

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, 2019

OR

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

For the transition period from _____ to _____

Commission file number: 001-32979

MOLECULAR TEMPLATES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(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 Exchange Act:

Title of Each Class
Common Stock, \$0.001 Par Value Per Share

Trading Symbol
MTEM

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 Exchange 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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.

| | | | |
|-------------------------|--------------------------|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/> | Accelerated filer | <input checked="" type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
| | | Emerging growth company | <input type="checkbox"/> |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the closing price of \$8.35 of the common stock on The Nasdaq Capital Market as of the last business day of the registrant's most recently completed second fiscal quarter was approximately \$167,590,587. 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 12, 2020 there were 45,647,884 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2020 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days of the registrant's fiscal year ended December 31, 2019 are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

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

- the implementation of our business strategies, including our ability to pursue development pathways and regulatory strategies for MT-3724 and other engineered toxin body, or ETB, drug candidates;
- the timing and our ability to advance the development of our drug 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 drug candidates;
- our financial condition, including our ability to obtain the funding necessary to advance the development of our drug candidates;
- the anticipated progress of our drug candidate development programs, including whether our ongoing and potential future clinical trials will achieve clinically relevant results;
- our ability to generate data and conduct analyses to support the regulatory approval of our drug candidates;
- our ability to establish and maintain intellectual property rights for our drug candidates;
- whether any drug candidates that we are able to commercialize are safer or more effective than other marketed products, treatments or therapies;
- our ability to discover and develop additional drug candidates suitable for clinical testing;
- our ability to identify, in-license or otherwise acquire additional drug candidates and development programs;
- our anticipated research and development activities and projected expenditures;
- our ability to complete preclinical and clinical testing successfully for new drug 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 anticipated use of proceeds from any financing activities;
- our ability to retain and hire necessary employees and appropriately staff our development programs;
- our projected financial performance; and
- the sufficiency of our cash resources; and other risks and uncertainties, including those listed under Part I, Item 1A, “Risk Factors”.

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 company focused on the discovery and development of differentiated, targeted, biologic therapeutics for cancer and other serious diseases. 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 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 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 is developing ETBs for various targets, including CD20, CD38, HER2, PD-L1, CTLA-4, SLAMF-7, and CD45. 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 three Phase II studies: a monotherapy study, a combination study with lenalidomide, and a combination study with gemcitabine/oxaliplatin (GemOx). The combination study with lenalidomide has demonstrated preliminary evidence of tolerability and efficacy with lenalidomide at standard doses and MT-3724 at 10 µg/kg. MT-3724 dosing at higher doses with lenalidomide is ongoing. The combination study with GemOx has demonstrated preliminary evidence of efficacy but Grade 2 innate immune adverse effects were seen with standard doses of gemcitabine and oxaliplatin and 10 µg/kg doses of MT-3724. The study protocol has been amended to include a revised schedule where MT-3724 dosing is initially sequenced with GemOx dosing. MTEM expects to announce updates on interim clinical results from all three MT-3724 Phase II studies throughout 2020. MT-5111 (ETB targeting HER2) and TAK-169 (ETB targeting CD38) are both in ongoing Phase I studies. Molecular expects to announce results from the MT-5111 Phase I study throughout 2020. Molecular also expects to file an IND for MT-6402 (ETB targeting PD-L1) in the second half of 2020.

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 Current Good Manufacturing Process, or cGMP standards and continues to make improvements to its manufacturing processes. Molecular has conducted multiple cGMP 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 65 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 biopharmaceutical company focused on compounds with unique and differentiated biology.* Molecular believes that differentiated mechanisms of action are crucial for improving outcomes in cancer and other serious diseases. 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-5111, or any future drug 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 cGMP 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.













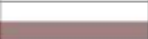


In subsequent ETBs, Molecular utilizes a highly potent and proprietarily de-immunized SLTA scaffold that elicits significantly reduced innate and adaptive immunogenic responses as demonstrated in preclinical and animal studies (presented at the 2017 American Association for Cancer Research, or AACR, 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 to 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 highlights this 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 |  | DLBCL ^a monotherapy (CD20) |  |  |  |  |
| |  | DLBCL combinations (CD20) | | |  | |
| MT-5111 |  | Multiple – solid tumors (HER2) |  |  | | |
| TAK-169 |  | Multiple Myeloma (CD38) |  |  | | |
| MT-6402 (antigen seeding) |  | Multiple – solid tumors (PD-L1) |  | | | |

a) Potential for Phase 2 to be pivotal in relapsed/refractory setting as monotherapy

 Completed
  In-Progress
  Planning
  Phase 2 is potentially pivotal

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 an 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. In 2019, Molecular initiated a Phase II monotherapy study that has the potential to be pivotal as well as two Phase II combination studies of MT-3724 in earlier lines of DLBCL; one in combination with chemotherapy (gemcitabine/oxaliplatin, or GemOx) and one in combination with lenalidomide.

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.

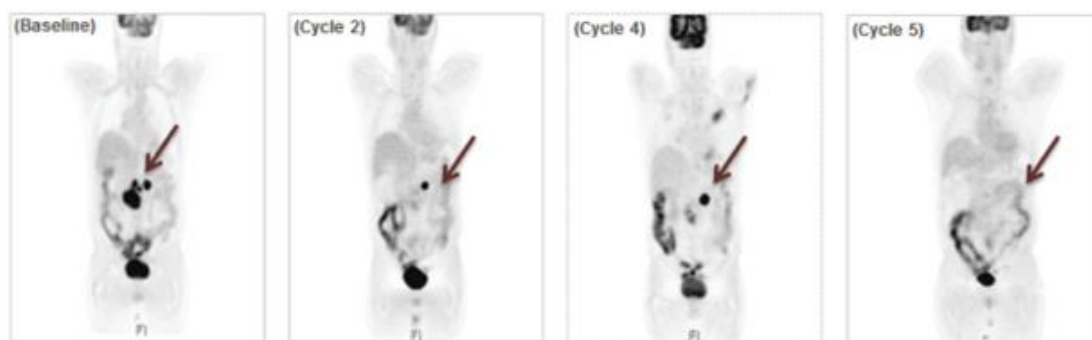
Twenty-one patients were treated with escalating doses of MT-3724 starting at the 5 mcg/kg dose level. Nearly all patients experienced at least one adverse event, with peripheral edema, diarrhea, myalgia, cough, fatigue, constipation, nausea, anemia, stomatitis, pyrexia, dizziness, headache, insomnia, 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 = 65) 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. The final results from Phase I/Ib study were presented at the American Society of Hematology (ASH) 2019 Annual Meeting, in December 2019. 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 and 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. Of the 5 serum Rituxan-negative subjects with DLBCL who received MT-3724 at 50 µg/kg, the maximum tolerated dose (MTD), 3 responded (2 CRs, 1 PR).

In 2019, Molecular 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. In 2019, Molecular 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 was initiated in 2019.

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.

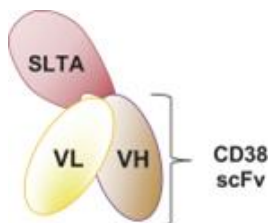
In 2019, Molecular and its partner Takeda presented preclinical data on TAK-169 at the American Association of Cancer Research (AACR) annual meeting, the IND for TAK-169 was accepted by the FDA, and Takeda initiated a Phase 1 study in relapsed/refractory multiple myeloma in the fourth quarter of 2019. In December 2019, TAK-169 received Orphan Drug Designation from the FDA.

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.

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 Takeda Collaboration Agreement. To date, we have received the \$2.0 million under this Takeda Collaboration Agreement.

In connection with the Takeda Collaboration Agreement, we entered into an Individual Project Agreement (the "Takeda Individual Project Agreement") with Takeda in June 2018 that was 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 were entitled to receive up to \$2.2 million in compensation. To date we have received the \$2.2 million under the Takeda Individual Project Agreement.

Takeda Development and License Agreement

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

The agreement has a total transaction price of \$29.8 million, consisting of (1) the \$30.0 million upfront payment, (2) a \$10.0 million development milestone payment which was achieved in the first quarter of 2020, (3) minus \$10.2 million in expected co-share payments payable to Takeda during Early Stage Development. In July 2019, we exercised our co-development option and the agreed upon collaboration budget was increased to cover additional research and development activities whereby both parties will continue to cost share. If we continue our option to co-develop, we will be eligible to receive up to an additional \$307.5 million in milestone payments upon the achievement of certain development and regulatory milestone events and up to an additional \$325 million in milestone payments upon the achievement of certain sales milestone events. If we do not continue to exercise our co-development option, we may receive up to an additional \$162.5 million in milestone payments upon the achievement of certain development and regulatory milestone events and up to an additional \$175 million in milestone payments upon the achievement of certain sales milestone events. We will also be entitled to receive tiered royalties, subject to certain reductions, as percentages of annual aggregate net sales, if any, of Licensed Products. The royalty percentages would range from low double-digits to low twenties if we continue to exercise our option to co-develop, and from high-single digits to low teens if we do not continue to exercise our option to co-develop.

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

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

Takeda Multi-Target Agreement

In June 2017, we entered into a multi-target collaboration and license agreement with Takeda (the "Takeda Multi-Target Agreement"), pursuant to which we will collaborate with Takeda to identify, generate and evaluate ETBs, against certain targets designated by Takeda. Pursuant to the Takeda Multi-Target Agreement, Takeda will designate certain targets of interest as the focus of the research. Takeda will provide to us targeting moieties against the designated targets and we will create and characterize ETBs against those targets and provide them to Takeda for further evaluation. We are entitled to receive up to \$5.0 million in technology access fees and research and development fees associated with our performance and completion of our obligations under the agreement. In December 2017, Takeda nominated both targets under the Takeda Multi-Target Agreement. At December 31, 2019, we have received \$5 million under the Takeda Multi-Target Agreement.

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

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

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

Vertex Pharmaceuticals

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

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

Pursuant to the Vertex Collaboration Agreement, Vertex will pay the Company an upfront payment of \$38 million, consisting of \$23 million in cash and a \$15 million equity investment pursuant to a Share Purchase Agreement (the "SPA"), described further below. In addition to the upfront payments, the Company may also receive an additional \$22 million through the exercise of the options to license ETB products or to add an additional target. The Company shall provide, and Vertex will reimburse the Company for, certain mutually agreed manufacturing technology transfer activities.

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

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

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

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

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. We may terminate this agreement at any time with 45 days prior written notice.

CPRIT Grant

On September 18, 2018, we entered into a Cancer Research Grant Contract (the "CPRIT Agreement") with the Cancer Prevention Research Institute of Texas (CPRIT), which was extended in November 2019, in connection with a grant of approximately \$15.2 million awarded by CPRIT to us in November 2016 to fund research of a cancer therapy involving an ETB that is targeting CD38 (the "Award"). Pursuant to the CPRIT Agreement, we may also use such funds to develop a replacement CD38 targeting ETB (such as TAK-169), with or without a partner. The Award is contingent upon funds being available during the term of the CPRIT Agreement and subject to CPRIT's ability to perform its obligations under the CPRIT Agreement as well as our progress towards achievement of specified milestones, among other contractual requirements. In December 2011, Private Molecular (defined below) was awarded a \$10.6 million product development grant from CPRIT for its CD20-targeting ETB MT-3724.

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

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

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

Manufacturing

Molecular has built a cGMP 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 cGMP 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 cGMP standards.

Molecular has established well-defined, cost efficient manufacturing under cGMP, 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.

As part of our manufacturing process, we endeavor to utilize cGMP grade materials and reagents, if commercially available; however, certain critical materials and reagents are currently qualified for research use only. Additionally, we obtain key components required for the manufacture of our investigational products from third-party manufacturers and suppliers, which include, in some instances, sole source manufacturers and suppliers. We do not currently have long-term commitments or supply agreements in place to obtain certain key components used in the manufacture of our drug candidates.

Intellectual Property Portfolio

Molecular seeks to protect proprietary rights in its platform technologies through a combination of patents and patent applications, trade secrets and know-how. Molecular's platform technologies include ETBs, in which a Shiga toxin A subunit construct is associated, directly or indirectly, to immunoglobulin domains directed to the molecular target, resulting in ETBs for treating cancer, killing cancer cells and selectively delivering payload molecules into target cells. While each ETB targets at least one specific molecular target, many of Molecular's platform technologies are target agnostic. Molecular's platform technologies include the Shiga toxin components of ETBs, including improved Shiga toxin A subunit constructs engineered to have reduced innate and adaptive immunogenicity, including by disrupting of B-cell epitopes and T-cell epitopes.

To cover its proprietary technologies and its current pipeline of proprietary ETB therapeutic candidates and related methods, such as methods for therapeutic use, Molecular has pending patent applications representing 17 patent families, together covering 166 patents and pending U.S. and foreign applications worldwide, including 23 pending U.S. patent applications and 118 foreign patent applications currently pending in the European Patent Office and in thirteen other jurisdictions outside of the U.S. and Europe (Australia, Canada, China, Hong Kong, Israel, India, Japan, Mexico, and South Korea). Patents have been granted from ten of these patent families, including in Australia, China, Europe, Hong Kong, Israel, Japan, South Korea, and U.S.

Molecular has 16 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. Patent rights in these patent families, if granted and if all relevant maintenance fees or annuities are paid, are expected to expire during 2034–2040. Molecular also has a patent family directed to the screening of large ETB libraries, in which patents, if granted and if all relevant maintenance fees or annuities are paid, are expected to expire in 2035. One patent in this family has granted as US 10421958 and is expected to expire February 4, 2035. With respect to its ETB pipeline, Molecular’s lead compound MT-3724, which targets CD20, and pharmaceutical compositions and uses of MT-3724, are covered by three patent families. Patents in these patent families, if granted and if all relevant maintenance fees or annuities are paid, are expected to expire in 2034 or 2036. Granted patents in these families include US 10450354, which is expected to expire February 21, 2035; US 10392425, which is expected to expire February 4, 2036; EP 2970487, which is expected to expire March 11, 2034; JP 6472784, which is expected to expire March 11, 2034; JP 6548630, which is expected to expire March 11, 2034; and JP 6444486, which is expected to expire February 4, 2036. Molecular’s current pipeline also includes ETBs which target CD38, HER2, or PD-L1, and are covered by numerous patent applications and patent families, including one patent family from which patents, if granted and if all relevant maintenance fees or annuities are paid, are expected to expire in 2036. Some of the expected expiration dates referenced above do not include adjustment for patent office delay. The expected expiration dates referenced above do not include any patent term extension for regulatory review.

As of December 31, 2019, Molecular owned 95 U.S. and foreign patents and patent applications relating to hypoxia-activated prodrugs, including the investigational prodrug evofosfamide currently in clinical development for treating cancer; the manufacturing of prodrugs’, formulation of the prodrugs; and their use. These patents and patent applications include 14 issued U.S. patents, expected to expire from 2024 to 2031, and 57 issued foreign patents expected to expire from 2024 to 2036 (in each case, if all relevant maintenance fees or annuities are paid, and without accounting for any patent term extension), as well as five pending U.S., one pending international (Patent Cooperation Treaty) and 19 pending foreign patent applications, which, if issued and if all relevant maintenance fees or annuities are paid, would in each case be expected to expire from 2024 to 2037 (without accounting for any patent term extension or adjustment).

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 drug 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 PHSA, 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 drug candidates must be approved by the FDA through either a New Drug Application, or NDA, or Biologics License 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 good laboratory practice, or GLP, requirements;
- Submission to the FDA of an Investigational New Drug, or IND, application, 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;
- Submission to the FDA of an NDA or BLA for marketing approval, including payment of application user fees;
- 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 drug 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 holds also may be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

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 drug 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.

In addition, an institutional review board (“IRB”) representing each institution that is participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct a continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to clinical trial subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific timeframes to the National Institutes of Health for public dissemination on the ClinicalTrials.gov data registry. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

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.

During the development of a new drug or biologic, sponsors have the opportunity to meet with the FDA at certain points, including prior to submission of an IND, at the end of Phase II, and before submission of an NDA or BLA. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase II meeting to discuss their Phase II clinical results with the agency and to present their plans for the pivotal Phase III studies that they believe will support approval of the new drug or biologic.

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. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, potency and purity of the final drug or biologic. For biologics in particular, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined in order to help reduce the risk of the introduction of adventitious agents. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that MT-3724, TAK-169 and any future drug candidates do not undergo unacceptable deterioration over their shelf life.

NDA/BLA Submission 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, potency and efficacy 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 fee for the submission of an NDA or BLA for which clinical data is required is substantial (for example, for fiscal year 2020 this application fee exceeds \$2.9 million), and the annual program fee assessed on each sponsor of an approved NDA or BLA is currently more than \$300,000 per program.

The FDA reviews all submitted NDAs and BLAs to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may refuse to file the application and request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt and inform the sponsor by the 74th day after the FDA's receipt of the submission whether an application is sufficiently complete to permit substantive review. 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 review of a new molecular-entity (NME) NDA or an 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. For non-NME NDAs, the review goals are ten months from the date of receipt for a standard application and six months from the date of receipt for a priority submission. 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. After the submission is accepted for filing, the FDA begins an in-depth substantive review. As noted above, the FDA has agreed to specified performance goals in the review process of NDAs and BLAs. The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

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 the manufacturing processes and facilities 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 independent scientific 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. The FDA also may require submission of a risk evaluation and mitigation strategy, or “REMS” plan, if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug or biologic. The REMS plan could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS plan is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve an NDA or BLA without a REMS, if one is required.

The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product’s identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product’s continued safety, purity and potency. On the basis of the FDA’s evaluation of the NDA or BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue either 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 and may require substantial additional testing or information in order for the FDA to reconsider the application. The Complete Response Letter may require additional clinical or other data, 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 choose either to resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or to withdraw the application. If and when all deficiencies have been addressed to the FDA’s satisfaction in a resubmitted NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued Complete Response Letter in either two or six months, depending on the type of information included. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the regulatory criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than Molecular interprets the same data. If a product receives regulatory approval from the FDA, the approval is limited to the conditions of use (e.g., patient population, indication) described in the application. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including Phase IV clinical trials, be conducted to further assess a product’s safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Orphan Drug Designation and Exclusivity

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 is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to an existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the NDA or BLA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA. In addition, fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging in the clinical trial process. 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.

The FDA also may designate a product for priority review if it is a drug or biologic that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. When a marketing application is submitted with a request for priority review, the FDA determines on a case-by-case basis whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months for an original BLA or an NME NDA from the date of filing (or from ten months to six months from the date of receipt for a non-NME NDA).

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 FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Fast track designation, priority review, and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process.

Accelerated Approval Pathway

Products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug or biologic when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. 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 to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. 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. Drugs and biologics granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval when the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, would allow the FDA to withdraw approval of the drug or biologic. All promotional materials for products approved for marketing under the accelerated approval program are subject to prior review by the FDA.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, amendments to the FDCA, an NDA or BLA or supplement to a NDA or BLA must contain data that are adequate 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, enacted in 2020, made permanent PREA 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. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Prescription drug promotional materials also 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 the applicant to develop additional data or conduct additional 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. 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. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our drug candidates must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities satisfaction before any product is approved and our commercial products can be manufactured. Molecular relies, and expects 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.

Once an approval or clearance of a drug is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs/BLAs or supplements to approved NDAs/BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Most recently, the Drug Supply Chain Security Act, or DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Companion Diagnostics and Complementary Diagnostics

Molecular believes that the success of Molecular's drug 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 associated with a new diagnostic test combined with available controls to mitigate risk determines whether a companion diagnostic device requires Premarket Approval (PMA) from the FDA or if it can be cleared by the agency through the 510(k) premarket notification process based on a showing of substantial equivalence to a commercially available device. 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 PMA-approved or 510(k)-cleared contemporaneously with the therapeutic product. The use of the companion diagnostic device will be stipulated in the labeling of the therapeutic product.

U.S. Patent-term Restoration

Depending upon the timing, duration and specifics of FDA approval of MT-3724, TAK-169 and any future drug 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 to the FDCA. 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. Patent and Trademark Office, or USPTO, 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.

Marketing Exclusivity for Small-Molecule Drug Products

In 1984, with passage of the Hatch-Waxman Amendments, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD. Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug."

Following approval of an ANDA, the FDA indicates whether the generic product is “therapeutically equivalent” to the RLD in its publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” also referred to as the “Orange Book.” In addition, by operation of certain state laws and numerous health insurance programs, the FDA’s designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant’s product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant submits its application to the FDA, the applicant is required to certify to the FDA concerning any patents listed for the RLD in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that a Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, such an applicant also is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Section 505(b)(2) permits the filing of a new drug application, or NDA, where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, they may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness.

Specifically, an ANDA or 505(b)(2) applicant for a follow-on drug product must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product’s listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the ANDA applicant is not seeking approval).

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA owner and patent holders once the ANDA in question has been accepted for filing by the FDA. The NDA owner and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent or a decision in the infringement case that is favorable to the ANDA applicant.

In addition, under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. These 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 drug containing 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 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 traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either 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.

Reference Product Exclusivity for Biological Products

In March 2010, the Patient Protection and Affordable Care Act was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. This amendment to the PHSA, in part, attempts to minimize duplicative testing.

A federal district court ruling in Texas struck down the Affordable Care Act in its entirety based on constitutionality last year, and in December 2019 the Fifth Circuit Court of Appeals upheld lower court's finding that the individual mandate in the law is unconstitutional. However, the Fifth Circuit also reversed and remanded the case to the district court to determine if other reforms enacted as part of the Affordable Care Act but not specifically related to the individual mandate or health insurance, including the BPCIA, could be severed from the rest of the Affordable Care Act so as not to be declared invalid. It is unclear how this decision, subsequent appeals including potentially to the U.S. Supreme Court, and other efforts to repeal and replace the Affordable Care Act will affect the implementation of that law and our business. To date, the FDA has approved a number of biosimilars, and numerous biosimilars have been approved in Europe. The FDA has also issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biosimilars.

Biosimilarity 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. The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency. 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. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product, although to date no such products have been approved for marketing in the United States. 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 first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed. If pediatric studies are performed and accepted by the FDA as responsive to a Written Request, as described further below, the 12-year exclusivity period will be extended for an additional six months. In addition, 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. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. 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.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to significant uncertainty.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity available in the United States. Pediatric exclusivity, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. This six-month exclusivity may be granted if an NDA or BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. The issuance of a Written Request does not require the sponsor to undertake the described studies.

If granted, pediatric exclusivity attaches to both the twelve-year and four-year exclusivity periods for reference biologics approved pursuant to BLAs, as well as the five-year and three-year marketing exclusivity periods available to NDA sponsors under the Hatch-Waxman Amendments and the seven-year orphan drug exclusivity period, as may be applicable.

Other U.S. Health Care Laws and Regulations

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 Centers for Medicare and Medicaid Services (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, the Occupational Safety and Health Administration, 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 ten 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 two of the five 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 these two provisions in the statute or specific intent to violate them; specifically with respect to the prohibition on executing or attempting to execute a scheme or artifice to defraud or to fraudulently obtain money or property of any health care benefit program and the prohibition on disposing of assets to enable a person to become eligible for Medicaid. 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. There also are federal transparency requirements under the Physician Payments Sunshine Act that require manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to CMS information related to payments and other transfers of value to physicians, teaching hospitals, and certain advanced non-physician health care practitioners and physician ownership and investment interests. Prescription drug and biologic products also 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. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, or the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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 defends 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.

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 and biologics, which are referred to collectively as medicinal products, can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained. Whether or not we obtain FDA approval for a drug candidate, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before we may commence clinical trials or market products in those countries or areas. It is not yet clear how the United Kingdom's withdrawal from the European Union, which took place on January 31, 2020, will affect the approval of medicinal products in the United Kingdom.

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. Specifically, in April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation) was adopted and it is anticipated to come into application in late 2020 or early 2021. The Clinical Trials Regulation will be directly applicable in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

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 or biosimilar 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 can 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. 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. The 10-year period of exclusivity 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. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

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 fails 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.

Coverage, Pricing, and Reimbursement

Sales of Molecular's products approved for marketing by the FDA and foreign regulatory authorities 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 repeal and 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 maximum amount that a manufacturer may charge a 340B covered entity for a given product is the AMP reduced by the rebate amount paid by the manufacturer to Medicaid for each unit of that product. 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 expects 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 receives 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. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our drug candidate to currently available therapies (so called health technology assessment, or HTA) in order to obtain reimbursement or pricing approval. 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.

