Molecular Templates, Inc.,
- 4) Registration Statement (Form S-3 No. 333-207745) of Threshold Pharmaceuticals, Inc.,
- 5) Registration Statement (Form S-3 No. 333-202043) of Threshold Pharmaceuticals, Inc.,
- 6) Registration Statement (Form S-8 No. 333-225826) of Molecular Templates, Inc. pertaining to the Molecular Templates, Inc. 2018 Equity Incentive Plan
- 7) Registration Statement (Form S-8 No. 333-221002) of Molecular Templates, Inc. pertaining to the 2009 Stock Plan, as amended, the 2014 Equity Incentive Plan, as amended, and the Amended and Restated 2004 Employee Stock Purchase Plan,
- 8) Registration Statement (Form S-8 No. 333-210089) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Employee Stock Purchase Plan,
- 9) Registration Statement (Form S-8 No. 333-202476) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Employee Stock Purchase Plan,
- 10) Registration Statement (Form S-8 No. 333-196249) of Threshold Pharmaceuticals, Inc. pertaining to the 2014 Equity Incentive Plan, and the Amended and Restated 2004 Employee Stock Purchase Plan,
- 11) Registration Statement (Form S-8 No. 333-187107) of Threshold Pharmaceuticals, Inc. pertaining to the 2004 Amended and Restated Equity Incentive Plan, and the Amended and Restated 2004 Employee Stock Purchase Plan,
- 12) Registration Statement (Form S-8 No. 333-180149) of Threshold Pharmaceuticals, Inc. pertaining to the 2004 Amended and Restated Equity Incentive Plan, and the Amended and Restated 2004 Employee Stock Purchase Plan,
- 13) Registration Statement (Form S-8 No. 333-173047) of Threshold Pharmaceuticals, Inc. pertaining to the 2004 Amended and Restated Equity Incentive Plan, and the Amended and Restated 2004 Employee Stock Purchase Plan,
- 14) Registration Statement (Form S-8 No. 333-167260) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Equity Incentive Plan,
- 15) Registration Statement (Form S-8 No. 333-164865) of Threshold Pharmaceuticals, Inc. pertaining to the 2004 Amended and Restated Equity Incentive Plan, and the Amended and Restated 2004 Employee Stock Purchase Plan,
- 16) Registration Statement (Form S-8 No. 333-156733) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Equity Incentive Plan,
- 17) Registration Statement (Form S-8 No. 333-143130) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Equity Incentive Plan,
- 18) Registration Statement (Form S-8 No. 333-134598) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Equity Incentive Plan, and the 2004 Employee Stock Purchase Plan, and
- 19) Registration Statement (Form S-8 No. 333-126276) of Threshold Pharmaceuticals, Inc. pertaining to the 2001 Equity Incentive Plan, the 2004 Equity Incentive Plan, and the 2004 Employee Stock Purchase Plan;

of our report dated March 29, 2019, with respect to the consolidated financial statements of Molecular Templates, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Austin, Texas
March 29, 2019

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

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

1. I have reviewed this Annual Report on Form 10-K 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 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: March 29, 2019

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

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

I, Adam Cutler, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 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: March 29, 2019

/s/ Adam Cutler

Adam Cutler

Chief Financial Officer

Molecular Templates, Inc.

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

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

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

Date: March 29, 2019

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

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

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 Annual Report of Molecular Templates, Inc. (the "Company") on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Adam Cutler, 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: March 29, 2019

/s/Adam Cutler

Adam Cutler
Chief Financial Officer

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