Health Care Reform in the U.S. and Potential Changes to Health Care Laws

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and devices and to spur innovation, but its ultimate implementation is uncertain. In addition, in August 2017, the FDA Reauthorization Act was signed into law, which reauthorized the FDA's user fee programs and included additional drug and device provisions that build on the Cures Act. 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 not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

As previously mentioned, the primary trend in the US health care industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other health care funding and applying new payment methodologies. For example, in March 2010, the Affordable Care Act was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced 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; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; and established a Center for Medicare Innovation at the US Centers for Medicare and Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. The current Presidential administration and members of the US Congress have indicated that they may continue to seek to modify, repeal or otherwise invalidate all, or certain provisions of, the Affordable Care Act. For example, the Tax Cuts and Jobs Acts was enacted in 2017, which, among other things, removed penalties for not complying with the individual mandate to carry health insurance. As noted above, a 2018 federal district court ruling struck down the Affordable Care Act in its entirety although the Fifth Circuit Court of Appeals recently limited it to the individual mandate and remanded the case to the district court to determine if other reforms not specifically related to the individual mandate or health insurance could be severed from the rest of the Affordable Care Act. It is unclear how this decision, subsequent appeals including potentially to the U.S. Supreme Court, and other efforts to repeal and replace the Affordable Care Act will affect the implementation of that law and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act that affect health care expenditures. There has been heightened governmental scrutiny in recent years over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical and biologic products. Notably, on December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94) that includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 or the "CREATES Act." The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. Because generic and biosimilar product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic and biosimilar products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

U.S. Foreign Corrupt Practices Act

In general, the Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, prohibits offering to pay, paying, promising to pay, or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business for or with, or in order to direct business to, any person. The prohibitions apply not only to payments made to "any foreign official," but also those made to "any foreign political party or official thereof," to "any candidate for foreign political office" or to any person, while knowing that all or a portion of the payment will be offered, given, or promised to anyone in any of the foregoing categories. "Foreign officials" under the FCPA include officers or employees of a department, agency, or instrumentality of a foreign government. The term "instrumentality" is broad and can include state-owned or state-controlled entities.

Importantly, United States authorities that enforce the FCPA, including the Department of Justice, deem most health care professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public health care or public education systems to be “foreign officials” under the FCPA. When we interact with foreign health care professionals and researchers in testing and marketing our products abroad, we must have policies and procedures in place sufficient to prevent us and agents acting on our behalf from providing any bribe, gift or gratuity, including excessive or lavish meals, travel or entertainment in connection with marketing our products and services or securing required permits and approvals such as those needed to initiate clinical trials in foreign jurisdictions. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the maintenance of books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and the development and maintenance of an adequate system of internal accounting controls for international operations.

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. 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 velzutuzumab (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), 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

At December 31, 2019, we had 151 full-time employees and 17 part-time and temporary employees, 126 of whom 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 condensed consolidated financial statements and the related notes, before making any decision to purchase our common stock. If any of the possible adverse events described below actually occurs, we may be unable to conduct our business as currently planned and our prospects, financial condition, operating results and cash flows could be materially harmed. In addition, the trading price of our common stock could decline due to the occurrence of any of the events described below, and you may lose all or part of your investment. In assessing these risks, you should refer to the other information contained in this Annual Report on Form 10-K, including our condensed consolidated financial statements and related notes.

Risks Related to Our Financial Condition and Capital Requirements

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

We are a clinical development-stage biopharmaceutical company with a limited operating history. We have incurred net losses in each year since 2009, including net losses attributable to common shareholders of \$69.4 million for the year ended December 31, 2019. At December 31, 2019, we had an accumulated deficit of \$164.1 million.

At December 31, 2019, we had cash, cash equivalents, and marketable securities of \$126.6 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 a public offering of 9,430,000 shares of common stock at an offering price of \$5.50 per share, which included the exercise in full by the underwriters of their option to purchase up to 1,230,000 additional shares of common stock. We received net proceeds of approximately \$48.1 million, after deducting underwriting discounts, commissions and estimated offering related transaction costs. On December 21, 2018, we filed a universal shelf registration statement on Form S-3 (Registration No. 333-228975) with the U.S. Securities and Exchange Commission, or the SEC, which was automatically declared effective on February 13, 2019. In December 2018 we entered into the Sales Agreement with Cantor, pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to \$50,000,000 from time to time through Cantor acting as our agent. Under the Sales Agreement, Cantor may sell the shares by any method permitted by law and deemed to be an “at the market” offering as defined in Rule 415 of the Securities Act. To date, we have not sold any shares under the Sales Agreement. In November 2019, we completed a public offering of 6,000,000 shares of common stock at an offering price of \$8.00 per share and 250 shares of newly designated Series A convertible preferred stock at an offering price of \$8,000.00 per share, which included the exercise in full by the underwriters of their option to purchase up to 900,000 additional shares of common stock. We received net proceeds of approximately \$53.4 million, after deducting underwriting discounts, commissions and estimated offering related transaction costs. We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our drug candidates.

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

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

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

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

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

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

As of December 31, 2019, we had approximately \$126 million of federal net operating loss carryforwards, of which \$63 million will begin to expire in 2024, if not utilized, and the remaining \$63 million of which can be carried forward indefinitely. Tax loss carryforwards that were created prior to December 31, 2017 expire through 2037, all tax loss carryforwards created after that date do not expire. In the United States, utilization of the net operating loss carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state provisions due to ownership change limitations that have occurred previously or that could occur in the future. The merger with Private Molecular (the “Merger”) resulted in an ownership change under Section 382 of the Code for us, and our pre-Merger NOL carryforwards and certain other tax attributes will be subject to limitation or elimination. The NOL carryforwards and certain other tax attributes of ours may also be subject to limitations as a result of ownership changes. If we were to lose the benefits of these loss carryforwards, our future earnings and cash resources would be materially and adversely affected. We have incurred net losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our NOLs.

We have identified a material weakness in our internal control over financial reporting, and if we are unable to remediate such material weakness and to maintain effective internal control over financial reporting in the future, there could be an elevated possibility of a material misstatement, and such a misstatement could cause investors to lose confidence in our financial statements, which could have a material adverse effect on our stock price.

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

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

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

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

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

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

We have never generated any revenue from product sales and may 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 collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize one or more of our drug candidates. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

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

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

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

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

To the extent that we raise additional capital through the sale of equity, convertible debt or other securities convertible into equity, the ownership interest of our stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect rights of our stockholders. Debt financing, if available at all, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions or declaring or paying dividends. For instance, our term loan facility with Perceptive Credit Holdings II, LP limits additional indebtedness, liens, guaranties, mergers and consolidations, substantial asset sales, investments and loans, sale and leasebacks, transactions with affiliates

and fundamental changes. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our drug candidates or future revenue streams or grant licenses on terms that are not favorable to us. We cannot be assured that we will be able to obtain additional funding if and when necessary to fund our entire portfolio of drug candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any drug candidates or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially harm our business, financial condition, and results of operations. In addition, securing additional financing would require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our drug candidates.

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

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

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

Risks Related to the Development of Our Drug Candidates

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

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

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

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

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

- limited capacity of manufacturing facilities;
- contamination of drug candidates in the manufacturing process;
- natural or other disasters, including hurricanes, earthquakes, volcanoes or fires;
- labor disputes or shortages, including the effects of health emergencies or natural disasters;
- compliance with regulatory requirements;
- changes in forecasts of future demand;
- timing and actual number of production runs and production success rates and yields;
- contractual disputes with our suppliers and contract manufacturers;
- timing and outcome of product quality testing;
- power failures and/or other utility failures;
- breakdown, failure, substandard performance or improper installation or operation of equipment;
- following New Drug Application, or NDA, or Biologics License Application, or BLA, approval, a change in the manufacturing site could require additional approval from the U.S. Food and Drug Administration, or the FDA. This approval would require new testing and compliance inspections;
- we may be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any; and
- as a drug candidate manufacturer, we are subject to ongoing periodic unannounced inspection by the FDA and some state agencies to ensure strict compliance with cGMPs and other U.S. and corresponding foreign requirements, and we carry the risk of non-compliance with these regulations and standards.

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

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

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

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

- inability to generate satisfactory preclinical, toxicology or other in vivo or in vitro data or to develop diagnostics capable of supporting the initiation or continuation of clinical trials;
- delays in reaching agreement on acceptable terms with clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;

- delays or failure in obtaining required institutional review board, or IRB, approval at each clinical trial site;
- failure to obtain or delays in obtaining a permit from regulatory authorities to conduct a clinical trial;
- delays in recruiting or failure to recruit sufficient eligible volunteers or patients in our clinical trials;
- failure by clinical trial sites or CROs or other third parties to adhere to clinical trial requirements;
- failure by our clinical trial sites, CROs or other third parties to perform in accordance with the good clinical practices requirements of the FDA or applicable foreign regulatory guidelines;
- subjects or patients withdrawing from our clinical trials;
- adverse events or other issues of concern significant enough for the FDA, or comparable foreign regulatory authority, to put a clinical trial or an IND on clinical hold;
- occurrence of adverse events associated with our drug candidates;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of our drug candidates;
- negative or inconclusive results from our clinical trials which may result in us deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in other ongoing or planned indications for a drug candidate; and
- delays in reaching agreement on acceptable terms with third-party manufacturers or an inability to manufacture sufficient quantities of our drug candidates for use in clinical trials.

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

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

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

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

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

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

We have concentrated our research and development efforts to date on a limited number of drug candidates based on our ETB therapeutic platform and identifying our initial targeted disease indications. We have invested substantially all of our efforts and financial resources to identify, acquire and develop our portfolio of drug candidates. Our future success is dependent on our ability to successfully further develop, obtain regulatory approval for, and commercialize one or more drug candidates. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a drug candidate. We currently have one ETB drug candidate, MT-3724, with three active clinical trials: one study is a phase I/II monotherapy study and two studies are phase IIa combination studies. A second ETB drug candidate, MT-5111, has one Phase I study, which was initiated in the third quarter of 2019. Our CD38 SLT-A fusion protein, TAK-169, developed in collaboration with Takeda, has one Phase I study, which was initiated in the fourth quarter of 2019, and the remainder of our drug candidates are in preclinical development. MT-3724 has been administered in patients with non-Hodgkin's lymphoma. This is only one of the multiple indications for which we plan to develop this drug candidate. There can be no assurance that we will not experience problems or delays in developing our drug candidates and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved. Additionally, our clinical and preclinical data to date are not validated and we have no way of knowing if after validation our clinical trial data will be complete and consistent. There can be no assurance that the data that we develop for our drug candidates in our planned indications will be sufficient to obtain regulatory approval.

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

Additionally, the FDA and comparable foreign regulatory authorities have relatively limited experience with ETB products. No regulatory authority has granted approval to any person or entity, including us, to market or commercialize ETB drug candidates, which may increase the complexity, uncertainty and length of the regulatory approval process for our drug candidates. If our ETB drug candidates fail to prove to be safe, effective or commercially viable, our drug 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 drug candidate, vary substantially according to the type, complexity, novelty and intended use and market of the drug candidate. The regulatory approval process for novel drug candidates such as ETB drug candidates could be more expensive and take longer than for other, better known or more extensively studied drug candidates. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our drug candidates in either the United States or the European Union or elsewhere or how long it will take to commercialize our drug candidates, even if approved for marketing. Approvals by the EMA and other regulatory authorities may not be indicative of what the FDA may require for approval, and vice versa, and different or additional preclinical studies and clinical trials may be required to support regulatory approval in each respective jurisdiction. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a drug candidate to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects may be harmed.

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

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

The eligibility criteria of our planned clinical trials may further limit the available eligible trial participants as we require that patients have specific characteristics that we can measure or meet the criteria to assure their conditions are appropriate for inclusion in our clinical trials. For instance, the estimated incidence of non-Hodgkin's lymphoma in the United States is 74,200 new cases and approximately 19,970 deaths were attributable to non-Hodgkin's B-cell lymphomas in 2019. Patients must be diagnosed with relapsed or refractory B cell non-Hodgkin lymphoma to be considered as an eligible trial participant for our Phase II combination study of MT-3724 with GEMOX. We may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical trials in a timely manner because of the perceived risks and benefits of the drug candidate under study, the availability and efficacy of competing therapies and clinical trials, and the willingness of physicians to participate in our planned clinical trials. If patients are unwilling to participate in our clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of our drug candidates may be delayed.

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

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

Undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay, or terminate clinical trials or result in a restrictive label or delay regulatory approval. In addition, our MT-3724 drug 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 event was anemia, diarrhea, nausea, stomatitis, asthenia, fatigue, peripheral edema, pyrexia, pneumonia, hypoalbuminemia, hypokalemia, arthralgia, myalgia, headache, insomnia, cough, dyspnea, rash or hypotension.

In addition to the side effects that are known to be associated with MT-3724, continued clinical trials could reveal higher incidence of side effects, or AEs, previously unknown side effects, and side effects with greater severity, which could each or all lead to delays in our clinical programs or discontinuation of our trials. There is no guarantee that additional or more severe side effects will not be identified through ongoing clinical trials of our drug candidates for current and other indications. Undesirable side effects and negative results for any of our drug candidates may negatively impact the development and potential for approval of our drug candidates for their proposed indications.

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

- regulatory authorities may withdraw approvals of such products;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategies, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we may be required to change the way such drug candidates are distributed or administered, or change the labeling of the drug candidates;
- we may be subject to regulatory investigations and government enforcement actions;

- the FDA or a comparable foreign regulatory authority may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the product;
- we may decide to recall such drug candidates from the marketplace after they are approved;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

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

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

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Clinical trials may produce negative or inconclusive results, and we or any future collaboration partners may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our drug candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of larger, later-stage controlled clinical trials. Drug candidates that have shown promising results in early-stage clinical trials may still suffer significant setbacks or failure in subsequent clinical trials. Our clinical trials to date have been conducted on a small number of patients in limited numbers of clinical trial sites for a limited number of indications. We will have to conduct larger, well-controlled trials in our proposed indications to verify the results obtained to date and to support any regulatory submissions for further clinical development. A number of companies in the biopharmaceutical industry have suffered significant setbacks or failure in advanced clinical trials due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical trials. In particular, no ETB-based drug candidates have been approved or commercialized in any jurisdiction, and the outcome of our preclinical studies and early-stage clinical trials may not be predictive of the success of later-stage clinical trials.

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

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

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

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

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

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

Although we have product liability insurance covering our clinical trials in the United States for up to \$7.0 million per occurrence up to an aggregate limit of \$7.0 million, our insurance may be insufficient to reimburse us for any expenses or losses we may suffer. We also will likely be required to increase our product liability insurance coverage for the advanced clinical trials that we plan to initiate. If we obtain marketing approval for any of our drug candidates, we will need to expand our insurance coverage to include the sale of commercial products. There is no way to know if we will be able to continue to obtain product liability coverage and obtain expanded coverage if we require it, in sufficient amounts to protect us against losses due to liability, on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. Where we have provided indemnities in favor of third parties under our agreements with them, there is also a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that one of our drug candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and breach of warranties. Claims also could be asserted under state consumer protection acts. Any product liability claim brought against us, with or without merit, could result in:

- withdrawal of clinical trial volunteers, investigators, patients or trial sites or limitations on approved indications;
- the inability to commercialize, or if commercialized, decreased demand for, our drug candidates;
- if commercialized, product recalls, withdrawals of labeling, marketing or promotional restrictions or the need for product modification;
- initiation of investigations by regulators;
- loss of revenues;
- substantial costs of litigation, including monetary awards to patients or other claimants;
- liabilities that substantially exceed our product liability insurance, which we would then be required to pay;
- an increase in our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, if at all;
- the diversion of management's attention from our business; and
- damage to our reputation and the reputation of our products and our technology.

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

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

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

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

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

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

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

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

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

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

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

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

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our drug candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug 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 drug 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 drug candidates, but we might not receive such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.

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

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

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

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

Any regulatory approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the drug 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 drug candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit for our products. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval.

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

In addition, later discovery of previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or failure to comply with applicable regulatory requirements may result in a variety of risks. For example, a regulatory agency or enforcement authority may, among other things:

- impose restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- impose requirements to conduct post-marketing studies or clinical trials;
- issue warning or untitled letters if the regulator is the FDA, or comparable notice of violations from foreign regulatory authorities;
- issue consent decrees, injunctions or impose civil or criminal penalties;
- require the payment of fines, restitution or disgorgement of profits or revenues;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our CMOs' facilities; or
- require product seizure or detention, recalls or refuse to permit the import or export of products.

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

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

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

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

- the adequacy of supply of our drug candidates;
- the timing of any such marketing approval in relation to other product approvals;
- any restrictions on concomitant use of other medications;
- support from patient advocacy groups; and
- the effectiveness of sales, marketing and distribution efforts by us and our licensees and distributors, if any.

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

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

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, or the ACA, was passed. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

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

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

In addition, the Drug Supply Chain Security Act enacted in 2013 imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing, and that law is expected to be fully implemented over a ten-year period. Most recently, on December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94) that includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 or the "CREATES Act." The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. The CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on

“commercially reasonable, market-based terms.” Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown. Other legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our drug candidates, may be or whether such changes will have any other impacts on our business. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase order or recommendation of a good or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the U.S. False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; actions may be brought by the government or a whistleblower and may include an assertion that a claim for payment by federal health care programs for items and services which results from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, that imposes criminal and civil liability for executing a scheme to defraud any health care benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- analogous state and foreign laws and regulations relating to health care fraud and abuse, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers;

- the federal physician payment transparency requirements, sometimes referred to as the “Sunshine Act,” enacted as part of the ACA, which requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to CMS information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals (and, beginning in 2021, for transfers of value to other health care providers), as well as the ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;
- analogous state and foreign laws that require pharmaceutical companies to track, report and disclose to the government and/or the public information related to payments, gifts, and other transfers of value or remuneration to physicians and other health care providers, marketing activities or expenditures, or product pricing or transparency information, or that require pharmaceutical companies to implement compliance programs that meet certain standards or to restrict or limit interactions between pharmaceutical manufacturers and members of the health care industry;
- the U.S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal health care programs;
- HIPAA, which imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- state and foreign laws that govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws and regulations will involve substantial costs. If the FDA or a comparable foreign regulatory authority approves any of our drug candidates, we will be subject to an expanded number of these laws and regulations and will need to expend resources to develop and implement policies and processes to promote ongoing compliance. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations, resulting in government enforcement actions. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

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

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

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

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

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

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

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

During the course of our development of our lead drug candidate, we have been funded in significant part through state grants, including but not limited to the substantial funding we have received from the Cancer Prevention & Research Institute of Texas, or CPRIT. We entered our first CPRIT award grant contract, or the 2011 CPRIT Agreement, on December 1, 2011. On September 18, 2018, we entered into a second CPRIT award grant contract for our CD38 targeted ETB program, or the 2018 CPRIT CD38 Agreement, which was extended in November 2019. In addition to the funding we have received to date, we have applied and intend to continue to apply for federal and state grants to receive additional funding in the future, which may or may not be successful. Contracts and grants funded by the U.S. government, state governments and their related agencies, including our contracts with the State of Texas pertaining to funds we have already received, include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

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

In addition to those powers set forth above, the government funding we may receive could also impose requirements to make payments based upon sales of our products in the future. For example, under the terms of our 2018 CPRIT CD38 Agreement, we are required to pay CPRIT a percentage of our revenues from sales of products directly funded by CPRIT, or received from our licensees or sub licensees, at a percentage in the low to mid-single digits until the aggregate amount of such payments equals 400% of the funds we receive from CPRIT, and thereafter at a rate of one-half percent.

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

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

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

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

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

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of our drug 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 drug candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business rely, which could negatively impact our business.

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologic products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, including from December 22, 2018 through January 25, 2019, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Intellectual Property

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

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

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

Intellectual property rights have limitations and do not necessarily address all potential threats to our competitive advantage. Our ability to obtain patent protection for our proprietary technologies, drug 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 licensors or collaboration partners may not have been the first to file patent applications covering our ETB technology, drug candidates, compositions or their uses;
- others may independently develop identical, similar or alternative methods, products, drug candidates or compositions and uses thereof;
- we or our current or future licensors or collaboration partners' disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our or our current or future licensors or collaboration partners' pending patent applications may not result in issued patents;
- we or our current or future licensors or collaboration partners may not seek or obtain patent protection in countries that may eventually provide us with a significant business opportunity;
- any patents issued to us or our current or future licensors or collaboration partners may not provide a basis for commercially viable products, may not provide any competitive advantages or may be successfully challenged by third parties;
- we or our current or future licensors or collaboration partners' products, drug candidates, compositions, methods or uses thereof may not be patentable;
- others may design around our or our current or future licensors or 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 licensors or collaboration partners' patents;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we or our current or future licensors or collaboration partners do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in major commercial markets; or
- we or our current or future licensors or collaboration partners may not develop additional proprietary technologies or products that are patentable.

Further, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsettled. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our or our competitors' drug candidates or their uses in the United States or in other countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our drug 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 drug candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our collaboration partners, have filed several patent applications covering various aspects of our ETB technology, drug 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 drug candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a drug 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 drug 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 drug 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 resources, efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

Patent term extensions under the Hatch-Waxman Act in the United States, and regulatory extensions in Japan and certain other countries, and under Supplementary Protection Certificates in Europe, may be available to extend the patent or market or data exclusivity terms of our drug candidates depending on the timing and duration of the regulatory review process relative to patent term. In addition, upon issuance of a United States patent, any patent term may be adjusted based on specified delays during patent prosecution caused by the applicant(s) or the United States Patent and Trademark Office, or the USPTO. Although we will likely seek patent term extensions in the U.S. and in one or more foreign jurisdictions where available, we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our drug 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 drug 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 benefit or priority of a patent application filed before March 16, 2013, there is a greater level of uncertainty in the patent law. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO has promulgated regulations and developed procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first inventor to file a provisional patent application, did not come into effect until March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition or results of operations.

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

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

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

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

Even if our or our current or future collaboration partners' patents do successfully issue and even if such patents cover our drug candidates and methods of use, third parties may initiate interference, re-examination, post-grant review, IPR or derivation actions in the USPTO; may initiate third party oppositions in the European Patent Office, or EPO; or may initiate similar actions challenging the validity, enforceability or scope of such patents in other patent administrative proceedings worldwide, which may result in patent claims being narrowed or invalidated. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover competitive technologies, drug candidates or methods of use. Further, if we initiate legal proceedings against a third party to enforce a patent covering our technologies, drug 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 novelty, nonobviousness (or inventive step), clarity, adequate written description and 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 or unenforceability are unpredictable. With respect to patent claim validity, for example, we cannot be certain that there is no invalidating prior art, of which we or the patent examiner was unaware during prosecution. Further, we cannot be certain that all of the potentially relevant art relating to our patents and patent applications has been brought to the attention of every patent office. If a defendant or other patent challenger were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least in part, and perhaps all, of the patent protection on our ETB technology, drug 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 collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that the patent covering our drug candidate is invalid and/or unenforceable. In addition, a third party might initiate legal proceedings against us alleging that our patent covering one or more of our drug candidates is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, nonobviousness, adequate written description, clarity or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

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

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

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

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

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

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

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

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

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

There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding foreign patent offices. Third parties own numerous U.S. and foreign issued patents and pending patent applications in the fields in which we are developing drug candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may be subject to claims of infringement of the patent rights of third parties. Parties making patent infringement claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our drug candidates. Defense of these claims, regardless of their merit, may involve substantial litigation expense and may require a substantial diversion of employee resources from our business. In the event of a successful claim of patent infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Further, if we were to seek a license from the third-party holder of any applicable intellectual property rights, we may not be able to obtain the applicable license rights when needed or on reasonable terms, or at all. Some of our competitors may be able to sustain the costs of complex patent litigation or proceeding more effectively than us due to their substantially greater resources. The occurrence of any of the above events could prevent us from continuing to develop and commercialize one or more of our drug candidates and our business could materially suffer.

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

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

For example, we have previously 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 us, and vice versa. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

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

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

While we normally seek to gain the right to fully prosecute the patent applications relating to our drug candidates, there may be times when certain patents or patent applications relating to our drug candidates, their uses or their manufacture may be controlled by our collaboration partners. If any of our collaboration partners fail to appropriately or broadly prosecute patent applications and maintain patent protection of claims covering any of our drug candidates, their uses or their manufacture, our ability to develop and commercialize those drug 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, presently or in the future, we may still be adversely affected or prejudiced by actions or inactions of our licensors in effect from actions prior to us assuming control over patent prosecution.

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

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

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

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

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

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

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

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

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

Risks Related to Our Reliance on Third Parties

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

We have relied upon and plan to continue to rely upon third-party CROs to conduct, monitor and manage our ongoing clinical programs. We rely on these parties for execution of clinical trials and we manage and control only some aspects of their activities. We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with all applicable laws, regulations and guidelines, including those required by the FDA and comparable foreign regulatory authorities for all of our drug 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 drug candidates. CROs also may involve higher costs than anticipated, which could negatively affect our financial condition and operations.

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

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

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

- we may be unable to identify manufacturers to manufacture our drug candidates on acceptable terms or at all, because the number of qualified potential manufacturers is limited. Following BLA approval, a change in the manufacturing site could require additional approval from the FDA. This approval would require new testing and compliance inspections;
- our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- our future third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our drug candidates;
- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMPs and other government regulations and corresponding foreign standards, and we do not have control over third-party manufacturers' compliance with these regulations and standards;
- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates; and
- our third-party manufacturers could breach or terminate their agreements with us.

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

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

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

Under the License Agreement, we granted Takeda an exclusive license to co-develop one or more licensed products, meaning any product that incorporates or is comprised of one or more of the CD38 SLT-A fusion proteins, up to and including Phase Ia clinical trials, and thereafter we would have an option to continue to co-develop the licensed products. We exercised our co-development option in July 2019 and may elect to end our co-development by providing Takeda with written notice of termination of the co-development. In the event we elect to end the co-development, we will be subject to reduced payments and royalty rates as set forth more specifically in the License Agreement.

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

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

Takeda may elect to terminate the License Agreement for convenience upon 90 days prior written notice. Takeda also maintains the right to terminate the License Agreement in connection with our material breach and our insolvency. Takeda reserves certain rights, such as to undertake any not yet completed early stage program activities to be conducted by us, solely and exclusively, upon any change in control of us. If Takeda terminates the License Agreement, it will result in a delay in or could prevent us from further developing or commercializing the CD38 SLT-A fusion proteins, and will delay and could prevent us from obtaining revenues for this drug 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 have entered into a Master Collaboration Agreement (“Vertex Collaboration Agreement”) with Vertex Pharmaceuticals Incorporated (“Vertex”) and, pursuant to the terms of that agreement, could become dependent on Vertex for development, manufacturing, regulatory and commercialization activities with respect to certain of our ETB products for novel targeted biologic therapies.

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

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

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

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

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

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

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

- collaboration partners often have significant discretion in determining the efforts and resources that they will apply to the collaboration, and may not commit sufficient resources to the development, marketing or commercialization of the product or products that are subject to the collaboration;
- collaboration partners may not perform their obligations as expected or may breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner;

- any such collaboration may significantly limit our share of potential future profits from the associated program, and may require us to relinquish potentially valuable rights to our current drug candidates, potential products or proprietary technologies or grant licenses on terms that are not favorable to us;
- collaboration partners may cease to devote resources to the development or commercialization of our drug candidates if the collaboration partners view our drug candidates as competitive with their own products or drug candidates;
- disagreements with collaboration partners, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of drug candidates, and might result in legal proceedings, which would be time consuming, distracting and expensive;
- collaboration partners may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from the collaboration;
- collaboration partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- the collaborations may not result in us achieving revenues sufficient to justify such transactions;
- by entering into certain collaborations, we may forego opportunities to collaborate with other third parties who do not wish to be associated with our existing third-party strategic partners; and
- collaborations may be terminated and, if terminated, may result in a need for us to raise additional capital to pursue further development or commercialization of the applicable drug candidate.

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

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

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

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

Risks Related to Commercialization of Our Drug Candidates

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

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

If commercialization collaboration partners do not commit sufficient resources to commercialize our future drugs 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 drug candidates are intended to address. Without appropriate capabilities, whether directly or through third-party collaboration partners, we may be unable to compete successfully against these more established companies.

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

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

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

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

Our estimates for the addressable patient population and our estimates for the prices we can charge for our drug candidates may differ significantly from the actual market addressable by our drug 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 74,200 new cases and approximately 19,970 deaths were attributable to the disease in the United States in 2019, only a subset of which may benefit from treatment with MT-3724. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, while we believe that the data in our Phase II clinical trials for MT-3724 will be supportive of application to other indications, there can be no assurance that our clinical trials will successfully address any additional indications. Similarly, the potentially addressable patient population for each of our drug candidates may be limited or may not be amenable to treatment with our drug candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our business, financial condition, results of operations and prospects.

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

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

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

If our competitors obtain marketing approval from the FDA or comparable foreign regulatory authorities for their drug 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 drugs to compete with these products. Failure of MT-3724 or other drug candidates to effectively compete against established treatment options or in the future with new products currently in development would harm our business, financial condition, results of operations and prospects.

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

Even with the approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our drugs will depend in part on the health care providers, patients and third-party payors accepting our drug 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 drugs will depend on a number of factors, including but not limited to:

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Ownership of Our Common Stock

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

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

- our ability to obtain regulatory approvals for MT-3724 or other drug candidates, and delays or failures to obtain such approvals;
- failure of any of our drug candidates, if approved, to achieve commercial success;
- failure to maintain our existing third-party license and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our drug candidates;
- any inability to obtain adequate supply of our drug candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;

- failure by securities or industry analysts to publish research or reports about our business, or issuance of any adverse or misleading opinions by such analysts regarding our business or stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- the trading volume of our common stock;
- the issuance of additional shares of our preferred stock or common stock, or the perception that such issuances may occur, including through our “at-the-market” offering program or any sales of our preferred stock or common stock by our stockholders in the future;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to ETB drugs generally, including with respect to other drugs and potential drugs in such markets;
- the introduction of technological innovations or new therapies that compete with our potential drugs;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

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

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

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of December 31, 2019, a total of 45,589,157 shares of our common stock were outstanding. Any sales of those shares or any perception in the market that such sales may occur could cause the trading price of our common stock to decline.

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

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

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

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

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

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

We have broad discretion over the use of our cash reserves, including the proceeds from our previous financings, including from the sale of shares of common stock under the Sales Agreement and from our public offering in November 2019. Our stockholders may not agree with our decisions, and our use of these funds may not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could compromise our ability to pursue our growth strategy, result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our drug candidates. Pending their use, we may invest our cash reserves in a manner that does not produce income or that loses value. It is possible that the proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure by our management to apply these funds effectively could have an adverse effect on our financial condition, results of operations or the trading price of our common stock.

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

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

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

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

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

- authorizing our board of directors to issue “blank check” preferred stock without any need for approval by stockholders;
- providing for a classified board of directors with staggered three-year terms;
- requiring supermajority stockholder votes to effect certain amendments to our amended and restated certificate of incorporation and amended and restated bylaws;

- eliminating the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

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

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

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

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

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

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

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

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

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

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

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

As of December 31, 2019, our directors, executive officers, and stockholders beneficially owning 5% or more of our shares or that may be affiliated with our board members, beneficially owned, in the aggregate, approximately 50% of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence almost all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

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

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

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

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

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

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

Risks Related to Our Business Operations

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

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

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

At December 31, 2019, we had 151 full-time employees and 17 part-time and temporary employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert its attention away from its day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional drug candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected or budgeted, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our currently anticipated business strategy. Our future financial performance and our ability to commercialize drug candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth. Failure to manage this growth could disrupt our business operations and negatively impact our ability to achieve success.

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

Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our information technology, or IT, systems. In the ordinary course of our business, we collect and store sensitive data, including personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and we also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. These applications and data encompass a wide variety of business-critical information including research and development information and business and financial information.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy. Despite the implementation of security measures, our IT systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, cyber-attacks, computer viruses, breaches, unauthorized access, interruptions due to employee error or malfeasance or other disruptions, or damage from natural disasters, terrorism, war and telecommunication and electrical failures. Moreover, despite network security and back-up measures, some of our and our vendors' servers are potentially vulnerable to physical or electronic break-ins, including cyber-attacks, computer viruses and similar disruptive problems. These events could lead to the unauthorized access, disclosure and use of non-public information including our intellectual property or proprietary business information.

The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated or remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. There can be no assurance that we will promptly detect any such disruption or security breach, if at all. If our computer systems are compromised, we could be subject to fines, damages, reputational harm, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business, in addition to possibly requiring substantial expenditures of resources to remedy. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. In addition, the loss of data from clinical trials for our drug 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, Molecular entered into a facility lease agreement for approximately 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 approximately 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 approximately 11,000 square feet of office and laboratory space. In June 2017, Molecular entered into a third amendment to the lease to set the Lease Commencement Date as such term is defined therein and provided that 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.

In January 2019, the Company entered into a sublease agreement for an additional 57,000 square feet of administrative office and R&D space in Austin, Texas. The sublease commenced March 2019, expires August 2028 and does not contain an option to renew.

We also lease one property for use as office space of approximately 10,000 square feet in Jersey City, New Jersey under a lease, as amended, expiring in January 2023. The lease has an option to renew for one additional five-year period at our discretion.

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 predicted with certainty, as of the date of this report, we do not believe we are party to any claim, proceeding or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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 45,647,884 holders of record of our common stock as of March 12, 2020. On March 12, 2020, the last reported sales price per share of our common stock was \$11.40 per share.

Unregistered Sales of Equity Securities

In connection with the Collaboration Agreement with Vertex the company entered into a share purchase agreement pursuant to which Vertex agreed to purchase 1,666,666 shares of Company's common stock, par value \$0.001 per share, at a price per share of \$9.00 for aggregate proceeds of \$14,999,994. The issuance of these shares was pursuant to a private placement exemption from registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D thereunder. We plan to use the proceeds from the sale of these shares to fund our ongoing clinical studies and for working capital and other general corporate purposes.

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

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

Business

ETBs use a genetically engineered version of the SLTA. In its wild-type form, SLT is thought to induce its own entry into a cell when proximal to the cell surface membrane, self-route to the cytosol, and enzymatically and irreversibly shut down protein synthesis via ribosome inactivation. SLTA is normally coupled to its cognate Shiga-like Toxin B subunit, or SLTB, to target the CD77 cell surface marker, a non-internalizing glycosphingolipid. In our scaffold, a genetically engineered SLTA subunit with no cognate SLTB component is genetically fused to antibody domains or fragments specific to a target, resulting in a biologic therapeutic that can identify the particular target and specifically kill the cell. The antibody domains may be substituted with other antibody domains having different specificities to allow for the rapid development of new drugs to selected targets in cancer and other serious diseases.

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

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

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

Our lead compound, MT-3724, is an ETB that recognizes CD20, a B cell marker and is currently in multiple Phase II studies. The dose escalation portion of its first Phase I clinical trial has been completed for MT-3724 and was followed by the initiation of a Phase Ib expansion cohort, which was initiated in the fourth quarter of 2017. Results of the Phase I/Ib study were presented at the American Society of Hematology (ASH) Annual Meeting, December 7-10, 2019 in Orlando, FL. Of the 13 serum rituximab negative (RTX-neg) DLBCL or mixed DLBCL/FL subjects, 5 responded (38% objective response rate) across the range of 5 to 100 µg/kg doses. Of the 5 responses, 2 were complete responses (CRs) and 3 were partial responses (PRs). Three patients had stable disease (including 2 patients with 49% and 47% tumor reductions) and 5 patients had progressive disease. Of the 5 serum RTX-neg subjects with DLBCL who received MT-3724 at 50 µg/kg, the maximum tolerated dose (MTD), 3 responded (2 CRs, 1 PR).

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

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

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

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

Collaboration Agreements

Takeda Pharmaceuticals

Takeda Collaboration and Individual Project Agreements

In October 2016, we entered into a collaboration and option agreement (the “Takeda Collaboration Agreement”) with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Ltd. (“Takeda”) to discover and develop CD38-targeting ETBs, which includes MT-4019 for evaluation by Takeda. Under the terms of the agreement, we are responsible for providing to Takeda (i) new ETBs generated using Takeda’s proprietary antibodies targeting CD38 and (ii) MT-4019 for *in vitro* and *in vivo* pharmacological and anti-tumor efficacy evaluations. We granted Takeda an exclusive option to negotiate and obtain an exclusive worldwide license to develop and commercialize any ETB that 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 Takeda Collaboration Agreement. To date, we have received the \$2.0 million under this Takeda Collaboration Agreement.

In connection with the Takeda Collaboration Agreement, we entered into an Individual Project Agreement (the “Takeda Individual Project Agreement”) with Takeda in June 2018 that was 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 were entitled to receive up to \$2.2 million in compensation. To date we have received the \$2.2 million under the Takeda Individual Project Agreement.

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. 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, with the exercise of our co-development option and funding of 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 \$325.0 million in milestone payments upon the achievement of certain sales milestone events. If we do not continue our co-development option, we may receive up to an additional \$162.5 million in milestone payments upon the achievement of certain development and regulatory milestone events and up to an additional \$175.0 million in milestone payments upon the achievement of certain sales milestone events. We will also be entitled to receive tiered royalties, subject to certain reductions, as percentages of annual aggregate net sales, if any, of Licensed Products. The royalty percentages would range from low double-digits to low twenties if we exercise our option to co-develop, and from high-single digits to low teens if we do not exercise its option to co-develop.

In July 2019, we exercised our co-development option and the agreed upon collaboration budget was increased to cover additional research and development activities whereby both parties will continue to cost share. The parties will share in co-development costs in accordance with the terms of the 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 \$2.0 million following the designation of each of the two targets in December 2017. As of December 31, 2019, 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.

Vertex Pharmaceuticals

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

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

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

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

For more information concerning our collaboration agreements, refer to Note 3, “Research and Development Agreements” to our audited consolidated financial statements for the years ended December 31, 2019, included in this Annual Report on Form 10-K.

Grant Agreements

CPRIT Grant Contract

In September 2018, we entered into a Cancer Research Grant Contract (the “CD38 CPRIT Agreement”) with CPRIT, which was extended in November 2019, in connection with a grant of approximately \$15.2 million awarded by CPRIT to us in November 2016 to fund research of a cancer therapy involving an ETB that is targeting CD38 (the “Award”). Pursuant to the CD38 CPRIT Agreement, we 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 CD38 CPRIT Agreement and subject to CPRIT’s ability to perform its obligations under the CD38 CPRIT Agreement as well as our progress towards achievement of specified milestones, among other contractual requirements.

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

Subject to the terms of the CD38 CPRIT Agreement, full ownership of any CPRIT funded technology and CPRIT funded intellectual property rights developed pursuant to the CD38 CPRIT Agreement will be retained by us, our Collaborators (as defined in the CD38 CPRIT Agreement) and, to the extent applicable, any participating third party (the “Project Results”). With respect to any Project Results, we agreed to grant to CPRIT a nonexclusive, irrevocable, royalty-free, perpetual, worldwide license, solely for academic, research and other non-commercial purposes, under the Project Results and to exploit any necessary additional intellectual property rights, subject to certain exclusions.

We will pay to CPRIT, during the term of the CD38 CPRIT Agreement, certain payments equal to a percentage of revenue ranging from the low- to mid-single digits. These payments will continue up to and until CPRIT receives an aggregate amount of 400% of the sum of all monies paid to us by CPRIT under the CD38 CPRIT Agreement. If we are required to obtain a license from a third party to sell any such product, the revenue sharing percentages may be reduced. In addition, once we pay CPRIT 400% of the monies we have received under the CD38 CPRIT Agreement, we will continue to pay CPRIT a revenue-sharing percentage of 0.5%.

The CD38 CPRIT Agreement will terminate, with certain obligations extending beyond termination, on the earlier of (a) November 30, 2019 or (b) the occurrence of any of the following events: (i) by mutual written consent of the parties, (ii) by CPRIT for an Event of Default (as defined in the CD38 CPRIT Agreement) by us, (iii) by CPRIT if allocated funds should become legally unavailable during the term of the CD38 CPRIT Agreement and CPRIT is unable to obtain additional funds or (iv) by us for convenience. CPRIT may approve a no cost extension for the CD38 CPRIT Agreement for a period not to exceed six months after the termination date if additional time is required to ensure adequate completion of the approved project, subject to the terms and conditions of the CD38 CPRIT Agreement.

For more information about our grant agreements, please see Note 3, “Research and Development Agreements” to our audited consolidated financial statements for the years ended December 31, 2019, included in this Annual Report on Form 10-K.

Financial Operations Overview

Revenue

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

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

Grant revenue relates to our CPRIT grants for a CD20 ETB (MT-3724) and a CD38 ETB (TAK-169). CPRIT grant funds for MT-3724 are provided to us in advance as conditional cost reimbursement where revenue is recognized as allowable costs are incurred. Amounts collected in excess of revenue recognized are recorded as deferred revenue. CPRIT grant funds for TAK-169 are provided to us in arrears as cost reimbursement where revenue is recognized as allowable costs are incurred. Revenue recognized in excess of amounts collected are recorded as unbilled revenue.

For more information about our revenue recognition policy, please see Note 1, “Organization and Summary of Significant Accounting Policies” to our audited consolidated financial statements for the years ended December 31, 2019, included in this Annual Report on Form 10-K.

Research and Development Expenses

Research and development expenses consist principally of:

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

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

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

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

General and Administrative Expenses

Our general and administrative expenses consist principally of:

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

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

Other Income (Expense)

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

Change in fair value of warrant liability

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

Results of Operations

Revenues

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

| | Year Ended December 31, | | | |
|---|--------------------------------|------------------|--------------------|-------------------|
| | 2019 | 2018 | Change (\$) | Change (%) |
| Research and development revenue - from related party | \$ 19,499 | \$ 7,087 | \$ 12,412 | 175% |
| Research and development revenue - other | — | 196 | (196) | -100% |
| Grant revenue | 2,771 | 6,002 | (3,231) | -54% |
| Total revenue | <u>\$ 22,270</u> | <u>\$ 13,285</u> | <u>\$ 8,985</u> | <u>68%</u> |

Research and Development Revenue – from related party

The increase in research and development revenue – from related party for the year ended December 31, 2019 was primarily due to research and development revenues that were recognized from the services provided under the Takeda Development and License Agreement (TAK-169) which was entered into in September 2018.

For more information about our collaboration agreements, please see Note 3 “Research and Development Agreements” to our audited consolidated financial statements for the year ended December 31, 2019, included in this Annual Report on Form 10-K.

Research and Development Revenue – other

For more information about our collaboration agreements, please see Note 3 “Research and Development Agreements” to our audited consolidated financial statements for the year ended December 31, 2019, included in this Annual Report on Form 10-K.

Grant Revenue

The decrease in grant revenue for the year ended December 31, 2019 was primarily due to the Company incurring significantly less expenses for the CD38 CPRIT Agreement grant during the year and cost decrease relating to the wind down of the CD20 grant. Additionally, the year ended December 31, 2018 included a true-up adjustment for the CD38 CPRIT Agreement grant.

Operating Expenses

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

| | Year Ended December 31, | | | |
|---|-------------------------|------------------|------------------|-------------|
| | 2019 | 2018 | Change (\$) | Change (%) |
| Research and development expenses | \$ 50,519 | \$ 30,202 | \$ 20,317 | 67% |
| General and administrative expenses | 20,077 | 14,082 | 5,995 | 43% |
| Loss on impairment of long-lived assets | 22,123 | — | 22,123 | 100% |
| Total operating expenses | <u>\$ 92,719</u> | <u>\$ 44,284</u> | <u>\$ 48,435</u> | <u>109%</u> |

Research and Development Expenses

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

| | Year Ended December 31, | | | |
|---|-------------------------|------------------|------------------|------------|
| | 2019 | 2018 | \$ Change | % Change |
| Program costs | \$ 25,026 | \$ 17,375 | \$ 7,651 | 44% |
| Employee compensation | 15,998 | 8,128 | 7,870 | 97% |
| Laboratory costs | 3,486 | 2,082 | 1,404 | 67% |
| Other research and development costs | 6,009 | 2,617 | 3,392 | 130% |
| Total research and development expenses | <u>\$ 50,519</u> | <u>\$ 30,202</u> | <u>\$ 20,317</u> | <u>67%</u> |

Research and development (“R&D”) expenses increased \$20.3 million during the year ended December 31, 2019 primarily due to research and development expenses related to the discovery and development of ETBs. The Company is party to multiple collaboration agreements with a related party which can also contribute to increased R&D expense, typically offset by revenue from the related party.

Program costs increased \$7.7 million during the year ended December 31, 2019 compared to the year ended December 31, 2018. The programs driving the increase were \$5.3 million for MT-3724, \$3.1 million for TAK-169, \$2.7 million for PD-L1. These increases were offset by year over year decreases of \$2.7 million for CD38-4019 and \$1.8 million for HER2.

Headcount increased in R&D 143% from December 31, 2018 to December 31, 2019 in support of increased clinical trials and ramp up of cGMP manufacturing facilities and support staff. This staffing increase resulted in an increase in employee compensation costs of \$7.9 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, respectively.

Laboratory costs increased \$1.4 million during the year ended December 31, 2019 compared to the year ended December 31, 2018. New lab facilities have been created to increase and refine the Company’s research and manufacturing capabilities. The increase in expense reflects the costs of outfitting, supplying and maintaining these facilities.

Other R&D costs increased \$3.4 million during the year ended December 31, 2019 compared to the year ended December 31, 2018, respectively. This increase was driven by partial allocation of facilities and facilities expansion charges to R&D of \$1.4 million, increased consulting and recruiting costs of \$1.0 million and \$0.5 million in depreciation.

General and Administrative Expenses

General and administrative expenses increased \$6.0 million during the year ended December 31, 2019 compared to the year ended December 31, 2018. The main driver of this increase being payroll and related costs.

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

The loss on impairment of long-lived assets relates to the impairment of in-process research and development relating to the Company's legacy program, Evofosfamide, which was acquired from Threshold Pharmaceuticals in 2017. The loss on impairment of long-lived assets is primarily due to the decrease in future projected cashflows of the in-process research and development relating to this program. The Company obtained a fair value estimate, from a third-party specialist as of August 1, 2019, and determined the asset was impaired and the value was not recoverable. During the year ended December 31, 2019, the Company recorded a related impairment of \$22.1 million. Additionally, the asset group was reclassified as held for sale as the Company plans to sell the asset within the year. Future write-downs of the asset are possible based upon the amount of proceeds from an eventual sale of the asset.

There can be no assurances whether any transaction involving Evofosfamide will result or, if any such transaction were to occur, its timing or value, or whether there may be additional future impairments regarding this legacy program. See Part II, Item 5 (Other Information) and Note 15 "In-Process Research Development" to our audited consolidated financial statements for the year ended December 31, 2019, included in this Annual Report on Form 10-K.

Nonoperating activities

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

| | Year Ended December 31, | | | |
|---|-------------------------|----------|-------------|------------|
| | 2019 | 2018 | Change (\$) | Change (%) |
| Interest and other income, net | \$ 2,323 | \$ 751 | \$ 1,572 | 209% |
| Interest and other expense, net | \$ (1,298) | \$ (990) | \$ (308) | 31% |
| Change in fair value of warrant liabilities | \$ 3 | \$ 951 | \$ (948) | -100% |

Interest and Other Income and Interest Expense

The increase in interest and other income for the year ended December 31, 2019, compared to December 31, 2018 was primarily due to the Company investing in marketable securities and cash equivalents starting at the end of the fourth quarter of 2018.

The increase in interest expense for the year ended December 31, 2019, compared to December 31, 2018 was primarily due to the increase in debt holdings to support the Phase 1 buildout of the cGMP facility that was completed in June 2018. This long-term debt matures in February 2022.

Change in fair value of warrant liability

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

Liquidity and Capital Resources

Sources of Funds

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

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

We expect to incur substantial additional losses in the future as we expand our research and development cost-sharing activities with our collaboration partners, we believe such investment is strategically aligned with increasing the value of our technology. For the year ended December 31, 2019 and 2018, we incurred net losses of \$69.4 million and \$30.3 million, respectively. At December 31, 2019, we had an accumulated deficit of \$164.1 million.

To date, we have financed our operations through public offerings of common and preferred stock, private placements of equity securities, a reverse merger, and upfront and milestone payments received from our collaboration agreements, as well as funding from governmental bodies and bank and bridge loans. From April 2014 through February 2018, we borrowed an aggregate of \$6.0 million from Silicon Valley Bank. In February 2018, we borrowed \$5.0 million through the Perceptive Credit Facility which was used to pay off the principal balance and final fee on the borrowings from Silicon Valley Bank. The Perceptive Credit Facility allows for aggregate borrowings of up to \$10.0 million, subject to our achievement of certain milestones. In September 2018, we entered into the CD38 CPRIT Agreement for a research grant related to CD38 targeting ETB of approximately \$15.2 million.

In September 2018, we completed a public offering of 9,430,000 shares of common stock at an offering price of \$5.50 per share, which included the exercise in full by the underwriters of their option to purchase up to 1,230,000 additional shares of common stock. We received net proceeds of approximately \$48.1 million, after deducting underwriting discounts, commissions and offering related transaction costs.

On December 21, 2018, we filed a universal shelf registration statement on Form S-3 (Registration No. 333-228975) with the SEC, which was automatically declared effective on February 13, 2019. In December 2018 we entered into a controlled equity offering sales agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor"), pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to \$50,000,000 from time to time through Cantor acting as our agent. Under the Sales Agreement, Cantor may sell the shares by any method permitted by law and deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act. To date, we have not sold any shares under the Sales Agreement.

In November 2019, we completed a public offering of 6,900,000 shares of common stock at an offering price of \$8.00 per share, and 250 shares of newly designated Series A Convertible Preferred Stock at an offering price of \$8,000.00 which included the exercise in full by the underwriters of their option to purchase up to 900,000 additional shares of common stock. We received net proceeds of approximately \$53.4 million, after deducting underwriting discounts and stock issuance costs.

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

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

At December 31, 2019 and December 31, 2018, we had cash, cash equivalents and marketable securities of \$126.6 million and \$98.0 million, respectively and grants revenue receivable of \$7.1 million and \$4.3 million, respectively. We expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into 2022. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect.

Cash Flows

Comparison of Years Ended December 31, 2019 and 2018

The table below summarizes our cash flows for the years ended December 31, 2019 and 2018.

| | Year Ended December 31, | | | |
|---|-------------------------|------------|-------------|----------|
| | 2019 | 2018 | \$ Change | % Change |
| Net cash used in operating activities | \$ (25,244) | \$ (4,465) | \$ (20,779) | 465% |
| Net cash used in investing activities | (39,724) | (15,945) | (23,779) | 149% |
| Net cash provided by financing activities | 65,698 | 49,221 | 16,477 | 33% |
| Net increase (decrease) in cash, cash equivalents and restricted cash | \$ 730 | \$ 28,811 | \$ (28,081) | -97% |

The increase in net cash used in operating activities for the year ended December 31, 2019 was primarily due to an increase in operating cash disbursements as result of an increase in operating activities.

The increase in net cash used in investing activities for the year ended December 31, 2019 was primarily due to increased purchases of marketable securities and the expansion of the cGMP and new R&D facilities. The R&D facility was completed in September 2019.

The increase in net cash provided by financing activities was primarily due to the proceeds from issuance of common stock of \$53.4 million through the 2019 Public Offering (defined below) and proceeds from the issuance of common stock of \$10.5 million in 2019 through the Vertex Collaboration Agreement, compared to proceeds from issuance of common stock of \$48.1 million through the 2018 Public Offering (defined below) during the year ended December 31, 2018.

Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and had an accumulated deficit of \$164.1 million at December 31, 2019. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our ETB candidates.

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

- support the ongoing Phase II monotherapy study of MT-3724, our lead ETB candidate;
- support the ongoing Phase Ib and initiate Phase II clinical trials of MT-3724;
- co-develop TAK-169 with Takeda;
- continue the research and development of our other ETB candidates, including completing pre-clinical studies and commencing clinical trials;
- research activities through the designation of the development candidate(s) with Vertex

- seek to enhance our technology platform using our antigen-seeding technology approach to immuno-oncology;
- seek regulatory approvals for any ETB candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any drugs for which we may obtain regulatory approval;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our increased operations;
- experience any delays or encounter any issues resulting from any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges,
- service long-term debt; and
- complete the expansion of the Company's cGMP facility.

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

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

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

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

Identifying potential ETB candidates and conducting pre-clinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our ETB candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs 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 from collaboration partners 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.

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 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) we satisfy each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer.

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, Collaborative Arrangements (“ASC 808”) to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards. This assessment is performed throughout the life of the arrangement based on changes to the arrangements. For collaboration arrangements within the scope of ASC 808 the Company may analogize to ASC 606 for certain elements.

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 "Organization and Summary of Significant Accounting Policies" to our audited consolidated financial statements for the year ended December 31, 2019, included in this Annual Report on Form 10-K.

Leases

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

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

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

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

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

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

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

We account for income taxes under the asset and liability method. We record deferred tax assets and liabilities for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, as well as for operating loss and tax credit carryforwards. We measure deferred tax assets and liabilities using enacted tax rates expected to apply to taxable income in the years in which we expect to recover or settle those temporary differences. We recognize the effect of a change in tax rates on deferred tax assets and liabilities in the results of operations in the period that includes the enactment date. We assess the likelihood that deferred tax assets will be realized, and we recognize a valuation allowance if it is more likely than not that some portion of the deferred tax assets will not be realized. This assessment requires judgment as to the likelihood and amounts of future taxable income by tax jurisdiction. To date, we have provided a valuation allowance against our deferred tax assets as we believe the objective and verifiable evidence of our historical pretax net losses outweighs any positive evidence of our forecasted future results. Although we believe that our tax estimates are reasonable, the ultimate tax determination involves significant judgment. We will continue to monitor the positive and negative evidence and will adjust the valuation allowance as sufficient objective positive evidence becomes available.

We account for uncertain tax positions by recognizing the financial statement effects of a tax position only when, based upon technical merits, it is more likely than not that the position will be sustained upon examination. We recognize potential accrued interest and penalties associated with unrecognized tax positions within our global operations in income tax expense.

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 “Organization and Summary of Significant Accounting Policies” to our audited financial statements for the year ended December 31, 2019, 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.

MOLECULAR TEMPLATES, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Stockholders 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, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity, 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, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 13, 2020 expressed an adverse opinion thereon.

Adoption of ASU 2016-02

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of ASU No. 2016-02, *Leases (Topic 842)*.

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 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. 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 13, 2020

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

| | December 31, | |
|---|--------------|------------|
| | 2019 | 2018 |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 85,451 | \$ 87,721 |
| Marketable securities, current | 39,633 | 10,234 |
| Prepaid expenses | 2,318 | 2,244 |
| Grant revenue receivable | 7,100 | 4,329 |
| Accounts receivable from related party | 408 | 240 |
| In-process research and development - held for sale | 4,500 | — |
| Other current assets | 489 | 95 |
| Total current assets | 139,899 | 104,863 |
| Marketable securities, non-current | 1,510 | — |
| Operating lease right-of-use assets, non-current | 9,959 | — |
| Property and equipment, net | 18,158 | 6,851 |
| In-process research and development | — | 26,623 |
| Other assets | 4,676 | 1,821 |
| Total assets | \$ 174,202 | \$ 140,158 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,465 | \$ 780 |
| Accrued liabilities | 14,544 | 5,357 |
| Deferred revenue, current | 17,291 | 26,231 |
| Other current liabilities | 2,501 | 141 |
| Total current liabilities | 35,801 | 32,509 |
| Deferred revenue, long-term | 19,385 | 2,670 |
| Long-term debt, net | 2,940 | 3,254 |
| Operating lease liabilities, non-current | 11,682 | — |
| Other liabilities | 1,366 | 819 |
| Total liabilities | 71,174 | 39,252 |
| Commitments and contingencies (Note 10) | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.001 par value: | | |
| Authorized: 2,000,000 at December 31, 2019 and 2018; Issued and outstanding: 250 and zero shares at December 31, 2019 and 2018, respectively. | — | — |
| Common stock, \$0.001 par value: | | |
| Authorized: 150,000,000 shares at December 31, 2019 and 2018; Issued and outstanding: 45,589,157 and 36,736,012 shares at December 31, 2019 and 2018, respectively. | 46 | 37 |
| Additional paid-in capital | 267,089 | 195,573 |
| Accumulated other comprehensive loss | 18 | — |
| Accumulated deficit | (164,125) | (94,704) |
| Total stockholders' equity | 103,028 | 100,906 |
| Total liabilities and stockholders' equity | \$ 174,202 | \$ 140,158 |

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, | |
|--|--------------------------|------------|
| | 2019 | 2018 |
| Research and development revenue - from related party | \$ 19,499 | \$ 7,087 |
| Research and development revenue - other | — | \$ 196 |
| Grant revenue | 2,771 | 6,002 |
| Total revenue | 22,270 | 13,285 |
| Operating expenses: | | |
| Research and development | 50,519 | 30,202 |
| General and administrative | 20,077 | 14,082 |
| Loss on impairment of in-process research and development | 22,123 | — |
| Total operating expenses | 92,719 | 44,284 |
| Loss from operations | 70,449 | 30,999 |
| Interest and other income, net | 2,323 | 751 |
| Interest and other expense, net | (1,298) | (990) |
| Change in fair value of warrant liabilities | 3 | 951 |
| Net loss attributable to common shareholders | \$ 69,421 | \$ 30,287 |
| Net loss per share attributable to common shareholders: | | |
| Basic and diluted | \$ 1.86 | \$ 1.02 |
| Weighted average number of shares used in net loss per share calculations: | | |
| Basic and diluted | 37,770,378 | 29,601,692 |
| Other comprehensive loss: | | |
| Unrealized gain (loss) on available-for-sale securities | 18 | — |
| Comprehensive loss | \$ 69,403 | \$ 30,287 |

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

MOLECULAR TEMPLATES, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK and STOCKHOLDERS' EQUITY
(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, 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 |
| Issuance of common stock pursuant to stock plans | — | — | 286,479 | — | 1,748 | — | — | 1,748 |
| Issuance of common stock in a public offering, net of issuance costs of \$3.8 million | 250 | — | 6,900,000 | 7 | 53,442 | — | — | 53,449 |
| Issuance of common stock through Private Placement, net of issuance costs of \$75 thousand | — | — | 1,666,666 | 2 | 10,467 | — | — | 10,469 |
| Stock-based compensation | — | — | — | — | 5,859 | — | — | 5,859 |
| Other comprehensive income | — | — | — | — | — | 18 | — | 18 |
| Net loss | — | — | — | — | — | — | (69,421) | (69,421) |
| Balances, December 31, 2019 | 250 | \$ — | 45,589,157 | \$ 46 | \$ 267,089 | \$ 18 | \$ (164,125) | \$ 103,028 |

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

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

| | <u>Years Ended December 31,</u> | |
|---|---------------------------------|------------------|
| | <u>2019</u> | <u>2018</u> |
| Cash flows from operating activities: | | |
| Net loss | \$ 69,421 | \$ 30,287 |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation, amortization and other | 1,182 | 974 |
| Stock-based compensation expense | 5,859 | 3,992 |
| Amortization of debt discount and accretion related to debt | 486 | 318 |
| Change in common stock warrant fair value | (3) | (951) |
| Accretion of asset retirement obligations | 72 | 39 |
| Capitalized interest | — | (125) |
| Loss on extinguishment of debt | — | 115 |
| Loss on disposal of equipment | — | 35 |
| Loss on impairment of long-lived assets | 22,139 | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses | (74) | (825) |
| Accounts receivable from related party | (168) | (240) |
| Grant revenue receivable | (2,771) | (4,351) |
| Other assets | (286) | (450) |
| Operating lease right-of-use assets and liabilities | 2,816 | — |
| Accounts payable | 652 | (1,736) |
| Accrued liabilities | 6,534 | 2,667 |
| Other liabilities | (36) | 224 |
| Deferred revenue | 7,775 | 26,136 |
| Net cash used in operating activities | <u>(25,244)</u> | <u>(4,465)</u> |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (9,649) | (5,722) |
| Purchases of marketable securities | (90,159) | (10,223) |
| Sales of marketable securities | 60,084 | — |
| Net cash used in investing activities | <u>(39,724)</u> | <u>(15,945)</u> |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common stock through Private Placement, net of issuance costs | 10,469 | — |
| Proceeds from issuance of common stock in a Public Offering, net of issuance costs | 53,449 | 48,053 |
| Payments of capital and finance lease obligations | 32 | (47) |
| Proceeds from issuance of long-term debt and warrants, net | — | 4,537 |
| Repayment of long-term debt | — | (3,605) |
| Proceeds from stock option exercises | 1,748 | 283 |
| Net cash provided by financing activities | <u>65,698</u> | <u>49,221</u> |
| Net increase in cash and cash equivalents | 730 | 28,811 |
| Cash and cash equivalents and restricted cash, beginning of period | 87,721 | 58,910 |
| Cash and cash equivalents and restricted cash, end of period | <u>\$ 88,451</u> | <u>\$ 87,721</u> |
| Reconciliation of cash, cash equivalents and restricted cash: | | |
| Cash and cash equivalents | \$ 85,451 | \$ 87,721 |
| Restricted cash included in Other assets | 3,000 | — |
| Total cash, cash equivalents and restricted cash | <u>\$ 88,451</u> | <u>\$ 87,721</u> |
| Supplemental Cash Flow Information | | |
| Cash paid for interest | <u>\$ 684</u> | <u>\$ 629</u> |
| Non-Cash Investing and Financing Activities | | |
| Fixed asset additions in accounts payable and accrued expenses | <u>\$ 2,686</u> | <u>\$ —</u> |

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

NOTE 1—ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Nature of the Business

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

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

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.

Reclassifications

Certain amounts in the prior year’s presentations have been reclassified to conform to the current presentation. The condensed consolidated balance sheet at December 31, 2018 included herein was derived from the audited financial statements at that date, but includes a reclassification of \$4.3 million from Other current assets to Grants revenue receivable in order to conform to current period presentation.

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. Restricted cash is recorded in other assets, based on when the restrictions expire. Other assets include \$3.0 million of restricted cash at December 31, 2019.

Fair Value Measurement

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

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

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

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

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

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 88% and 53% of total revenues for the year ended December 31, 2019 and 2018, were derived from Takeda. See Note 3 “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.

Patents

The gross value of Patents was \$1.3 million at December 31, 2019 and 2018, and are recorded in Other assets. The Company recorded \$0.1 million of amortization expense for the year ended December 31, 2019 and an immaterial amount for the year ended December 31, 2018 with estimated expense to remain \$0.1 million for each of the five successive years subsequent to December 31, 2019.

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. The Company recognized impairment of \$22.1 million during the year ended December 31, 2019 and no impairment during the year ended December 31, 2018. See Note 15 “In-Process Research and Development” for further details on the recorded impairment.

Long-term debt

The Company records debt issuance costs related to its long-term debt as a deduction from the carrying amount. The costs are amortized to interest expense over the life of the debt.

Revenue Recognition

The Company’s revenue has consisted principally of collaboration agreements for 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.

The Company’s collaborative arrangements may include one or more of the following: licenses, or options to obtain licenses; up-front fees; research and development activities and associated costs; milestone payments related to the achievement of development, regulatory, or commercial goals; and royalties on net sales of licensed products. Each of these payments may result in collaboration revenues or an offset against research and development expense.

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.

ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which is expected to be received in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of ASC 606, the following five steps are performed: (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 analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* (“ASC 808”) to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards. This assessment is performed throughout the life of the arrangement based on changes to the arrangements. For collaboration arrangements within the scope of ASC 808 the company may analogize to ASC 606 for certain elements.

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.

Lease Accounting

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

The Company adopted the new lease standard on January 1, 2019 using the modified retrospective method, in which case the cumulative effect of applying the standard would be recognized at the date of initial application. Consequently, financial information will not be updated, and the disclosures required under the new standard will not be provided for dates and periods prior to the first quarter of fiscal 2019.

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

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

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

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

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

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

(1) Included in Other liabilities on the balance sheet.

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

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 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 over the service period, which is generally the vesting period. The Company accounts for forfeitures as they occur. 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. For awards with graded vesting, compensation cost is recognized on a straight-line basis over the requisite service period for the entire award.

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. 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.

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 according to ASC 480, "Distinguishing Liabilities from 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 equity 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.

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

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

In August 2018, the FASB issued ASU 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement* (“ASU 2018-13”). ASU 2018-13 is intended to improve the effectiveness of disclosures in the notes to financial statements related to fair value measurements in Topic 820. This ASU will become effective for annual periods beginning after December 15, 2019, including interim periods within that period. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *Intangibles - Goodwill and Other - Internal-Use Software -Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* (“ASU 2018-15”). ASU 2018-15 aligns the accounting for implementation costs incurred in a hosting arrangement that is a service contract with the guidance on capitalizing costs associated with developing or obtaining internal-use software. This ASU will become effective for annual periods beginning after December 15, 2019, including interim periods within that period, and early adoption is permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

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

NOTE 2—NET LOSS PER SHARE

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period utilizing the two-class method. As discussed further in Note 11 “Stockholders’ Equity”, Preferred Stock Shareholders participate equally with Common Stock Shareholders in earnings, but do not participate in losses, and are excluded from the Basic net loss calculation. Diluted net loss per share is computed by giving effect to all potential dilutive common shares, including outstanding options, warrants and convertible preferred stock. More specifically, at December 31, 2019 and December 31, 2018, stock options, warrants and if converted preferred stock totaling approximately 8,516,000 and 7,525,000 common shares, respectively, were excluded from the computation of diluted net loss per share as their effect would have been anti-dilutive. Additionally, the effects of the beneficial conversion feature (“BCF”) related to the Series A Convertible Preferred Stock increased the net loss attributable to common shareholders in the calculation of net loss per share. See Note 11 “Stockholders’ Equity” for additional information on the BCF.

NOTE 3 — RESEARCH AND DEVELOPMENT AGREEMENTS***Disaggregated Research and Development Revenue***

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

| | Year Ended December 31, | |
|---|-------------------------|-----------------|
| | 2019 | 2018 |
| Japan | \$ 19,499 | \$ 7,087 |
| United States | — | 196 |
| Total Research and Development Revenue | \$ 19,499 | \$ 7,283 |

Related Party Collaboration Agreements - Takeda Pharmaceuticals, Inc.

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

| | Year Ended December 31, | |
|--|-------------------------|-----------------|
| | 2019 | 2018 |
| Takeda Collaboration Agreement | \$ — | \$ 92 |
| Takeda Individual Project Agreement | 48 | 2,191 |
| Takeda Development and License Agreement | 18,468 | 3,903 |
| Takeda Multi-Target Agreement | 983 | 901 |
| Total research and development revenue - from related party | \$ 19,499 | \$ 7,087 |

At December 31, 2019 and December 31, 2018, the Company had \$36.7 million and \$28.9 million, respectively, of Deferred revenue related to research and development agreements. Deferred revenue and accounts receivable balances from the research and development agreements with Takeda were as follows (in thousands):

| | December 31, 2019 | December 31, 2018 |
|--|-------------------|-------------------|
| Contract Assets | | |
| Accounts receivable from related party | \$ 408 | \$ 240 |
| Contract Liabilities | | |
| Deferred revenue, current | \$ 8,780 | \$ 26,231 |
| Deferred revenue, non-current | 441 | 2,670 |
| Total deferred revenue | \$ 9,221 | \$ 28,901 |

Takeda Development and License Agreement

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

The Company, at its discretion, exercised the co-development option in July 2019 and as a result is eligible to receive pre-clinical and clinical development milestone payments of up to \$307.5 million upon the achievement of certain development milestones and regulatory approvals, and sales milestone payments of up to \$325.0 million upon the achievement of certain sales milestone events.

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

The Company will also be entitled to receive tiered royalties, subject to certain reductions, as percentages of annual aggregate net sales, if any, of Licensed Products. The royalty percentages would range from low double-digits to low twenties if the Company continues its option to co-develop, and from high-single digits to low teens if the Company does not continue 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 \$29.8 million consists of (1) the \$30.0 million upfront payment, (2) a \$10.0 million development milestone payment which was achieved in the first quarter of 2020, (3) minus \$10.2 million in expected co-share payments payable to Takeda during Early Stage Development, as defined in the Takeda Development and License Agreement. The expected co-share payment is considered variable consideration, and the Company applied a constraint using the expected value method. Significant judgement was involved in determining transaction consideration, including the determination of the variable consideration, including the constraint on consideration.

At December 31, 2019, the other potential development milestones and sales milestones are not currently deemed probable of being achieved, as they are dependent on factors outside the Company's control. Therefore, these future development milestones and sales-based milestone payments have been fully constrained and are not included in the transaction price at December 31, 2019.

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

In July 2019, the Company exercised its co-development option and the agreed upon collaboration budget was increased to cover additional research and development activities whereby both parties will continue to cost share. The Company evaluated the additional research and development services and concluded these services were distinct from services currently being provided and represented a cost sharing arrangement between the Company and Takeda. As such, research and development expenses for this performance obligation will be expensed as incurred.

At December 31, 2019 and December 31, 2018, total deferred revenue related to the performance obligation was \$6.1 million and \$24.8 million, respectively.

Takeda Multi-Target Agreement

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

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

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

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

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

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

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

At December 31, 2019 and December 31, 2018, deferred revenue related to the performance obligation was \$3.1 million and \$4.1 million, respectively.

Takeda Collaboration Agreement

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

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 received \$2.2 million in compensation that included an increase in transaction consideration of \$1.1 million as a result of the amendment to the Takeda Individual Project Agreement in July 2018.

All research and development services under the Takeda Collaboration Agreement were performed at March 31, 2019. As such, the Company recognized less than \$0.1 million and \$2.2 million of research and development revenue for the year ended December 31, 2019 and 2018, respectively. This revenue is deemed to be revenue from a related party (as discussed further in Note 7, Related Party Transactions).

Vertex Collaboration Agreement

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

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

Vertex paid the Company an upfront payment of \$38 million, consisting of \$23 million in cash and a \$15 million equity investment pursuant to a Share Purchase Agreement (the “SPA”). In addition to the upfront payments, the Company may also receive an additional \$22 million through the exercise of the options to license ETB products or to add an additional target. Additionally, Vertex will reimburse the Company for certain mutually agreed manufacturing technology transfer activities. The Company had \$8.5 million of Deferred revenue, current, and \$19.0 million of Deferred revenue, non-current, at December 31, 2019 related to the Vertex Collaboration Agreement. There was no deferred revenue at December 31, 2018 related to the Vertex Collaboration Agreement.

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

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

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

The Company identified one performance obligation at the inception of the Vertex Collaboration Agreement consisting of research and development services. The Company recognizes revenue under the Vertex Collaboration Agreement using a cost-based input measure. In applying the cost-based input method of revenue recognition, the Company will use actual costs incurred relative to budgeted costs expected to be incurred. These costs consist primarily of internal employee efforts and third-party contract costs. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligation over the estimated service period.

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

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

Other Collaboration Agreements

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

Under the Other Collaboration Agreement, the Company recognized no research and development revenue for the year ended December 31, 2019 and \$0.2 million of research and development revenue for the year ended December 31, 2018. All research and development services under the Other Collaboration Agreement were performed at December 31, 2018.

Grant Agreements

In September 2018, the Company entered into a Cancer Research Agreement (the "CD38 CPRIT Agreement") with CPRIT, which was extended in November 2019, under which CPRIT awarded a \$15.2 million product development grant to fund research of a cancer therapy involving a CD38 targeting ETB. Pursuant to the CD38 CPRIT Agreement, the Company may also use such funds to develop a replacement CD38 targeting ETB, with or without a partner.

In 2011, the Company entered into a Cancer Research Agreement (the "CPRIT Agreement") with CPRIT under which CPRIT awarded a \$10.6 million product development grant for the CD20-targeting ETB MT-3724, this grant ended in November 2019. At December 31, 2019 the Company had received \$9.6 million and anticipates receiving the remaining \$1.0 million in the first half of 2020.

During the year ended December 31, 2019 and 2018, the Company recognized \$2.7 million and \$6.0 million, respectively, in grant revenue under these awards. Qualified expenditures submitted for reimbursement in excess of amounts received are recorded as receivables in Grant revenue receivable. At December 31, 2019 and December 31, 2018, the Company had \$7.1 million and \$4.3 million, respectively, recorded in Grants revenue receivable.

NOTE 4—MARKETABLE SECURITIES AND FAIR VALUE MEASUREMENTS

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, 2019 and 2018:

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

| (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>\$ 95,668</u> | <u>\$ 82,843</u> | <u>\$ 12,825</u> | <u>\$ —</u> |
| Amounts included in: | | | | |
| Cash and cash equivalents | 85,434 | | | |
| Marketable securities, current | 10,234 | | | |
| Total | <u>\$ 95,668</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, 2019 and 2018:

| As of December 31, 2019 (in thousands): | Cost Basis | Unrealized Gain | Unrealized Loss | Fair Value |
|---|------------------|--------------------|--------------------|------------------|
| Cash equivalents - money market funds, commercial paper and corporate bonds | <u>\$ 84,361</u> | <u>\$ 1</u> | <u>\$ —</u> | <u>\$ 84,362</u> |
| Marketable securities, current - commercial paper, Treasury bills and corporate bonds | <u>39,616</u> | <u>17</u> | <u>—</u> | <u>39,633</u> |
| Marketable securities, non-current - Treasury bills | <u>1,510</u> | <u>—</u> | <u>—</u> | <u>1,510</u> |
| As of December 31, 2018 (in thousands): | Cost Basis | Unrealized Gain | Unrealized Loss | Fair Value |
| Cash equivalents - money market funds | <u>\$ 85,434</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 85,434</u> |
| Marketable securities, current - commercial paper | <u>10,234</u> | <u>—</u> | <u>—</u> | <u>10,234</u> |

The following summarized the contractual maturities of the Company's available-for-sale investment at December 31, 2019:

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

The Company received \$1.3 million of proceeds with immaterial realized gains in the year ending December 31, 2019, and no realized gains or losses in years ending December 31, 2018.

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. 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 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, 2019 | Basis of Fair Value Measurements | | |
|----------------------------|--|----------------------------------|---------|---------|
| | | Level 1 | Level 2 | Level 3 |
| 2017 Common stock warrants | \$ — | \$ — | \$ — | \$ — |

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

The fair value of these warrants on December 31, 2019 and 2018 was determined using a Black-Scholes model with the following key level 3 inputs:

| | December 31, 2019 | December 31, 2018 |
|-------------------------------|----------------------|----------------------|
| Risk-free interest rate | 1.6% | 2.6% |
| Expected life (in years) | 0.1 | 1.1 |
| Dividend yield | — | — |
| Volatility | 86% | 77% |
| Stock price at valuation date | \$ 13.99 | \$ 4.04 |

During the year ended December 31, 2019 and 2018 the change in fair value of \$3,000 and \$1.0 million 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

NOTE 5—PROPERTY AND EQUIPMENT

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

| | December 31, | |
|--|------------------|-----------------|
| | 2019 | 2018 |
| Laboratory equipment | \$ 10,587 | \$ 4,676 |
| Leasehold improvements | 10,383 | 3,274 |
| Furniture and fixtures | 150 | 89 |
| Computer and equipment | 331 | 145 |
| | 21,451 | 8,184 |
| Less: Accumulated depreciation | (3,293) | (1,333) |
| Total property and equipment, net | \$ 18,158 | \$ 6,851 |

Depreciation expense was \$2.0 million and \$1.0 million for the years ended December 31, 2019 and 2018, respectively.

In connection with the continued expansion of the Company's facilities, at December 31, 2019 and 2018, the Company had net ARO assets totaling \$1.0 million and \$0.1 million, respectively. The ARO assets are included in Leasehold improvements.

NOTE 6—BALANCE SHEET COMPONENTS

Accrued liabilities comprise the following (in thousands):

| | December 31, | |
|--|------------------|-----------------|
| | 2019 | 2018 |
| Accrued liabilities: | | |
| General and administrative | \$ 4,521 | \$ 297 |
| Clinical trial related costs | 1,383 | 598 |
| Non-clinical research and manufacturing operations | 5,774 | 2,644 |
| Payroll related | 2,849 | 1,787 |
| Other accrued expenses | 17 | 31 |
| Total accrued liabilities | <u>\$ 14,544</u> | <u>\$ 5,357</u> |

NOTE 7 — RELATED PARTY TRANSACTIONS

Takeda Agreements

In connection with the Takeda Stock Purchase Agreement described in Note 3 "Research and Development Collaboration Agreements", Takeda became a related party, following the stock purchase. Refer to Note 3, Research and Development Collaboration Agreements, for more details about the Takeda Collaboration Agreement, the Takeda Multi-Target Agreement and the Takeda Development and License Agreement. 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.

Public Offerings

On September 25, 2018, the Company closed its underwritten public offering (the "2018 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, in which Longitude Venture Partners III, L.P. and CDK Associates, L.L.C., current stockholders of the Company, purchased 365,000 and 545,454 shares of common stock, respectively, at the public offering price. Scott Morenstein, a director of the Company is a Managing Director of Caxton Alternative Management LP, the investment manager of CDK Associates, L.L.C., David Hirsch, a director of the Company, is a member of Longitude Capital Partners III, LLC, the general partner of Longitude Venture Partners III, L.P.

On November 25, 2019, the Company closed its underwritten public offering (the "2019 Public Offering") of 6,900,000 shares of its common stock and 250 shares of our newly designated Series A Convertible Preferred Stock, which included the exercise in full by the underwriters of their option to purchase 900,000 additional shares of common stock, at a price to the public of \$8.00 per share, in which Longitude Venture Partners III, L.P. and CDK Associates, L.L.C., current stockholders of the Company, purchased 937,500 and 468,750 shares of common stock, respectively, at the public offering price.

NOTE 8 — 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 \$0.4 million due at the loan maturity date in addition to the principal and interest payments. The company drew \$6.1 million on this loan from 2015 to 2016.

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, \$0.4 million in a final fee interest during the year ended December 31, 2018. As of December 31, 2018 the Growth Capital Loan had been repaid, and the balance was zero.

Perceptive Credit Facility

On February 27, 2018, the Company entered into a term loan facility with Perceptive Credit Holdings II, LP (“Perceptive”) in the amount of \$10.0 million (the “Perceptive Credit Facility”). The Perceptive Credit Facility consists of a \$5.0 million term loan, which was drawn on the effective date of the Perceptive Credit Facility, and an additional \$5.0 million term loan that can be drawn down at a future date. The principal on the facility accrues interest at an annual rate equal to a three-month LIBOR plus the Applicable Margin. The Applicable Margin is 11.00%. Upon the occurrence, and during the continuance, of an event of default, the Applicable Margin, defined above, will be increased by 4.00% per annum. The interest rate at December 31, 2019 was 12.9%. Payments for the first 24 months are interest only and are paid quarterly. After the second anniversary of the closing date of the Perceptive Credit Facility, principal payments of \$0.2 million are due each calendar quarter, with a final payment of \$3.4 million due on February 27, 2022. This term loan facility matures on February 27, 2022 and includes both financial and non-financial covenants, including a minimum cash balance requirement. The Company is required to pay an exit fee of \$100,000 on a pro rata basis on the maturity date or the earlier date of repayment of the term loans in full. Additionally, the Company incurred \$0.5 million in deferred finance costs and issued the debt net of a \$1.5 million discount. The exit fee, deferred finance costs and discount are being accreted to interest expense over the term of the Perceptive Credit Facility using the effective interest method.

For the year ended December 31, 2019 and December 31, 2018, the Company recorded \$0.7 million and \$0.6 million of interest expense, respectively. For the years ended December 31, 2019 and December 31, 2018, the Company recorded \$0.3 million of amortization of debt discount related to the Perceptive Credit Facility for both periods.

In connection with the Perceptive Credit Facility, on February 27, 2018 the Company issued Perceptive a warrant to purchase 190,000 shares of the Company’s common stock. The warrant is exercisable for a period of seven years from the date of issuance at an exercise price per share of \$9.5792, subject to certain adjustments as specified in the Warrant. 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, 2019 and December 31, 2018 the Perceptive Credit Facility principal balance was \$5.0 million and \$5.0 million, respectively, with principal payment due one calendar year, or more, from the balance sheet being classified as non-current. As of December 31, 2019, the Company was in compliance with the non-financial covenants of the Perceptive Credit Facility.

As of December 31, 2019 and 2018 the carrying value of the long-term debt was \$3.7 million and \$3.3 million, respectively.

Future required principal payments on the Perceptive Credit facility were as follows as of December 31, 2019 (in thousands):

| Year Ending December 31, | | |
|---------------------------------|----|--------------|
| 2020 | \$ | 800 |
| 2021 | | 800 |
| 2022 | | 3,500 |
| 2023 | | — |
| 2024 | | — |
| Total | \$ | <u>5,100</u> |

NOTE 9 – LEASES

In January 2019, the Company entered into a lease agreement for an additional 57,000 square feet of administrative office and R&D space in Austin, Texas. The lease commenced March 2019 and expires August 2028 and does not contain an option to renew. The tables below include the impact of this lease. Upon the commencement of the lease, the Company recorded an operating lease ROU asset and a lease liability of \$7.2 million. The Company subsequently adjusted the lease liability to \$7.4 million due to changes in cash receipts related to a tenant improvement allowance. In connection with entering into the lease and in lieu of a cash deposit, the Company obtained a letter of credit of \$3.0 million. Additionally, the Company has recorded an asset retirement obligation as a result of this lease which has a balance of \$0.4 million at December 31, 2019.

Changes in the carrying amounts of the Company's AROs for the years ended December 31, 2019 and 2018 are shown below (in thousands):

| | 2019 | 2018 |
|--|-----------------|---------------|
| Balance at beginning of year | \$ 344 | \$ 261 |
| Liabilities incurred in the current period | 949 | 44 |
| Accretion expense | 72 | 39 |
| Balance at end of year | <u>\$ 1,365</u> | <u>\$ 344</u> |

At December 31, 2019, the Company did not have any operating and finance leases that have not yet commenced.

The components of lease expense for the year ended December 31, 2019 were as follows (in thousands):

| | | |
|------------------------------------|----|--------------|
| Operating leases | | |
| Operating lease expense | \$ | 2,175 |
| Variable lease expense | | 456 |
| Total operating lease expense | \$ | <u>2,631</u> |
| Finance leases | | |
| Amortization of right-of-use asset | \$ | 8 |
| Interest on lease liabilities | | 2 |
| Total finance lease expense | \$ | <u>10</u> |
| Sublease rental income | \$ | <u>138</u> |

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

The following table summarizes the balance sheet classification of leases at December 31, 2019 (in thousands):

| | | |
|---|----|---------------|
| Operating leases | | |
| Operating lease right-of-use assets, non-current | \$ | 9,959 |
| Operating lease liabilities, current ¹ | \$ | 1,683 |
| Operating lease liabilities, non-current | | 11,682 |
| Total operating lease liabilities | \$ | <u>13,365</u> |
| Finance leases | | |
| Property and equipment, at cost | \$ | 77 |
| Accumulated depreciation | | 41 |
| Property and equipment, net | \$ | <u>36</u> |
| Finance lease liabilities, current ¹ | \$ | 18 |
| Finance lease liabilities, non-current ² | | 1 |
| Total finance lease liabilities | \$ | <u>19</u> |

1. Included in other current liabilities.

2. Included other liabilities.

The following table presents other information on leases as of December 31, 2019:

| | Weighted Average Remaining Lease Term | Weighted Average Discount Rate |
|-------------------------|---|-----------------------------------|
| Operating leases | 7.2 | 6.72% |
| Finance leases | 0.8 | 6.88% |

Future minimum payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year as of December 31, 2019 (in thousands):

| | Operating Leases | Finance Leases |
|-------------------------|------------------|----------------|
| 2020 | \$ 2,517 | \$ 20 |
| 2021 | 2,589 | — |
| 2022 | 2,650 | — |
| 2023 | 1,961 | — |
| 2024 | 1,474 | — |
| Thereafter | 5,762 | — |
| Total lease payments | <u>16,953</u> | <u>20</u> |
| Less: | | |
| Imputed interest | (3,588) | (1) |
| Total lease liabilities | <u>\$ 13,365</u> | <u>\$ 19</u> |

Supplemental cash flow information related to the Company's leases were as follows for the year ended December 31, 2019 (in thousands):

| | | |
|---|----|-------|
| Cash paid for amounts included in the measurement of lease liabilities: | | |
| Operating cash flows from operating leases | \$ | 1,278 |
| Operating cash flows from finance leases | \$ | 3 |
| Financing cash flows from finance leases | \$ | 31 |
| Right-of-use asset obtained in exchange for lease obligations: | | |
| Operating leases | \$ | 7,501 |

NOTE 10—COMMITMENTS AND CONTINGENCIES

Commitments

The Company has entered into project work orders for each of its clinical trials with clinical research organizations ("CRO") and related laboratory vendors. Under the terms of these agreements, the Company is required to pay certain upfront fees for direct services costs. Based on the particular agreement some of the fees may be for services yet to be rendered and are reflected as a current prepaid asset and have an unamortized balance of approximately \$1.0 million at December 31, 2019. In connection with the Company's clinical trials, it has entered into separate project work orders for each trial with its CRO. The Company has entered into agreements with CROs and other external service providers for services, primarily in connection with the clinical trials and development of the Company's drug candidates. The Company was contractually obligated for up to approximately \$41.8 million of future services under these agreements at December 31, 2019, for which amounts have not been accrued as services have not been performed. The Company's actual contractual obligations will vary depending upon several factors, including the progress and results of the underlying services.

We have entered into estimated purchase obligations which in total range from \$6.4 million to \$7.0 million and include signed orders for capital equipment.

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

Contingencies

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to vendors, lessors, business partners, collaborators 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, clinical trial 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.

The Company believes that its product liability, clinical trial and comprehensive general liability insurance are adequate for current operations. However, the coverage limits of this insurance may not be adequate to cover all potential claims. Product liability, clinical trial and comprehensive general liability insurance is expensive and may be difficult to obtain or maintain on commercially reasonable terms. A successful claim against the Company in excess of the Company's insurance coverage or outside the scope of an indemnity given by any vendors, lessors, business partners, collaborators and other parties in Company agreements could adversely affect the Company's results of operations.

NOTE 11—STOCKHOLDERS' EQUITY

Private Placement and Related Warrants

On August 1, 2017, the Company entered into the a securities purchase agreement with Longitude Venture Partners III, L.P. and certain other accredited investors (the "Longitude Securities Purchase Agreement"), pursuant to which the Company sold an aggregate of 5,793,063 units (the "Units") 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, 2019, there were warrants outstanding under this agreement to purchase 2,896,528 shares of common stock. The warrants 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. The warrants were exercisable upon issuance and expire August 1, 2024.

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 are 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, 2019, there were Wedbush warrants outstanding to purchase 57,930 shares of common stock. The Wedbush Warrants 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 warrants were exercisable upon issuance and expire December 1, 2024.

Subsequent Private Placements

In connection with the execution of the Takeda Multi-Target Agreement, the Company entered into the Takeda Stock Purchase Agreement. Pursuant to the Takeda Stock Purchase Agreement, following the consummation of 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 \$20.0 million.

In connection with the execution of the Vertex Collaboration Agreement, the Company entered into the Vertex Stock Purchase Agreement. Pursuant to the Vertex Stock Purchase Agreement, Vertex purchased 1,666,666 shares of the Company common stock, at a price per share of \$9.00, for an aggregate purchase price of \$15.0 million. See Note 3 “Research and Development Agreements” for more information.

Public Offerings

On September 25, 2018, the Company closed its underwritten public offering (the “2018 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 2018 Public Offering, after deducting the underwriting discounts and commissions and offering expenses payable by the Company, were approximately \$48.1 million.

On November 25, 2019, the Company closed its underwritten public offering (the “2019 Public Offering”) of 6,900,000 shares of its common stock at a price to the public of \$8.00 per share, and 250 shares of newly designated Series A Convertible Preferred Stock (“Series A Preferred Stock”) at a price to the public of \$8,000 per share. The offering included the exercise in full by the underwriters of their option to purchase up to 900,000 additional shares of common stock. 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 \$53.4 million. Each share of Series A Preferred Stock is convertible to 1,000 shares of Common Stock, provided that the holder of Series A Preferred Stock will be prohibited from converting the Series A Preferred Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of the Company’s common stock then issued and outstanding. In the event of the Company’s liquidation, dissolution, or winding up, holders of Series A Preferred Stock will receive a payment equal to \$0.001 per share of Series A Preferred Stock before any proceeds are distributed to the holders of the Company’s common stock and *pari passu* with any distributions to the holders of the Company’s Series A Preferred Stock. Series A Preferred Stock participate in earnings equally with Common Stock shareholders, with the same dividend rate, but do not participate in losses as discussed in Note 2 “Net Loss per Common Share”. The Series A Preferred Stock has no voting rights, except as required by law and except that the consent of the Series A Preferred Stockholders will be required to amend the terms of the Series A Preferred Stock. Based on the guidance in ASC 470-20-20, the Company determined that a BCF existed, as the effective conversion price for the Series A Preferred Stock at issuance was less than the fair value of the common stock which the preferred shares are convertible into. The BCF based on the intrinsic value of the date of issuances for the Series A Preferred Stock was \$0.7 million.

Subsequent Common Stock Warrants

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. They 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 8, “Borrowing Arrangements”, for further detail about the Perceptive Credit Facility.

NOTE 12—EQUITY INCENTIVE PLANS AND STOCK-BASED COMPENSATION

2018 Equity Incentive Plan

In May 2018, the Company adopted the 2018 Equity Incentive Plan (“2018 Plan”). The 2018 Plan serves as a successor to the 2004 Equity Incentive Plan (“2004 Plan”), 2009 Equity Incentive Plan (“2009 Plan”) and 2014 Equity Incentive Plan (“2014 Plan”) with any forfeited awards under those plans being absorbed into the 2018 plan for future issuance. 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 335,040 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, 2019, options to purchase 736,916 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 years ended December 31, 2019 and December 31, 2018, no shares were purchased by employees under the 2004 Purchase Plan. At December 31, 2019 and 2018, 8,636 were authorized and available for issuance under the 2004 Purchase Plan.

The following table summarizes information about stock option activity for years ended December 31, 2019 and 2018:

| | Outstanding Options Number of Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value of December 31, 2018 (in millions): |
|----------------------------------|---|------------------------------------|---|--|
| 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 | 4,002,999 | \$ 10.43 | 6.4 | \$ 1.5 |
| Options granted | 2,003,600 | 6.01 | | |
| Options exercised | (286,479) | 6.10 | | |
| Options canceled | (976,130) | 22.37 | | |
| Balances, December 31, 2019 | 4,743,990 | \$ 6.37 | 8.2 | \$ 36.5 |
| Vested and expected to vest | | | | |
| December 31, 2019 | 4,743,990 | \$ 6.37 | 8.2 | \$ 36.5 |
| Exercisable at December 31, 2019 | 1,779,916 | \$ 5.98 | 7.0 | \$ 14.6 |

At December 31, 2019, 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 - 1.85 | 478,366 | 3.80 | \$ 1.07 | 475,308 | \$ 1.06 |
| \$ 4.04 - 4.28 | 6,681 | 7.72 | \$ 4.22 | 4,191 | \$ 4.20 |
| \$ 4.66 - 4.66 | 1,030,126 | 9.11 | \$ 4.66 | 105,638 | \$ 4.66 |
| \$ 4.74 - 5.81 | 428,825 | 8.93 | \$ 5.06 | 73,716 | \$ 5.16 |
| \$ 6.31 - 6.31 | 1,227,849 | 8.41 | \$ 6.31 | 531,659 | \$ 6.31 |
| \$ 6.54 - 8.21 | 537,662 | 8.78 | \$ 7.63 | 123,674 | \$ 8.03 |
| \$ 8.35 - 9.28 | 134,450 | 9.56 | \$ 8.53 | 7,499 | \$ 9.24 |
| \$ 9.40 - 9.40 | 537,500 | 7.77 | \$ 9.40 | 348,437 | \$ 9.40 |
| \$ 10.78 - 61.27 | 360,713 | 8.71 | \$ 12.58 | 107,976 | \$ 13.22 |
| \$ 70.29 - 70.29 | 1,818 | 2.37 | \$ 70.29 | 1,818 | \$ 70.29 |
| \$ 0.42 - 70.29 | 4,743,990 | 8.16 | | 1,779,916 | \$ 5.98 |

The total intrinsic value of stock options exercised during the years ended December 31, 2019 and 2018 were \$0.6 million and \$2.6 million, respectively, determined at the date of the option exercise. Cash received from stock option exercises were \$1.7 million and \$0.3 million for the years ended December 31, 2019 and 2018, respectively. The Company issues new shares of common stock upon exercise of options. In connection with these exercises, there was no tax benefit realized by the Company due to its current loss position.

Stock-based Compensation

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

| | Years Ended December 31, | |
|-----------------------------------|--------------------------|-----------------|
| | 2019 | 2018 |
| Stock-based compensation expense: | | |
| Research and development | \$ 2,398 | \$ 1,192 |
| General and administrative | 3,461 | 2,800 |
| | <u>\$ 5,859</u> | <u>\$ 3,992</u> |

Employee Stock-based Compensation Expense

Valuation Assumptions

The fair value of employee stock options was estimated using the following weighted-average assumptions for the years ended December 31, 2019 and 2018:

| | Years Ended December 31, | |
|--|--------------------------|---------|
| | 2019 | 2018 |
| Employee Stock Options | | |
| Risk-free interest rate | 2.37% | 2.79% |
| Expected life (in years) | 6.08 | 6.03 |
| Dividend yield | — | — |
| Volatility | 108.70% | 107.15% |
| Weighted-average fair value of stock options granted | \$ 5.00 | \$ 5.79 |

As of December 31, 2019, the total unrecognized compensation cost related to unvested stock-based awards granted to employees under the Company's equity compensation plans was approximately \$15.0 million. This cost will be recorded as compensation expense ratably over the remaining weighted average requisite service period of approximately 2.71 years.

NOTE 13—INCOME TAXES

For the years ended December 31, 2019 and 2018, 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):

| | 2019 | 2018 |
|---|-------------|-------------|
| U.S. federal taxes (benefit) at statutory rate | \$ (14,578) | \$ (6,361) |
| State federal income tax benefit | (528) | (69) |
| Permanent differences | 34 | (160) |
| Stock compensation | 4,112 | 136 |
| Research and development credits | (1,677) | (608) |
| Change in valuation allowance due to operations | 12,756 | 2,758 |
| Expiring state carryovers and other | (119) | 4,304 |
| 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, | |
|---------------------------------------|----------------|----------------|
| | 2019 | 2018 |
| Deferred tax assets | | |
| Net operating loss carryforward | \$ 26,554 | \$ 19,941 |
| Research and development credits | 4,147 | 2,049 |
| Deferred stock compensation | 1,571 | 4,547 |
| Deferred revenue | 1,956 | 210 |
| Lease liability | 2,835 | — |
| Other | 736 | 404 |
| Total deferred tax assets | 37,799 | 27,151 |
| Total deferred tax liabilities | | |
| Depreciable and amortizable assets | (1,340) | (925) |
| Right-of-use asset | (2,112) | — |
| R&D intangible assets | (956) | (5,591) |
| Total deferred tax liabilities | (4,408) | (6,516) |
| Less: Valuation allowance | (33,391) | (20,635) |
| Net deferred tax assets | \$ — | \$ — |

At December 31, 2019, the Company had federal net operating loss carryforwards of approximately \$125.5 million available to offset future taxable income. The Company's federal net operating loss carryforwards will begin to expire in 2024 if not used before such time to offset future taxable income or tax liabilities. Federal tax loss carryforwards that were created prior to December 31, 2017 expire through 2037, all tax loss carryforwards created after that date do not expire. 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, 2019, the Company had tax credits available to offset future taxes of approximately \$3.5 million, which expire in the year beginning 2022, and state research and development tax credits of approximately \$0.8 million, which expire beginning 2033.

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 \$12.8 million from continuing operations, and the remaining changes in valuation allowance relates to the write-off of certain state tax attributes.

The total amount of unrecognized benefits as of December 31, 2019 and 2018 was \$0. The reconciliation of unrecognized tax benefits at the beginning and end of the year is as follows:

| <u>(in thousands)</u> | 2019 | 2018 |
|---|-------------|-------------|
| Gross unrecognized tax benefits at January 1, | \$ — | \$ 1,143 |
| Gross increases (decreases) related to acquisitions | — | (1,143) |
| Gross increases related to current year tax positions | — | — |
| Gross unrecognized tax benefits at December 31, | \$ — | \$ — |

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2019 and 2018, 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 until the statute of limitations closes for the tax year in which the net operating losses are utilized.

NOTE 14—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”). 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 \$0.2 million and \$0.1 million for the years ended December 31, 2019 and 2018, respectively.

NOTE 15 – IN-PROCESS RESEARCH AND DEVELOPMENT

In-process research and development represent the fair value of the Company’s legacy program, Evofosfamide, which was acquired as a part of the merger agreement with Threshold. For more information refer to Note 1 “Organization and Summary of Significant Accounting Policies”.

Fair value of In-process research and development is estimated based upon internal evaluation of each asset that includes quantitative analyses of net revenue and cash flows, review of recent sales of similar assets and market responses based upon discussions in connection with offers received from potential buyers. Certain factors used for these types of nonrecurring fair value measurements are considered Level 3 inputs. The Company obtained a fair value estimate, from a third party specialist as of August 1, 2019, and determined the asset was impaired and the value was not fully recoverable. During the year ended December 31, 2019, the Company recorded a related impairment of \$22.1 million. Future write-downs of the asset are possible based upon the amount of proceeds from an eventual sale of the asset.

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

NOTE 16—SUBSEQUENT EVENTS

Not Applicable

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, 2019. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to its management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2019, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were not effective due to a material weakness, as described below.

Notwithstanding the material weakness in internal control over financial reporting, our management concluded that our consolidated financial statements in this annual report on Form 10-K present fairly, in all material respects, the Company’s consolidated financial position, results of operations and cash flows as of the dates, and for the periods presented, in conformity with GAAP.

Management’s 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.

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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. 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). As a result of the material weakness described below, our internal control over financial reporting at December 31, 2019 was not effective.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Management's assessment identified a material weakness related to IT general controls for the significant applications used in the preparation of the financial statements. Specifically, controls were not designed and operating effectively over the manage access process to adequately restrict user and privileged access to the financial applications, including periodic review of appropriate access; and over program change management to ensure that program and data changes were tested, authorized and implemented appropriately. Accordingly, automated controls and manual controls that are dependent on the effective operation of the deficient IT general controls were also ineffective.

Attestation Report of Registered Public Accounting Firm

Our independent registered public accounting firm, Ernst & Young LLP has issued an attestation report on the effectiveness of our internal controls over financial reporting as of December 31, 2019, which is included below.

Remediation

Management has implemented and continues to implement a remediation plan to address the root causes which contributed to the material weakness and is committed to a strong Internal Control over Financial Reporting (ICFR) environment. The remediation plan includes, but is not limited to:

- Implementing improved IT change management policies and procedures, control activities, and tools to ensure changes affecting financial IT applications are identified, authorized, tested, and implemented appropriately;
- Implementing improved processes for requesting, authorizing, and reviewing user access to key systems which impact our financial reporting, including identifying access to roles where manual business process controls may be required;
- The implementation of appropriate segregation of duties in all systems that impact internal control over financial reporting;
- Increasing resources dedicated to monitoring IT general controls to ensure compliance with policies and procedures;
- Engaging outside resources to assist with the design and implementation of a risk-based internal controls plan, enhance process documentation, provide company-wide training, and help with management's self-assessment and testing of internal controls.

Changes in Internal Control over Financial Reporting

Other than the material weakness 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 quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control Over Financial Reporting

We have audited Molecular Templates, Inc.'s internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, because of the effect of the material weakness described below on the achievement of the objectives of the control criteria, Molecular Templates, Inc. (the Company) has not maintained effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. Management has identified a material weakness related to IT general controls for the significant applications used in the preparation of the financial statements.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Molecular Templates, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the 2019 consolidated financial statements, and this report does not affect our report dated March 13, 2020, which expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying

Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 of the company are being made only in accordance with authorizations of management and directors of the company; and (3) 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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

/s/ Ernst & Young LLP

Austin, Texas
March 13, 2020

ITEM 9B. OTHER INFORMATION

Not applicable

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 2019 fiscal year pursuant to Regulation 14A for our 2020 Annual Meeting of Stockholders, or the 2020 Proxy Statement, will be filed pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended. If the 2020 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 2020 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 2020 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 2020 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 2020 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 2020 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 [^] | <u>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).</u> |
| 3.1 | <u>Amended and Restated Certificate of Incorporation of the Company, as subsequently amended (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 6, 2014).</u> |
| 3.2 | <u>Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Company, dated August 1, 2017 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on August 1, 2017).</u> |
| 3.3 | <u>Certificate of Amendment (Name Change) of Amended and Restated Certificate of Incorporation of the Company, dated August 1, 2017 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on August 7, 2017).</u> |
| 3.4 | <u>Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, dated November 22, 2019 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-32979), filed on November 25, 2019).</u> |
| 3.5 | <u>Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.4 to the Company's Annual Report on Form 10-K (File No. 001-32979), filed on March 29, 2019).</u> |
| 4.1 | <u>Form of Warrant issued pursuant to the Company's prospectus supplement, dated February 18, 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).</u> |
| 4.2 | <u>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 on August 7, 2017).</u> |
| 4.3 | <u>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 on March 30, 2018).</u> |
| 4.4 | <u>Warrant to Purchase Common Stock issued to Perceptive Credit Holdings II, LP (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on March 2, 2018).</u> |
| 4.5 | <u>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), filed on December 21, 2018).</u> |
| 4.6 | <u>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), filed on December 21, 2018).</u> |
| 10.1+ | <u>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).</u> |
| 10.2+ | <u>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).</u> |

- 10.3 [Amended and Restated Non-Employee Director Compensation Policy, adopted by the Board of Directors of the Company on June 14, 2018 \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K \(File No. 001-32979\), filed on December 19, 2019\).](#)
- 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 \(File No. 001-32979\) filed 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 \(File No. 001-32979\), filed 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 \(File No. 001-32979\), filed 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 \(File No. 333-217993\) filed 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 \(File No. 333-217993\) filed 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 \(File No. 001-32979\), filed 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 \(incorporated by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-4, filed on May 15, 2017, as amended on June 27, 2017\).](#)
- 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 \(File No. 001-32979\), filed 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 \(File No. 001-32979\), filed 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 \(File No. 333-217993\), filed 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 \(File No. 333-217993\), filed 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 \(File No. 333-217993\), filed 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 \(File No. 333-217993\), filed 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 \(File No. 001-32979\), filed 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 \(File No. 001-32979\), filed 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 \(File No. 333-217993\), filed 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 \(File No. 333-217993\), filed 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 \(File No. 001-32979\) filed 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 \(File No. 001-32979\) filed 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 \(File No. 333-217993\), filed 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 \(File No. 001-32979\) filed 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. \(incorporated by reference to Exhibit 10.48 to the Company's Registration Statement on Form S-4, filed on May 15, 2017, as amended on June 27, 2017\).](#)
- 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 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 \(File No. 001-32979\) filed 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-8 \(File No. 333-225826\), filed 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-8 \(File No. 333-225826\) filed 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 \(File No. 001-32979\) filed on November 13, 2018\).](#)

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|----------|---|
| 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) filed 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 (incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K (File No. 001-32979), filed on March 29, 2019). |
| 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, L.P, 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 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 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 to the Company's Current Report on Form 8-K (File No. 001-32979), filed on September 24, 2018). |
| 10.41 | Sales Agreement, dated December 21, 2018, by and among Molecular Templates, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3 (File No. 333-228975), filed on December 21, 2018). |
| 10.42 | Sublease Agreement, dated as of January 23, 2019, by and between Molecular Templates, Inc. and State Farm Mutual Automobile Insurance Company (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-32979), filed on May 13, 2019). |
| 10.43 | First Amendment to Sublease Agreement, dated as of May 16, 2019, by and between Molecular Templates, Inc. and State Farm Mutual Automobile Insurance Company (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-32979), filed on August 12, 2019). |
| 10.44†† | First Amendment to the Development Collaboration and Exclusive License Agreement, dated as of July 18, 2019, by and between Molecular Templates, Inc. and Millennium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-32979), filed on November 12, 2019). |
| 10.45 | Underwriting Agreement, dated November 20, 2019, among Molecular Templates, Inc. and Cowen and Company, LLC, Barclays Capital Inc. and Stifel, Nicolaus & Company, Incorporated, as representatives of the several underwriters named therein (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K (File No. 001-32979), filed on November 25, 2019). |
| 10.46*†† | Master Collaboration Agreement, dated November 18, 2019, by and between Vertex Pharmaceuticals Incorporated and Molecular Templates, Inc. |
| 10.47* | Share Purchase Agreement, dated November 18, 2019, by and between Vertex Pharmaceuticals Incorporated and Molecular Templates, Inc. |
| 10.48+ | Executive Employment Agreement, dated February 19, 2019, by and between the Company and Roger J. Waltzman, M.D. |
| 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 and 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.

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

+ 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 13, 2020

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.

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---|--|----------------|
| <u> </u> /s/ Eric E. Poma, Ph.D. Eric E. Poma, Ph.D. | Chief Executive Officer and Chief Scientific Officer (Principal Executive Officer) | March 13, 2020 |
| <u> </u> /s/ Adam Cutler Adam Cutler | Chief Financial Officer (Principal Financial and Accounting Officer) | March 13, 2020 |
| <u> </u> /s/ Harold E. Selick, Ph.D. Harold E. Selick, Ph.D. | Director | March 13, 2020 |
| <u> </u> /s/ Jonathan Lanfear Jonathan Lanfear | Director | March 13, 2020 |
| <u> </u> /s/ David R. Hoffmann David R. Hoffmann | Director | March 13, 2020 |
| <u> </u> /s/ David Hirsch David Hirsch | Director | March 13, 2020 |
| <u> </u> /s/ Kevin Lalande Kevin Lalande | Director | March 13, 2020 |
| <u> </u> /s/ Scott Morenstein Scott Morenstein | Director | March 13, 2020 |
| <u> </u> /s/ Corazon "Corsee" Sanders, Ph.D. Corazon "Corsee" Sanders, Ph.D. | Director | March 13, 2020 |

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

Execution Version

MASTER COLLABORATION AGREEMENT
BETWEEN
VERTEX PHARMACEUTICALS INCORPORATED
AND
MOLECULAR TEMPLATES, INC.

November 18, 2019

MASTER COLLABORATION AGREEMENT

This Master Collaboration Agreement (this “**Agreement**”) is entered into as of November 18, 2019 (the “**Effective Date**”) by and between Vertex Pharmaceuticals Incorporated, a corporation organized under the laws of the Commonwealth of Massachusetts (“**Vertex**”) and Molecular Templates Inc., a corporation organized under the laws of the State of Delaware (“**Company**”). Vertex and Company each may be referred to herein individually as a “**Party**” or collectively as the “**Parties**.”

RECITALS

WHEREAS, Company controls certain Patents and Know-How, technology and expertise useful for generating ETBs (as defined below) capable of directing compounds to specific tissues or cells;

WHEREAS, Vertex is a biopharmaceutical company that possesses expertise in developing and commercializing human therapeutics;

WHEREAS, Vertex and Company desire to enter into a strategic collaboration focused on the development of novel products containing ETBs directed against certain Targets; and

WHEREAS, Vertex desires to receive from Company, and Company desires to grant to Vertex, a series of exclusive options to cause Company to grant to Vertex one or more exclusive licenses to exploit products containing ETBs directed against Collaboration Targets;

NOW, THEREFORE, in consideration of the respective covenants, representations, warranties and agreements set forth herein, the Parties agree as follows:

ARTICLE 1. DEFINITIONS

For purposes of this Agreement, the following capitalized terms will have the following meanings:

1.1. “**AAA**” has the meaning set forth in Section 13.12.2.

1.2. “**Acceptance of an IND**” means the 30th day following filing of an IND or, if a clinical hold is imposed by the FDA during such 30-day period, the day such hold is lifted.

1.3. “**Additional Target**” has the meaning set forth in Section 2.3.

1.4. “**Additional Target Option**” has the meaning set forth in Section 2.3.

1.5. “**Additional Target Option Exercise Fee**” has the meaning set forth in Section 7.4.

1.6. “**Additional Target Option Exercise Notice**” has the meaning set forth in Section 2.3.

1.7. “**Additional Target Option Period**” means the date starting on the Effective Date and ending on the later of (a) [***] of the Effective Date or (b) [***].

1.8. “**Additional Target Research Budget**” has the meaning set forth in Section 2.3.

1.9. “**Adverse Event**” has the meaning set forth in the Applicable Law for such term (or comparable term), and will generally mean any untoward medical occurrence in a subject in any Clinical Trial or patient who has received a pharmaceutical product, medical device or placebo, which occurrence does not necessarily have a causal relationship with such pharmaceutical product, medical device or placebo, including any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of the applicable pharmaceutical product, medical device or placebo whether or not related to such pharmaceutical product, medical device or placebo.

1.10. “**Affiliate**” means, as of any point in time and for so long as such relationship continues to exist with respect to any Person, any other Person that controls, is controlled by or is under common control with such Person. A Person will be regarded as in control of another Person if it (a) owns or controls, directly or indirectly, more than 50% of the equity securities of the subject Person entitled to vote in the election of directors (or, in the case of a Person that is not a corporation, for the election of the corresponding managing authority), or (b) possesses, directly or indirectly, the power to direct or cause the direction of the management or policies of such Person (whether through ownership of securities or other ownership interests, by contract or otherwise).

1.11. “**Agreement**” has the meaning set forth in the Preamble.

1.12. “**Agreement Know-How**” means any and all Know-How discovered, developed, invented or created solely by a Party or its Affiliates or Third Parties acting on its or their behalf, or jointly by both Parties or their respective Affiliates or Third Parties acting on their behalf, in each case, in the performance of activities under this Agreement.

1.13. “**Agreement Patents**” means any and all Patents that Cover any Agreement Know-How.

1.14. “**Agreement Technology**” means any Agreement Know-How and Agreement Patents.

1.15. “**Alliance Manager**” has the meaning set forth in Section 3.4.1.

1.16. “**Antibody**” means an unconjugated polyclonal or monoclonal antibody (whether (a) fully human, fully mouse, humanized, fully synthetic, bivalent, monovalent, phage display, in vitro display, ribosome-display, RNA display, DNA display, cell-display, chimeric, polyclonal, polyclonal mixes or any other type of antibody, (b) multiple or single chain, recombinant, in vivo, in vitro or naturally occurring, or a combination of the foregoing in any species, or (c) monospecific or bi-specific) or any analog, derivative, fragment or modification thereof (including a full antibody, single chain antibody, single domain antibody (sdAb (e.g., VHH)), scFv, scFvFc, Fab, or minibody). For clarity, Antibody does not include any ETB.

1.17. “**Antibody Agreement**” has the meaning set forth in Section 2.4.

1.18. “**Antibody Agreement Technology**” means, with respect to a Collaboration Target, any Product Agreement Technology specifically pertaining to an Antibody directed against such Collaboration Target.

1.19. “**Applicable Law**” means all applicable laws, statutes, rules, regulations and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, agency or other body, domestic or foreign, including any applicable rules, regulations, guidelines, or other requirements of the Regulatory Authorities that may be in effect from time to time, including the FD&C Act, PHSA, GCP, GLP and GMP, anti-bribery laws, such as the United States Anti-Kickback Statute, Foreign Corrupt Practices Act and UK Bribery Act, as well as all applicable data protection and privacy laws, rules and regulations, including the United States Department of Health and Human Services privacy rules under the Health Insurance Portability and Accountability Act, as amended, and the Health Information Technology for Economic and Clinical Health Act and the EU General Data Protection Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, along with other country-level data protection laws, as may be applicable.

1.20. “**Approval Application**” means an NDA, BLA or similar application or submission for a Licensed Product filed with a Regulatory Authority in a country or group of countries to obtain Marketing Approval for a pharmaceutical or biologic product in that country or group of countries, including any amendment thereof.

1.21. “**Audited Party**” has the meaning set forth in Section 7.11.

1.22. “**Auditing Party**” has the meaning set forth in Section 7.11.

1.23. “**Bankrupt Party**” has the meaning set forth in Section 5.5.

1.24. “**Bankruptcy Code**” means Title 11, United States Code, as from time to time in effect.

1.25. [***]

1.26. “**BLA**” means a biologics license application that is submitted to the FDA for a Licensed Product, pursuant to 21 C.F.R. § 601.2.

1.27. “**Blocking Third Party Intellectual Property**” means, [***].

1.28. “**Blocking Third Party Intellectual Property Costs**” means [***].

1.29. “**Breaching Party**” means the Party that is believed by the other Party to be in material breach of this Agreement.

1.30. “**Business Day**” means a Monday, Tuesday, Wednesday, Thursday or Friday that is not a day on which banking institutions in Boston, Massachusetts, or Austin, Texas, are authorized or obligated to close.

1.31. “**Calendar Quarter**” means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 or December 31, during the Term, or the applicable part thereof during the first or last calendar quarter of the Term.

1.32. “**Calendar Year**” means any calendar year ending on December 31, or the applicable part thereof during the first or last year of the Term.

1.33. “**Calendar Year Net Sales**” means, on a Vertex Target-by-Vertex Target basis, total Net Sales by Vertex, its Affiliates and Sublicensees in the Territory of all Licensed Products directed against the applicable Vertex Target in a particular Calendar Year.

1.34. “**CDA**” means that certain Mutual Confidentiality Agreement between Vertex and Company, dated June 14, 2019.

1.35. “**Change of Control**” means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than 50% of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of more than 50% of the combined voting power of the outstanding voting securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party’s business to which the subject matter of this Agreement relates. For clarity, a Change of Control does not include (i) an internal consolidation, merger, share exchange or other reorganization of a Party between or among such Party and one or more of its Affiliates, (ii) a sale of assets, merger, or other transaction effected exclusively for the purpose of changing domicile of a Party, or (iii) any public offering of a Party’s equity securities or other issuance of stock by a Party in an equity financing.

1.36. “**Clinical Trial**” means a study in humans conducted in accordance with GCP that is designed to generate data in support or maintenance of an Approval Application.

1.37. “**CMO**” means a contract manufacturing organization.

1.38. “**Collaboration Program**” means, on a Collaboration Target-by-Collaboration Target basis, a Research program directed to the Research of ETBs directed against such Collaboration Target pursuant to the Research Plan.

1.39. “**Collaboration Target**” means each of the Initial Target and, if Vertex exercises the Additional Target Option, the Additional Target, but excluding any Terminated Target.

1.40. **“Combination Product”** has the meaning set forth in Section 1.141.

1.41. **“Commercialize”** or **“Commercializing”** means to (a) market, promote, distribute, offer for sale, sell, have sold, import, export or otherwise commercialize a Licensed Product, (b) conduct activities, other than Research, Development and Manufacturing, in preparation for the foregoing activities, including obtaining Price Approval, or (c) conduct post-Marketing Approval studies (including Clinical Trials). When used as a noun, **“Commercialization”** means any activities involved in Commercializing.

1.42. **“Commercially Reasonable Efforts”** means, with respect to the efforts to be expended by any Person with respect to any objective, reasonable, [***] and good faith efforts to accomplish such objective. Without limiting the foregoing, **“Commercially Reasonable Efforts”** means (a) with respect to the conduct of the Research Activities and Follow-On Research by Company, [***] and (b) with respect to any objective relating to the Development or Commercialization of a Licensed ETB or Licensed Product by Vertex, that [***], taking into account [***]. **“Commercially Reasonable Efforts”** with respect to any objective relating to the Development or Commercialization of a Licensed ETB or Licensed Product by Vertex will be determined on a country-by-country basis and activities that are conducted in one country that have an effect on achieving the relevant objective in another country will be considered in determining whether Commercially Reasonable Efforts have been applied in such other countries.

1.43. **“Company”** has the meaning set forth in the Preamble.

1.44. **“Company Agreement Know-How”** means any ETB Agreement Know-How and any other Agreement Know-How solely owned by Company pursuant to Section 8.1.2(d).

1.45. **“Company Agreement Patent”** means any ETB Agreement Patent and any other Agreement Patent solely owned by Company pursuant to Section 8.1.2(d).

1.46. **“Company Background Know-How”** means, on a Development Candidate-by-Development Candidate basis, any Know-How, other than Company Agreement Know-How or Joint Agreement Know-How, that (a) Company or any of its Affiliates Controls as of the Effective Date or that comes into the Control of Company or any of its Affiliates during the Term and (b) is necessary [***] for the Research, Development, Manufacture or Commercialization of the applicable Development Candidate or any corresponding Licensed ETBs or Licensed Products. On a Development Candidate-by-Development Candidate basis, Company Background Know-How will exclude any Know-How (i) [***].

1.47. **“Company Background Patents”** means, on a Development Candidate-by-Development Candidate basis, any Patent, other than Company Agreement Patents or Joint Agreement Patents, that (a) Company or any of its Affiliates Controls as of the Effective Date or that comes into the Control of Company or any of its Affiliates during the Term and (b) claims any Company Background Know-How or is otherwise necessary [***] for the Research, Development, Manufacture or Commercialization of the applicable Development Candidate or any corresponding Licensed ETBs or Licensed Products. On a Development Candidate-by-Development Candidate basis, Company Background Patents will exclude any Patents (i) [***].

1.48. **“Company Background Technology”** means all Company Background Know-How and Company Background Patents.

1.49. **“Company Breach Event”** has the meaning set forth in Section 11.4.1.

1.50. **“Company Indemnified Party”** has the meaning set forth in Section 10.1.1.

1.51. **“Competitive Infringement”** has the meaning set forth in Section 8.4.1.

1.52. **“Competitive Product”** means, with respect to a particular Licensed Product in a particular country, a product on the market in such country being commercialized by any Third Party that is not a Sublicensee and that did not purchase such product in a chain of distribution that included any of Vertex or its Affiliates or Sublicensees, that (a) is approved by the applicable Regulatory Authority for at least one of the same Indications for which a Licensed Product has been approved in such country, under any then-existing laws and regulations in the applicable country pertaining to approval of generic or biosimilar biologic products, as a “generic” or “biosimilar” version of such Licensed Product, which approval uses such Licensed Product as a reference product and relies on or references information in the Approval Application for such Licensed Product, or (b) is otherwise recognized by the applicable Regulatory Authority as a biosimilar or interchangeable product to such Licensed Product.

1.53. **“Confidential Information”** means, with respect to each Party, all Know-How or other information, including proprietary information (whether or not patentable) regarding or embodying such Party’s technology, products, business information or objectives, that is communicated in any way or form by or on behalf of the Disclosing Party to the Receiving Party or its permitted recipients, pursuant to this Agreement or the CDA, whether or not such Know-How or other information is identified as confidential at the time of disclosure. Notwithstanding the foregoing, Confidential Information does not include any Know-How or information that, as evidenced by contemporaneous written records: (a) was already known by the Receiving Party (other than under an obligation of confidentiality to the Disclosing Party) at the time of disclosure by or on behalf of the Disclosing Party; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party, other than through any act or omission of the Receiving Party or its permitted recipients in breach of its obligations under this Agreement; (d) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to the Receiving Party; or (e) was independently discovered or developed by or on behalf of the Receiving Party without the use of any Confidential Information belonging to the Disclosing Party. Confidential Information disclosed to the Receiving Party hereunder will not be deemed to fall within the foregoing exceptions merely because broader or related information falls within such exceptions, nor will combinations of elements or principles be considered to fall within the foregoing exceptions merely because individual elements of such combinations fall within such exceptions. Without limiting the foregoing, and notwithstanding the exceptions set forth in clauses (a) through (e): (i) the terms of this Agreement will be considered Confidential Information of both Parties, with both Parties

deemed to be the Receiving Party of such Confidential Information; (ii) except as expressly set forth in clauses (iii) and (iv), any Know-How that is subject to a Party's ownership rights under this Agreement shall be deemed to be the Confidential Information of such Party and the other Party shall be deemed to be the Receiving Party of such Know-How; (iii) any Know-How or other non-public information specifically regarding a Development Candidate that is generated by or on behalf of Company or its Affiliates will be deemed to be (x) the Confidential Information of both Parties, with both Parties deemed to be the Receiving Party of such Confidential Information, prior to and until the License Effective Date (if Vertex exercises the Option) or the Option Deadline (if Vertex does not exercise the Option) with respect to such Development Candidate, (y) the Confidential Information of Vertex, with Company deemed to be the Receiving Party of such Confidential Information, commencing upon the License Effective Date (if Vertex exercises the Option) with respect to such Development Candidate, and (z) the Confidential Information of Company, with Vertex deemed to be the Receiving Party of such Confidential Information in the event Vertex does not exercise the Option with respect to such Development Candidate; *provided, however*, that, if any such Know-How or information is regarding more than one Development Candidate, and Vertex exercises the Option for some but not all of such Development Candidates, then such Know-How and information shall remain the Confidential Information of both Parties, with both Parties deemed to be the Receiving Party of such Confidential Information, following the applicable License Effective Date(s); and (iv) any Know-How or other non-public information within the Antibody Agreement Technology or otherwise regarding any Antibody directed against a Collaboration Target will be the Confidential Information of Vertex; *provided* that Company shall have the right to use and disclose such information as permitted pursuant to ARTICLE 12 in connection with the exercise of its rights and license under Section 5.2.2.

1.54. **“Control” or “Controlled”** means (a) with respect to a Party and any Know-How or Patent, possession of the ability by such Party or its Affiliate (whether by sole or joint ownership, license or otherwise), other than pursuant to this Agreement, to grant to the other Party, without violating the terms of any agreement with a Third Party, a license, access or other right in, to or under such Know-How or Patent, and (b) with respect to a Party and any tangible embodiments of Know-How, Regulatory Filings or documentation, possession of the ability by such Party or its Affiliate (whether by sole or joint ownership, license or otherwise), other than pursuant to this Agreement, to grant to the other Party, without violating the terms of any agreement with a Third Party, access to or disclosure of such tangible embodiments of Know-How, Regulatory Filings or documentation. Notwithstanding anything in this Agreement to the contrary, a Party and its Affiliates will be deemed to not Control any Know-How or Patents that are owned or controlled by a Third Party described in the definition of “Change of Control,” or such Third Party's Affiliates (other than such Party and its Preexisting Affiliates), (a) prior to the closing of such Change of Control, except to the extent that any such Know-How or Patents were developed by such Third Party prior to such Change of Control using or incorporating such Party's or its Preexisting Affiliate's Know-How or Patents or (b) after the closing of such Change of Control to the extent that such Know-How or Patents are developed or conceived by such Third Party or its Affiliates (other than such Party or its Preexisting Affiliates) after such Change of Control without using or incorporating such Party's or its Preexisting Affiliate's Know-How or Patents.

1.55. “**Cover**,” “**Covering**” or “**Covers**” means (a) as to a method, compound or product and Patent, that, in the absence of a license granted under, or ownership of, such Patent, the making, using, selling, offering for sale or importation of such method, compound or product would infringe any claim of such Patent or, as to a pending claim included in such Patent, the making, using, selling, offering for sale or importation of such method, compound or product would infringe the claim of such Patent if such pending claim were to issue in an issued patent without modification, and (b) [***] would infringe such Patent if such pending claim were to issue in an issued patent without modification.

1.56. “**Defending Party**” has the meaning set forth in Section 8.3.

1.57. “**Demand for Arbitration**” has the meaning set forth in Section 13.12.3(a).

1.58. “**Development**” means, with respect to a Licensed ETB or Licensed Product, all clinical and non-clinical research and development activities conducted after filing of an IND for such Licensed ETB or Licensed Product, including toxicology, pharmacology test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, Clinical Trials (other than post-Marketing Approval Clinical Trials), regulatory affairs, pharmacovigilance, Clinical Trial regulatory activities and obtaining and maintaining Marketing Approval. When used as a verb, “Develop” or “Developing” means to engage in Development.

1.59. “**Development Candidate**” means, with respect to any Collaboration Program, an ETB developed under this Agreement and directed against the Collaboration Target with respect to such Collaboration Program that has satisfied the applicable criteria set forth in the Research Plan or that has otherwise been designated as a “Development Candidate” by the JAC.

1.60. “**Development Milestone Event**” has the meaning set forth in Section 7.5.1.

1.61. “**Development Milestone Payment**” has the meaning set forth in Section 7.5.1.

1.62. “**Development Plan**” has the meaning set forth in Section 6.1.2.

1.63. “**directed against**” means, with respect to a Target and an ETB or product, that such ETB or product is selected, generated or optimized to preferentially bind to such Target.

1.64. “**Disclosing Party**” has the meaning set forth in Section 12.1.

1.65. “**Dispute**” has the meaning set forth in Section 13.12.

1.66. “**Distributor**” means a Third Party (a) to which Vertex or any of its Affiliates or Sublicensees grants a right to sell or distribute a Licensed Product, (b) that purchases its requirements for such Licensed Product from Vertex or its Affiliates or Sublicensees, (c) that has no significant responsibility for marketing and promotion of the Licensed Product, and (d) that does not otherwise make any royalty or other payments to Vertex or its Affiliates or Sublicensees with respect to its or their intellectual property rights or Licensed Products, including any payments that are calculated on the basis of a percentage of, or profit share on, such Third Party’s sale of Licensed Products.

1.67. “**DOJ**” has the meaning set forth in Section 4.2.2.

1.68. “**Effective Date**” has the meaning set forth in the Preamble.

1.69. “**EMA**” means the European Medicines Agency and any successor entity thereto.

1.70. “**Establishment of Proof of Concept**”, with respect to a Licensed Product, has the meaning for such term that is generally understood in drug development with respect to the potential for such Licensed Product to be approved, and will require [***].

1.71. “**ETB**” means any toxin, or subunit, fragment, or derivative thereof, including variants, such as deimmunized variants, variants with heterologous epitopes, furin-cleavage resistant variants and combinations thereof and any improvements to or derivatives of any of the foregoing, in each case, that is conjugated, fused (*e.g.*, as a single polypeptide chain), or otherwise combined with any Antibody or other targeting moiety.

1.72. “**ETB Agreement Know-How**” has the meaning set forth in Section 8.1.2(b).

1.73. “**ETB Agreement Patents**” has the meaning set forth in Section 8.1.2(b).

1.74. “**ETB Agreement Technology**” has the meaning set forth in Section 8.1.2(b).

1.75. “**ETB Platform**” means Company’s proprietary technology, including Know-How and Patents, relating to discovery, development, production or commercialization of ETBs that incorporate a bacterial toxin, or subunit, fragment, or derivative thereof, including variants, such as deimmunized variants, variants with heterologous epitopes, furin-cleavage resistant variants and combinations thereof and any improvements to or derivatives of any of the foregoing that is target independent, in each case, that is conjugated, fused (*e.g.*, as a single polypeptide chain) or otherwise combined with any Antibody or other targeting moiety, regardless of the target.

1.76. “**European Commission**” means the European Commission or any successor entity that is responsible for granting Marketing Approvals authorizing the sale of pharmaceuticals in the European Union.

1.77. “**European Union**” or “**EU**” means (a) the economic, scientific and political organization of member states known on the Effective Date as the European Union, as it may be constituted from time to time, which as of the Effective Date consists of Austria, Belgium, Bulgaria, Croatia, the Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the U.K., and (b) any member country of the European Economic Area that is not otherwise a member of the European Union. For clarity, and notwithstanding the foregoing, European Union will at all times include each of Germany, France, and the U.K.

1.78. “**Exclusive License**” has the meaning set forth in Section 5.1.1.

- 1.79. “**Executive Officers**” means the Chief Executive Officer of Company, initially (as of the Effective Date) Eric Poma, and the Chief Scientific Officer of Vertex, initially (as of the Effective Date) David Altshuler.
- 1.80. “**Existing Background Know-How**” has the meaning set forth in Section 9.2(i).
- 1.81. “**Existing Background Patents**” has the meaning set forth in Section 9.2(i).
- 1.82. “**Existing Background Technology**” has the meaning set forth in Section 9.2(i).
- 1.83. “**FDA**” means the United States Food and Drug Administration and any successor entity thereto.
- 1.84. “**FD&C Act**” means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.
- 1.85. “**Field**” means the treatment, prevention and diagnosis of all indications in humans.
- 1.86. “**First Commercial Sale**” means, with respect to a Licensed Product, the first sale of such Licensed Product by Vertex, its Affiliate or its Sublicensee to a Third Party resulting in Net Sales in a particular country after any required Marketing Approval has been obtained in such country; *provided* that the following will not constitute a First Commercial Sale: (a) any sale of a Licensed Product to an Affiliate or Sublicensee for resale; (b) any sale of a Licensed Product for use in Clinical Trials, pre-clinical studies or other Research or Development activities; (c) the disposal or transfer of a Licensed Product at or below cost for a *bona fide* charitable purpose; or (d) compassionate use and “named patient sales” at or below cost. Notwithstanding the foregoing, any compassionate use and “named patient sales” above cost shall constitute a sale of a Licensed Product, and such sale will qualify as a “First Commercial Sale” even if prior to obtaining the relevant Marketing Approval.
- 1.87. “**Follow-On Research**” has the meaning set forth in Section 2.5.
- 1.88. “**Follow-On Research Budget**” has the meaning set forth in Section 2.5.
- 1.89. “**Follow-On Research Plan**” has the meaning set forth in Section 2.5.
- 1.90. “**Force Majeure**” means a condition, the occurrence and continuation of which is beyond the reasonable control of a Party, including an act of God, governmental acts or restrictions, war, civil commotion, labor strike or lock-out, epidemic, flood, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe.
- 1.91. “**FTC**” has the meaning set forth in Section 4.2.2.

1.92. “**FTE**” means 1800 hours of work per annum, which number of hours shall be pro-rated based on the number of days when used for periods of less than 12 months, devoted to or in support of the Research Activities, Follow-On Research or Manufacturing Technology Transfer that is carried out by one or more scientific or technical employees (excluding Third Party contractors) of Company or its Affiliates.

1.93. “**FTE Costs**” means, for any period, the FTE Rate multiplied by the number of FTEs who perform a specified activity under this Agreement. FTEs will be pro-rated on a daily basis if necessary.

1.94. “**FTE Rate**” means \$[***]; *provided* that such rate will increase on January 1 of each Calendar Year (starting with January 1, 2021) in accordance with the percentage year-over-year increase in the Consumer Price Index – Urban Wage Earners and Clerical Workers, US City Average, All Items, 1982-84 = 100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index) over the 12-month period preceding each such January 1. The FTE Rate includes (a) all wages and salaries, employee benefits, bonus, travel and entertainment, supplies and other direct expenses and (b) indirect allocations, including all general and administrative expenses, human resources, finance, occupancy and depreciation, in each case ((a) and (b)), expended in connection with such FTE’s performance of activities under this Agreement.

1.95. “**Fully Burdened Manufacturing Cost**” will mean: (a) to the extent that Licensed ETB or Licensed Product is Manufactured by a CMO, (i) the actual reasonable costs of Company invoiced by such CMO to Company or its Affiliates, including, as applicable, the costs of raw materials, intermediates and components, reference materials, or standards required for release testing, materials necessary to support stability studies (including methods, reference materials, and consumables), drug substance and drug product Manufacturing, quality assurance and stability testing, characterization testing, quality control release testing of drug substance and drug product, quality assurance batch record review and release of product, insurance, storage and freight, shipping, tariffs, sales and excise taxes imposed thereon, customs and duty and charges levied by Governmental Authorities (including export fees) and all costs of labeling and packaging (if applicable), plus (ii) any [***] incurred by Company in connection with and attributable to such Manufacturing, including for process development, project management, Manufacturing oversight (including at the [***] for any person-in-plant of Company), and quality control and assurance; or (b) to the extent that Licensed ETB or Licensed Product is Manufactured by Company or its Affiliates, the fully burdened costs that are attributable to and reasonably allocated to such Manufacturing, including the cost of raw materials and any costs incurred by Company for time spent by Company’s personnel to obtain such raw materials (at the [***]), direct labor and benefits, a proportionate share of indirect Manufacturing costs to the extent allocable to the Manufacture of Licensed ETB or Licensed Product (but in no event any capital expenditures of Company or its Affiliates), and all other reasonable and customary Manufacturing-related costs for Licensed ETB or Licensed Product, including actual product inventory write-offs, factory, plant, or equipment start-up or start-up amortization costs, scale-up expenses, failed lots resulting from Force Majeure, quality assurance and stability testing, characterization testing, quality control release testing, quality assurance batch record review and release of product, insurance, storage and freight, shipping, tariffs, customs and duty and charges levied by Governmental Authorities (including export fees), and all costs of packaging and labeling. Such fully burdened costs will be calculated in accordance with GAAP.

- 1.96. “**GAAP**” means United States generally accepted accounting principles, consistently applied.
- 1.97. “**Gatekeeper**” has the meaning set forth in Section 2.3.2.
- 1.98. “**Gatekeeper Account**” has the meaning set forth in Section 2.3.2.
- 1.99. “**Gatekeeper Agreement**” has the meaning set forth in Section 2.3.2.

1.100. “**GCP**” means good clinical practices, which are the then-current standards for Clinical Trials for pharmaceuticals, as set forth in the FD&C Act or other Applicable Law, and such standards of good clinical practice as are required by the Regulatory Authorities of the European Union and other organizations and governmental authorities in countries for which the applicable Licensed ETB or Licensed Product is intended to be Developed, to the extent such standards are not less stringent than United States standards.

1.101. “**GLP**” means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, or the successor thereto, or comparable regulatory standards in jurisdictions outside of the United States as they may be updated from time to time, to the extent such standards are not less stringent than United States standards.

1.102. “**GMP**” means the then-current Good Manufacturing Practices as specified in the United States Code of Federal Regulations, ICH Guideline Q7A, or equivalent laws, rules or regulations of an applicable Regulatory Authority at the time of manufacture.

1.103. “**Governmental Authority**” means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

1.104. “**Grantor**” has the meaning set forth in Section 7.7.1(a).

1.105. “**HSR Act**” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

1.106. “**HSR Clearance Date**” means the later of (a) the earliest date on which the Parties have actual knowledge that all applicable waiting periods under the HSR Act with respect to the transactions contemplated under this Agreement upon Vertex’s exercise of an Option have expired or have been terminated, and (b) the Parties’ receipt of any other such antitrust clearance(s) as Vertex reasonably determines are necessary as a result of Vertex’s exercise of such Option.

1.107. “**HSR Filing**” means a filing by Company and Vertex, or their ultimate parent entities, as that term is defined in the HSR Act, with the FTC and the DOJ of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the transactions contemplated under this Agreement upon Vertex’s exercise of an Option, together with all required documentary attachments thereto.

1.108. “**Incomplete Data Package Notice**” has the meaning set forth in Section 4.1.1.

1.109. “**IND**” means any Investigational New Drug application (including any amendment or supplement thereto) filed with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, including any amendments thereto or if applicable, a comparable application or submission filed with a Regulatory Authority outside the U.S. for the investigation of any product in any other country or group of countries (such as a Clinical Trial Application in the EU).

1.110. “**Indemnified Party**” has the meaning set forth in Section 10.1.3.

1.111. “**Indemnifying Party**” has the meaning set forth in Section 10.1.3.

1.112. “**Indication**” means a separate and distinct disease or medical condition in humans (a) for which a compound or product that is in Clinical Trials is intended to be used in the treatment, diagnosis, prevention, cure or amelioration of subjects in such Clinical Trials, or (b) for which a compound or product has received a separate and distinct Marketing Approval with an approved label claim to be used in the treatment, diagnosis, prevention, cure or amelioration of such disease or condition, as applicable. For clarity, (i) different genetic subtypes of the same disease or condition shall be considered a separate and distinct Indication and (ii) [***].

1.113. “**Initial Target**” means [***], also known as [***].

1.114. “**Insolvency Event**” has the meaning set forth in Section 11.2.5.

1.115. “**IP Committee**” has the meaning set forth in Section 3.2.

1.116. “**JAC**” has the meaning set forth in Section 3.1.1.

1.117. “**Joint Agreement Know-How**” means any Agreement Know-How jointly owned by the Parties pursuant to Section 8.1.2(d).

1.118. “**Joint Agreement Patent**” means any Agreement Patent jointly owned by the Parties pursuant to Section 8.1.2(d).

1.119. “**Joint Agreement Technology**” means all Joint Agreement Know-How and Joint Agreement Patents.

1.120. “**Know-How**” means all non-public proprietary data, results, pre-clinical and clinical protocols and data from studies and Clinical Trials, chemical structures, chemical sequences, materials, information, inventions, know-how, formulas, trade secrets, techniques, methods, processes, procedures, technology, practices, knowledge and developments, whether or not patentable; *provided that* Know-How does not include Patents.

1.121. “**Knowledge**” means, with respect to Company, the actual knowledge of Company’s C-level officers, [***].

1.122. “**Later Company License Agreement**” has the meaning set forth in Section 7.7.2.

1.123. “**Liability**” has the meaning set forth in Section 10.1.1.

1.124. “**License Effective Date**” means, on a Development Candidate-by-Development Candidate basis for any Development Candidate for which Vertex exercises an Option (and all corresponding Licensed ETBs and Licensed Products), (a) if Vertex determines in accordance with Section 4.2.1 that an HSR Filing is required to be made under the HSR Act as a result of Vertex’s exercise of an Option with respect to such Development Candidate and notifies Company of such determination in accordance with Section 4.2.1, the date on which the Option Exercise Fee is paid following the HSR Clearance Date, and (b) other than under the circumstances described in clause (a), the date on which the Option Exercise Fee is paid following the delivery by Vertex to the Company of the Option Exercise Notice with respect to such Development Candidate in accordance with Section 4.1.2.

1.125. “**Licensed ETB**” means (a) any Development Candidate with respect to which Vertex has exercised the applicable Option and paid the Option Exercise Fee in accordance with this Agreement, and (b) any derivatives, improvements or modifications thereof developed by or on behalf of either Company or Vertex under this Agreement during the Term.

1.126. “**Licensed Know-How**” means the Company Background Know-How, the Company Agreement Know-How and Company’s interest in the Joint Agreement Know-How.

1.127. “**Licensed Patents**” means the Company Background Patents, the Company Agreement Patents and Company’s interest in the Joint Agreement Patents.

1.128. “**Licensed Product**” means any pharmaceutical or biologic product containing a Licensed ETB, either alone or in combination with other active pharmaceutical ingredients, including all forms, presentations, strengths, doses and formulations thereof.

1.129. “**Licensed Technology**” means the Licensed Patents and Licensed Know-How.

1.130. “**Licensee**” has the meaning set forth in Section 7.7.2.

1.131. “**Major EU Market**” means each of France, Germany and the U.K.

1.132. “**Major Market Country**” means each of France, Germany, Japan, the U.K. and the U.S.

1.133. “**Manufacture,**” “**Manufactured**” or “**Manufacturing**” means activities directed to making, having made, producing, formulating, manufacturing, processing, filling, finishing, packaging, labeling, quality control testing and quality assurance release, shipping or storage of a Licensed ETB or Licensed Product.

1.134. “**Manufacturing Technology Transfer**” has the meaning set forth in Section 6.3.3.

1.135. “**Manufacturing Technology Transfer Budget**” has the meaning set forth in Section 6.3.3.

1.136. “**Manufacturing Technology Transfer Plan**” has the meaning set forth in Section 6.3.3.

1.137. “**Marketing Approval**” means, with respect to a Licensed Product in a particular jurisdiction, all approvals (including approvals resulting from any priority review, breakthrough therapy, accelerated approval or fast track application or submission), licenses, registrations or authorizations necessary for the Commercialization of such Licensed Product in such jurisdiction, including, with respect to the United States, approval of an Approval Application for such Licensed Product by the FDA and with respect to the European Union, approval of an Approval Application for such Licensed Product by the European Commission or the applicable Regulatory Authority in any particular country in the EU, but excluding, in each case, Price Approval.

1.138. “**Milestone Event**” has the meaning set forth in Section 7.5.2.

1.139. “**Milestone Payment**” has the meaning set forth in Section 7.5.2.

1.140. “**NDA**” means a new drug application that is submitted to the FDA for a Licensed Product, pursuant to 21 C.F.R. § 314.3.

1.141. “**Net Sales**” means the [***] invoiced price for Licensed Products sold by Vertex, its Affiliates or Sublicensees (the “**Selling Party**”) to Third Parties (excluding sales deferred for GAAP accounting purposes until such sales are recognized), less the following deductions from such [***] amounts (if not already deducted in the amount invoiced), provided and only to the extent that such items are actually allowed and taken by the Selling Party:

- (a) c[***];
- (b) [***]; *provided* that, the Selling Party shall use Commercially Reasonable Efforts to [***];
- (c) [***];
- (d) [***], to the extent incurred by a Selling Party and not reimbursed by a non-related party;
- (e) [***]; and
- (f) [***], to the extent borne by the Selling Party, *provided* that [***].

Only items in (a)-(f) above that are deducted from the Selling Party's [***] sales of Licensed Product(s), as included in the Selling Party's published financial statements and that are in accordance with GAAP, applied on a consistent basis, will be deducted from such [***] sales for purposes of the calculation of Net Sales. Notwithstanding the foregoing, amounts written off by the Selling Party by reason of uncollectible debt or pursuant to clause (f) above may be deducted from Net Sales in accordance with clause (b) and clause (f) above, respectively, regardless of its classification in the Selling Party's published financial statements.

A qualifying amount may be deducted only once regardless of the number of the preceding categories that describes such amount. If a Selling Party makes any adjustment to such deductions after the associated Net Sales have been reported pursuant to this Agreement, the adjustments and payment of any royalties due will be reported with the next quarterly report. Sales between or among Vertex, its Affiliates and Sublicensees will be excluded from the computation of Net Sales, but Net Sales will include the subsequent final sales to Third Parties by Vertex or any such Affiliates or Sublicensees. A Licensed Product will not be deemed to be sold if the Licensed Product is provided free of charge to a Third Party in reasonable quantities as a sample consistent with industry standard promotional and sample practices.

If a sale, transfer or other disposition with respect to a Licensed Product involves consideration other than cash or is not at arm's length, the Net Sales from such sale, transfer or other disposition will be calculated on the average Net Sales price of the Licensed Product in arm's length sales for cash in the relevant country during the same Calendar Quarter as such sale, transfer or other disposition or in the absence of such sales, the fair market value of the Licensed Product as mutually determined by the Parties in good faith.

Solely for purposes of calculating Net Sales, if, in any country, Vertex or its Affiliates or any permitted Sublicensee sells [***] (each, an "Other Product") [***] (such combination product, a "Combination Product"), Net Sales of such Combination Product in such country for the purpose of determining the payments due to Company pursuant to this Agreement will be calculated by [***] ("Combination Product Net Sales") [***].

1.142. "New Company Agreement" has the meaning set forth in Section 7.7.2.

1.143. "New Platform Agreement" has the meaning set forth in Section 7.7.1.

1.144. "Non-Bankrupt Party" has the meaning set forth in Section 5.5.

1.145. "Non-Breaching Party" means the Party that believes the other Party is in material breach of this Agreement.

1.146. "Non-Defending Party" has the meaning set forth in Section 8.3.

1.147. "Option" has the meaning set forth in Section 4.1.

1.148. "Option Deadline" has the meaning set forth in Section 4.1.2.

1.149. “**Option Exercise Data Package**” means, with respect to each Development Candidate, a package containing the information specified in Schedule 1.149 to be included in the Option Exercise Data Package for such Development Candidate.

1.150. “**Option Exercise Fee**” has the meaning set forth in Section 7.3.

1.151. “**Option Exercise Notice**” has the meaning set forth in Section 4.1.2.

1.152. “**Other Company License Agreement**” has the meaning set forth in Section 7.7.1.

1.153. “**Other Product**” has the meaning set forth in Section 1.141.

1.154. “**Out-of-Pocket Costs**” means, with respect to a Party, costs and expenses actually paid by such Party or its Affiliates to Third Parties (or payable to Third Parties and accrued in accordance with GAAP), other than employees of such Party or its Affiliates. For clarity, Out-of-Pocket Costs includes costs and expenses paid by Company to Third Party contractors in the performance of Follow-On Research and Manufacturing Technology Transfer.

1.155. “**Party**” or “**Parties**” has the meaning set forth in the Preamble.

1.156. “**Patents**” means all rights and interests in and to granted or issued patents and pending patent applications in any country, jurisdiction or region (including inventor’s certificates and utility models), including all provisionals, non-provisionals, substitutions, continuations, continuations-in-part, divisionals, renewals and all patents granted thereon, and all reissues, reexaminations, extensions, confirmations, revalidations, registrations and patents of addition thereof, including patent term extensions and supplementary protection certificates, international patent applications filed under the Patent Cooperation Treaty (PCT) and any national stage application and any equivalents to any of the foregoing.

1.157. “**Person**” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision or department or agency of a government.

1.158. “**Phase 2 Clinical Trial**” means any Clinical Trial of a Licensed Product as described in 21 C.F.R. § 312.21(b), or, with respect to a jurisdiction other than the United States, a similar Clinical Trial of a Licensed Product. For clarity, Phase 2 Clinical Trial includes any Phase 2a clinical study of a Licensed Product or Phase 2b clinical study of a Licensed Product.

1.159. “**PHSA**” means the U.S. Public Health Service Act, as amended, and the rules and regulations promulgated thereunder.

1.160. **“Pivotal Clinical Trial”** means, with respect to a Licensed Product, (a) a pivotal Clinical Trial in humans performed to gain evidence of the efficacy of such Licensed Product in a target population, and to obtain expanded evidence of safety for such Licensed Product that is needed to evaluate the overall benefit-risk relationship of such Licensed Product, [***] that could lead to obtaining Marketing Approval from a Regulatory Authority for such Licensed Product or (b) a Clinical Trial as described in 21 C.F.R. § 312.21(c), or, with respect to a jurisdiction other than the United States, a similar Clinical Trial of a Licensed Product.

1.161. **“Preexisting Affiliate”** means, with respect to a Party that is subject to a Change of Control, any Affiliate of such Party following such Change of Control that was an Affiliate of such Party prior to such Change of Control.

1.162. **“Price Approval”** means, in any country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of any government approval, agreement, determination or decision establishing such reimbursement authorization or pricing approval or determination.

1.163. **“Proceeding”** means any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), prosecution, contest, hearing, inquiry, inquest, audit, examination or investigation that is, has been or may in the future be commenced, brought, conducted or heard at law or in equity or before any Governmental Authority.

1.164. **“Product Agreement Know-How”** has the meaning set forth in Section 8.1.2(c).

1.165. **“Product Agreement Patents”** has the meaning set forth in Section 8.1.2(c).

1.166. **“Product Agreement Technology”** has the meaning set forth in Section 8.1.2(c).

1.167. **“Proposed New Company Agreement”** has the meaning set forth in Section 7.7.1.

1.168. **“Prosecution and Maintenance”** or **“Prosecute and Maintain”** means, with respect to a Patent, the preparing, filing, prosecuting and maintenance of such Patent, as well as handling re-examinations and reissues with respect to such Patent, together with the conduct of derivation proceedings, the defense of oppositions, post-grant patent proceedings (such as *inter partes* review and post grant review) and other similar proceedings with respect to such Patent.

1.169. **“R&D Supply Agreement”** has the meaning set forth in Section 6.3.2.

1.170. **“Receiving Party”** has the meaning set forth in Section 12.1.

1.171. **“Reduction Circumstances”** has the meaning set forth in Section 7.6.3.

1.172. **“Regulatory Authority”** means, with respect to a country in the Territory, any national (*e.g.*, the FDA), supra-national (*e.g.*, the European Commission, the Council of the European Union or the EMA), regional, state or local regulatory agency, department, bureau, board, commission, council or other Governmental Authority that holds responsibility for development and commercialization of, or the granting of Marketing Approval for, a pharmaceutical product in such country or region.

1.173. **“Regulatory Exclusivity”** means, with respect to a Licensed Product in a country, any data exclusivity rights or other exclusive right, other than a Patent, granted, conferred or afforded by any Regulatory Authority in such country or otherwise under Applicable Law with respect to such Licensed Product in such country, which either confers exclusive marketing rights with respect to a product or prevents another party from using or otherwise relying on the data supporting the approval of the Marketing Approval for a product without the prior written authorization of the Marketing Approval holder, as applicable, such as new chemical entity exclusivity, exclusivity associated with new Clinical Trials necessary to approval of a change (*e.g.*, new indication or use), orphan drug exclusivity, non-patent-related pediatric exclusivity, or any other applicable marketing or data exclusivity, including any such periods under national implementations in the EU of Article 10 of Directive 2001/83/EC, Article 14(11) of Parliament and Council Regulation (EC) No 726/2004, Parliament and Council Regulation (EC) No 141/2000 on orphan medicines, Parliament and Council Regulation (EC) No 1901/2006 on medicinal products for pediatric use and all international equivalents.

1.174. **“Regulatory Filings”** means, collectively: (a) all INDs, Approval Applications, establishment license applications, Drug Master Files, applications for designation as an “Orphan Product(s)” under the Orphan Drug Act, for “Fast Track” status under Section 506 of the FD&C Act (21 U.S.C. § 356) or for a Special Protocol Assessment under Section 505(b)(4)(B) and (C) of the FD&C Act (21 U.S.C. § 355(b)(4)(B)) and all other similar filings (including counterparts of any of the foregoing in any country or region in the Territory); (b) any applications for Marketing Approval or Price Approval and other applications, filings, dossiers or similar documents submitted to a Regulatory Authority in any country for the purpose of obtaining Marketing Approval or Price Approval from that Regulatory Authority; (c) any Patent-related filings with any Regulatory Authority; (d) all supplements and amendments to any of the foregoing; (e) all documents referenced in the complete regulatory chronology for each Marketing Approval; (f) foreign equivalents of any of the foregoing; and (g) all data and other information contained in, and correspondence with any Regulatory Authority relating to, any of the foregoing.

1.175. **“Research”** means conducting research activities to discover, design, optimize, deliver and advance potential Development Candidates, Licensed ETBs and Licensed Products, including pre-clinical studies and optimization, but specifically excluding Development, Manufacture and Commercialization. When used as a verb, “Researching” means to engage in Research.

1.176. **“Research Activities”** means the activities set forth in the Research Plan.

- 1.177. **“Research Plan”** means the research plan attached hereto as Schedule 1.177, as such research plan may be updated pursuant to Section 2.2.3 or Section 2.3.
- 1.178. **“Reserved Target”** has the meaning set forth in Section 2.3.1.
- 1.179. **“Reserved Target Designation Date”** has the meaning set forth in Section 2.3.1.
- 1.180. **“Reserved Target Notice”** has the meaning set forth in Section 2.3.1.
- 1.181. **“Reserved Target Outside Date”** means the date that is [***] after the Reserved Target Designation Date.
- 1.182. **“Residual Knowledge”** means knowledge, techniques, experience and Know-How that are (a) reflected in any Confidential Information owned or Controlled by the Disclosing Party and (b) retained in the unaided memory of any authorized representative of the Receiving Party after having access to such Confidential Information. A Person’s memory will be considered to be unaided if the Person has not intentionally memorized the Confidential Information for the purpose of retaining and subsequently using or disclosing it. In no event, however, will Residual Knowledge include any knowledge, techniques, experience or Know-How to the extent (at any time, for such time) within the scope of any Patent owned or Controlled by the Disclosing Party.
- 1.183. **“Royalty Term”** means, with respect to a Licensed Product in a country, the period commencing on the First Commercial Sale of such Licensed Product in such country and ending upon the latest of: (a) the expiration of the last Valid Claim of a Licensed Patent that Covers such Licensed Product or the method of use or manufacture of such Licensed Product in such country; (b) [***] after the First Commercial Sale of such Licensed Product in such country; or (c) expiration of Regulatory Exclusivity, if any, in such country with respect to such Licensed Product.
- 1.184. **“Rules”** has the meaning set forth in Section 13.12.3.
- 1.185. **“Sales Milestone Event”** has the meaning set forth in Section 7.5.2.
- 1.186. **“Sales Milestone Payment”** has the meaning set forth in Section 7.5.2.
- 1.187. **“Secondary Indication”** means, with respect to a Licensed Product and a regulatory jurisdiction, any Indication that is not the first Indication for which such Licensed Product has received Marketing Approval in such regulatory jurisdiction.
- 1.188. **“Selling Party”** has the meaning set forth in Section 1.141.
- 1.189. **“Subcontractor”** means a Third Party (including any consultant, subcontractor, academic researcher or other vendor) engaged by a Party to conduct activities on behalf of such Party or its Affiliates under this Agreement.

1.190. “**Sublicense**” means, directly or indirectly, to sublicense or grant any other right under the rights granted to Vertex hereunder. When used as a noun, “Sublicense” means any agreement to Sublicense.

1.191. “**Sublicensee**” means an Affiliate or Third Party, other than a Distributor, to whom Vertex (or a Sublicensee or Affiliate) Sublicenses any of the rights granted to Vertex under this Agreement during the Term.

1.192. “**Target**” means a specific protein that is associated with an ENSEMBL GENE ID, together with any and all naturally occurring mutations, variants and alternative sequences thereof, and fragments or peptides thereof that are of sufficient specificity or length to still uniquely match the original ENSEMBL GENE ID.

1.193. “**Target Availability Notice**” has the meaning set forth in Section 2.3.2.

1.194. “**Term**” has the meaning set forth in Section 11.1.

1.195. “**Terminated Target**” means any Collaboration Target with respect to which, as of the applicable Option Deadline for the final Development Candidate (as determined by the JAC), Vertex has not exercised any Option for any Development Candidate directed against such Collaboration Target.

1.196. “**Territory**” means worldwide.

1.197. “**Third Party**” means any Person other than Vertex, Company or their respective Affiliates.

1.198. “**Third Party Infringement Claim**” has the meaning set forth in Section 8.3.

1.199. “**Unavailable Target**” means any Target for which (a) Company has established an internal research program with respect to such Target whereby Company is actively pursuing, has committed an approved budget with respect to, or has entered into a Third Party contract with respect to, the identification of products directed against such Target using the ETB Platform, or (b) Company has executed a binding, arm’s length agreement with a Third Party, which agreement would be breached if such Target became a Reserved Target or an Additional Target pursuant to the terms of this Agreement.

1.200. “**United Kingdom**” or “**U.K.**” means the United Kingdom of Great Britain and Northern Ireland, as it may be constituted from time to time. For clarity, United Kingdom will at all times include England.

1.201. “**United States**” or “**U.S.**” means the United States of America and all of its districts, territories and possessions.

1.202. “**Valid Claim**” means a claim (a) of any issued or granted, unexpired United States or foreign Patent, which has not, in the country or jurisdiction of grant or issuance, been donated to the public, disclaimed, held invalid or unenforceable by a court of competent jurisdiction in an unappealed or unappealable decision, or (b) of any United States or foreign patent application, which has not, in the country in question, been cancelled, withdrawn, or abandoned (without the possibility of appeal, reinstatement or re-filing). Notwithstanding the foregoing, on a country-by-country or jurisdiction-by-jurisdiction basis, a patent application pending for more than seven years will not be considered to have any Valid Claim for purposes of this Agreement unless and until a Patent that meets the criteria set forth in clause (a) above with respect to such application issues.

1.203. “**Vertex**” has the meaning set forth in the Preamble.

1.204. “**Vertex Agreement Know-How**” means any Product Agreement Know-How and any other Agreement Know-How solely owned by Vertex pursuant to Section 8.1.2(d).

1.205. “**Vertex Agreement Patent**” means any Product Agreement Patent and any other Agreement Patent solely owned by Vertex pursuant to Section 8.1.2(d).

1.206. “**Vertex Agreement Technology**” means all Vertex Agreement Know-How and Vertex Agreement Patents.

1.207. “**Vertex Background Know-How**” means, on a Collaboration Target-by-Collaboration Target or Vertex Target-by-Vertex Target (with respect to Follow-On Research) basis, any Know-How, other than Vertex Agreement Know-How and Joint Agreement Know-How, that is Controlled by Vertex or its Affiliates as of the Effective Date or during the Term and is actually provided or made available by or on behalf of Vertex to Company under this Agreement for use in the Research Activities allocated to Company under each Research Plan with respect to such Collaboration Target or the Follow-On Research with respect to such Vertex Target, as applicable.

1.208. “**Vertex Background Patent**” means, on a Collaboration Target-by-Collaboration Target or Vertex Target-by-Vertex Target (with respect to Follow-On Research) basis, any Patent, other than Vertex Agreement Patents or Joint Agreement Patents, that is Controlled by Vertex or its Affiliates as of the Effective Date or during the Term and Covers any Vertex Background Know-How.

1.209. “**Vertex Background Technology**” means the Vertex Background Know-How and the Vertex Background Patents.

1.210. “**Vertex Indemnified Party**” has the meaning set forth in Section 10.1.2.

1.211. “**Vertex Target**” means any Collaboration Target for which Vertex has exercised an Option under this Agreement for at least one Development Candidate directed against such Collaboration Target.

1.212. “**Vertex Technology**” means the Vertex Background Technology, the Vertex Agreement Technology and Vertex’s interest in the Joint Agreement Technology.

**ARTICLE 2.
RESEARCH**

2.1. **Research Overview.** On a Collaboration Program-by-Collaboration Program basis, Company (directly or through its Affiliates or Subcontractors) will use Commercially Reasonable Efforts to perform the Research Activities for such Collaboration Program, for the purpose of generating Development Candidate(s) directed against the applicable Collaboration Target in accordance with the Research Plan. The Parties acknowledge that each Collaboration Program could result in the identification of no Development Candidate(s) for such Collaboration Program or multiple Development Candidates for such Collaboration Program.

2.2. **Research Activities.**

2.2.1. **Development and Approval of Research Plan.** The Research Plan sets forth, and any amendment or update to the Research Plan approved in accordance with the terms of this Agreement will set forth, (i) the anticipated start date of the Research Activities for the applicable Collaboration Target, (ii) a high-level description of the activities Company anticipates are reasonably necessary to identify a Development Candidate for the applicable Collaboration Target, (iii) projected high-level estimates on the timeline for activities under the Research Plan and (iv) anticipated FTEs intended to be allocated to activities under the Research Plan, which FTEs shall be suitably qualified to conduct such activities. In the event of any inconsistency between the Research Plan and this Agreement, the terms of this Agreement will prevail.

2.2.2. **Conduct of Collaboration Programs.** Company (directly or through its Affiliates or Subcontractors) will perform the Research Activities in accordance with the Research Plan in a professional and timely manner and in accordance with all Applicable Laws.

2.2.3. **Amendments to Research Plan.** Company or Vertex may provide any proposed amendments to the Research Plan to the JAC for review and approval. The JAC may amend the Research Plan at any time; *provided* that, notwithstanding Section 3.1.4, such amended Research Plan shall (a) at all times meet the requirements set forth in Section 2.2.1 and (b) not materially decrease the Research Activities or decrease the level of scientific experience and expertise of the FTEs performing Research Activities without Vertex’s written consent. Notwithstanding the foregoing or Section 3.1.4, [***], *provided* that Company will remain obligated to conduct all proposed Research Activities that are consistent with [***], or, if the Research Plan was previously amended in accordance with this Agreement, as of the most recent amendment effective date of the Research Plan, [***]. Any such costs that the Parties agree will be incurred by Company and reimbursed by Vertex will be reimbursed in accordance with Section 7.8.

2.2.4. **Costs of Research.** With respect to the Collaboration Program for the Initial Target, all Research Activities will be conducted by Company (directly or through its Affiliates or Subcontractors) at Company's sole cost and expense (except as set forth in Section 2.2.3 and Section 7.8 and as otherwise may be agreed by the Parties in writing) in accordance with the Research Plan. If Vertex exercises the Additional Target Option, then, with respect to the Collaboration Program for the Additional Target, Vertex shall reimburse Company in accordance with Section 7.8 for Company's [***] incurred in conducting (directly or through its Affiliates or Subcontractors) the applicable Research Activities in accordance with the Research Plan and the Additional Target Research Budget, as the same may be updated or amended.

2.3. **Additional Target Option.** During the Additional Target Option Period, subject to Section 2.3.2, Company hereby grants to Vertex an option (the "**Additional Target Option**") to designate (a) one additional Target or (b) in the case of exercise of the Additional Target Option for the purpose of generating Development Candidates that are [***], either (i) [***] or (ii) [***], in each case ((a) and (b)) as a Collaboration Target under this Agreement (any such Target, other than the Initial Target, described in [***], an "**Additional Target**"). Vertex may exercise the Additional Target Option at any time during the Additional Target Option Period by providing written notice to the Gatekeeper (or, in the case of exercise of the Additional Target Option for the Reserved Target, written notice to the Gatekeeper and Company) (in either case, the "**Additional Target Option Exercise Notice**"), which Additional Target Option Exercise Notice will identify the proposed Additional Target, *provided* that, after the [***] anniversary of the Effective Date until the end of the Additional Target Option Period, if applicable, Vertex may only exercise the Additional Target Option for the Reserved Target. If Vertex delivers an Additional Target Option Exercise Notice and (x) the proposed Additional Target is the Reserved Target or (y) the proposed Additional Target is not the Reserved Target, but the applicable Target Availability Notice delivered by the Gatekeeper pursuant to Section 2.3.2 states that such proposed Additional Target is not an Unavailable Target, then, in either case ((x) or (y)), Vertex will pay Company the Additional Target Option Exercise Fee in accordance with Section 7.4, and such proposed Additional Target will automatically be deemed the "Additional Target" under this Agreement upon such payment of the Additional Target Option Exercise Fee. [***]. Within [***] following Vertex's delivery to Company of the Additional Target Option Exercise Notice, Company will update the Research Plan to add (A) Research Activities designed to identify and Research ETBs directed against the Additional Target, which Research Activities will be substantially similar in scope to the Research Activities contemplated in Schedule 1.177 as of the Effective Date for the Collaboration Program for the Initial Target, unless otherwise agreed to by the Parties, (B) a budget for such Research Activities, which budget will use methodologies consistent with the internal budget used by Company for the Collaboration Program for the Initial Target (the "**Additional Target Research Budget**"), and (C) criteria for the designation of Development Candidates directed against the Additional Target, which criteria will be consistent with those criteria set forth in the Research Plan for the Initial Target, and will provide the updated Research Plan to the JAC for review and approval. Any such updated Research Plan will at all times meet the requirements set forth in Section 2.2.1.

2.3.1. **Reserved Targets.** At any time during the period between the Effective Date and the [***] anniversary of the Effective Date prior to Vertex's exercise of the Additional Target Option, subject to Section 2.3.2, Vertex may designate a single Target as reserved for the Additional Target Option (the "**Reserved Target**") by providing written notice to the Gatekeeper (the "**Reserved Target Notice**"), which Reserved Target Notice will identify the proposed Reserved Target. In such event, unless the applicable Target Availability Notice delivered by the Gatekeeper pursuant to Section 2.3.2 states that such proposed Reserved Target is an Unavailable Target, such proposed Reserved Target will automatically be designated as the Reserved Target as of the date the Gatekeeper identifies the Reserved Target in the Target Availability Notice provided to the Parties pursuant to Section 2.3.2 (such date, the "**Reserved Target Designation Date**"). [***]. Unless the applicable Target Availability Notice delivered by the Gatekeeper pursuant to Section 2.3.2 states that such proposed other Target is an Unavailable Target, such proposed other Target will automatically be designated as the Reserved Target, and the Target formerly designated as the Reserved Target will no longer be the Reserved Target; *provided* that the Reserved Target Designation Date shall remain the same and neither the Reserved Target Designation Date nor the Reserved Target Outside Date shall be modified in the event [***]. Notwithstanding anything to the contrary in this Agreement, if Vertex does not exercise its Additional Target Option to add the Reserved Target as an Additional Target prior to the Reserved Target Outside Date, such Reserved Target will no longer be a Reserved Target, *provided* that Vertex may still exercise the Additional Target Option for such former Reserved Target during the Additional Target Option Period, subject to the procedures set forth in Section 2.3.2 (for clarity, as long as such former Reserved Target does not become an Unavailable Target). If Vertex exercises the Additional Target Option to add Target(s) that are not the Reserved Target as the Additional Target, then the Reserved Target will cease to be a Reserved Target effective as of the exercise of the Additional Target Option.

2.3.2. **Unavailable Targets.** On or before the Effective Date, Company will have established an account (the "**Gatekeeper Account**") with a Third Party mutually agreed to by the Parties (the "**Gatekeeper**") for the purpose of depositing a list of Unavailable Targets, which Company will have deposited in the Gatekeeper Account on or before the Effective Date. Concurrently with the establishment of the Gatekeeper Account, the Parties and the Gatekeeper will enter into a three-way agreement (the "**Gatekeeper Agreement**") governing the use and purpose of the Gatekeeper Account, a form of which is attached hereto as Schedule 2.3.2. The Gatekeeper Agreement will provide that, if Vertex proposes to (a) exercise the Additional Target Option to designate an Additional Target or (b) designate a Reserved Target, then (i) Vertex shall provide to the Gatekeeper the Additional Target Option Exercise Notice or the Reserved Target Notice, as applicable, identifying the proposed Additional Target or the proposed Reserved Target, as applicable, (ii) the Gatekeeper shall notify Company within two Business Days that Vertex has indicated interest in an unspecified Additional Target or an unspecified Reserved Target, as applicable (without identifying the proposed Additional Target or Reserved Target, as applicable, to Company), (iii) within [***] after such notice, Company shall provide the Gatekeeper with an updated list of Unavailable Targets as of the date of the Additional Target Option Exercise Notice or the Reserved Target Notice, as applicable (which updated list shall remove any Target formerly identified as an Unavailable Target that no longer satisfies the definition of an Unavailable Target), and (iv) within [***] after the Gatekeeper's receipt of Company's updated list of Unavailable Targets, the Gatekeeper shall notify the Parties whether the proposed Additional Target or Reserved Target, as applicable, is an Unavailable Target (a "**Target Availability Notice**"). If the proposed Additional Target or Reserved Target, as applicable, is not an Unavailable Target, the Target Availability Notice will include the identity of such proposed Additional Target or Reserved Target, as applicable. Company will be solely responsible for all expenses relating to the Gatekeeper Account.

2.4. **Rights to Antibodies.** Company will use [***] to obtain rights to Antibodies directed against each Collaboration Target and having properties as specified in the Research Plan, either by license from a Third Party or through engaging a Subcontractor, each as identified in the Research Plan, to identify such Antibodies. Company and Vertex will confer and collaborate with respect to obtaining rights to such Antibodies, and the Parties shall mutually agree on whether to license or acquire such rights, and from which Third Party identified in the Research Plan. Following such agreement of the Parties, Company will use [***] to negotiate a license or subcontract with such Third Party (or, as applicable, a new statement of work under an existing agreement with such Third Party) and will provide Vertex with the right to review and approve any such contract between Company or its Affiliates and such Third Party (each such agreement, including any such statements of work, an “**Antibody Agreement**”). Company will not enter into or subsequently amend any Antibody Agreement without the prior written approval of Vertex, which approval may be conditioned, delayed or withheld in Vertex’s sole discretion. [***] shall be [***] responsible for any payment obligations arising under any Antibody Agreement approved by Vertex directly as a result of the Research of such Antibodies directed against a Collaboration Target by or on behalf of Company, Vertex or any of their respective Affiliates or Vertex’s Sublicensees; *provided that*, if any such payment obligations constitute milestone or royalty payments due under such Antibody Agreement, after application of all available reductions to and deductions from such payment obligations under the applicable Antibody Agreement, Company shall provide Vertex with a reasonably detailed invoice for such milestone and royalty payments made by Company within [***] of the end of each Calendar Quarter in which any such payments were made by Company, and Vertex shall pay the undisputed portion of such invoice within [***] of receipt thereof. The provision of Section 7.9 shall apply to such amounts paid or payable by Vertex, *mutatis mutandis*. In the event that Vertex does not approve an Antibody Agreement [***], Vertex may contract directly with the applicable Third Party to obtain rights to such Antibody, in which case, (a) [***] incurred in obtaining such Antibody (*i.e.*, [***]) up to [***] per Antibody Agreement for up to [***] Antibody Agreements, *provided that* (i) if Company has already entered into one Antibody Agreement, [***]. Without limiting the provisions of Section 8.1.2, if Vertex exercises the Option with respect to a Development Candidate and pays the applicable Option Exercise Fee in accordance with this Agreement, Company hereby assigns and agrees assign to Vertex or its designee (x) if the rights to the applicable Antibody(ies) have been licensed by Company, the Antibody Agreement related to the applicable Antibody(ies) or (y) if the rights to the applicable Antibody(ies) are owned by Company, all intellectual property rights related to the applicable Antibody(ies), in each case, that are included in the applicable Development Candidate with respect to such exercised Option (to the extent not already assigned to Vertex pursuant to Section 8.1.2).

2.5. **Follow-On Research.** On a Development Candidate-by-Development Candidate basis, following the License Effective Date with respect to such Development Candidate, Vertex may request for Company to conduct additional research activities with respect to the applicable Licensed ETBs or Licensed Products, and Company may agree, in its discretion, to conduct such additional research activities. On a Development Candidate-by-Development Candidate basis, any such additional research activities that are mutually agreed by the Parties with respect to such Development Candidate in accordance with this Section 2.5 will be “**Follow-On Research**” for such Development Candidate. Prior to Company commencing any Follow-On Research with

respect to a Development Candidate, the Parties shall mutually agree upon (a) a plan for such Follow-On Research, which plan shall specify the duration of such Follow-On Research (the “**Follow-On Research Plan**”) and (b) a corresponding budget for such Follow-On Research (the “**Follow-On Research Budget**”). Following the Parties’ agreement on a Follow-On Research Plan with respect to a Development Candidate, Company, directly or through its Affiliates or Subcontractors, will use Commercially Reasonable Efforts to perform the Follow-On Research for such Development Candidate in accordance with such Follow-On Research Plan, in a professional and timely manner and in accordance with all Applicable Laws. Either Party may, at any time, propose updates or amendments to any Follow-On Research Plan, which updates or amendments shall only become effective by mutual agreement of the Parties. Notwithstanding the foregoing or Section 3.1.4, [***], *provided* that Company will remain obligated to conduct all proposed Follow-On Research activities [***], or if the Follow-On Research Plan was previously amended in accordance with this Agreement, in the then-current Follow-On Research Plan as amended, [***]. Vertex shall reimburse Company in accordance with Section 7.8 for Company’s [***] incurred in conducting such Follow-On Research in accordance with the Follow-On Research Plan and Follow-On Research Budget, as the same may be updated or amended.

2.6. **Subcontracting.** Subject to Section 2.4, Company may engage Subcontractors to perform Research Activities or Follow-On Research (as applicable); *provided* that (a) the applicable provisions of each agreement between Company and a Subcontractor shall be consistent with the corresponding provisions of this Agreement, including Section 8.1, and shall include confidentiality provisions that are at least as restrictive as those described in ARTICLE 12; (b) Company shall include in each such contract an assignment provision that permits Company to assign such contract to Vertex after the applicable License Effective Date, to the extent such contract (i) [***], and (ii) either (x) [***] or (y) [***]; and (c) Company shall not engage any Subcontractor to conduct any such activities without Vertex’s prior written consent in each case, *provided* that Vertex’s approval of a Research Plan or a Follow-On Research Plan naming such Subcontractor and the relevant activities to be subcontracted shall be deemed to constitute Vertex’s consent to the engagement of such Subcontractor with respect to such activities. Subject to Section 2.4, Company will be responsible for the effective and timely management of, and payment, of its Subcontractors, at Company’s sole cost and expense, subject to Section 7.8. The engagement of any Subcontractor in compliance with this Section 2.6 shall not relieve Company of its obligations under this Agreement.

2.7. **Records; Reporting.**

2.7.1. **Records.** Company shall maintain, and shall cause its Affiliates and Subcontractors to maintain, records of the Research Activities and Follow-On Research (as applicable) in sufficient detail and in good scientific manner appropriate for scientific, patent and regulatory purposes, which shall be complete and accurate in all material respects and shall fully and properly reflect all work done, data and developments made, and results achieved.

2.7.2. **Progress Reports.** During any period that Company is conducting Research Activities or Follow-On Research, Company shall furnish to the JAC (or, if the JAC has disbanded, directly to Vertex), within [***] after the end of each Calendar Quarter, an update on Company's progress under the Research Plan for the applicable Collaboration Program or Follow-On Research Plan, as the case may be, with respect to the performance of the Research Activities or Follow-On Research (as applicable) during the relevant Calendar Quarter, including a summary of any results and data generated by Company under such Research Plan or Follow-On Research Plan and an overview of the resources, including an overview of FTEs, allocated to activities under such Research Plan or Follow-On Research Plan during the relevant Calendar Quarter. Company shall provide the JAC (or, if the JAC has disbanded, Vertex) with such other information with respect to the Collaboration Programs or Follow-On Research in Company's Control as any member of the JAC (or Vertex) may reasonably request. All such updates and other information provided by Company shall be Company's Confidential Information and shall be subject to the terms of ARTICLE 12, *provided, however*, that (a) any such updates and other information solely regarding a Development Candidate for which Vertex has exercised the Option shall, from and after the applicable License Effective Date, be Vertex's Confidential Information and (b) any such updates or other information regarding both a Development Candidate for which Vertex has exercised the Option and one or more other Development Candidates for which Vertex has not exercised the Option shall, from and after the applicable License Effective Date, be the Confidential Information of both Parties.

ARTICLE 3. GOVERNANCE

3.1. **Joint Advisory Committee.**

3.1.1. **Formation.** Within [***] after the Effective Date, the Parties will establish a joint advisory committee (the "JAC") to act as a forum to review, discuss and oversee activities under this Agreement and to address issues and share information relating to the Research Plan and, if applicable, any Follow-On Research Plan. The JAC will be comprised of [***] representatives from each Party, or such other equal number of representatives from each Party as the Parties may agree. Each Party's representatives on the JAC shall be of the seniority and experience appropriate in light of the functions and responsibilities of the JAC. In addition, each Party may invite a reasonable number of additional subject matter experts or relevant personnel of such Party to participate in discussions and meetings of the JAC; *provided* that no such experts or personnel will have the authority to vote on any matters under consideration by the JAC. Each Party's representatives on the JAC and all other individuals attending or participating in discussions and meetings of the JAC will be bound under written confidentiality and non-use obligations that are no less restrictive than the provisions of ARTICLE 12 with respect to information disclosed in such discussions or meetings. Each Party may replace its representatives on the JAC at any time upon written notice to the other Party (which notice may be given by email or in accordance with Section 13.5). The Company will designate the chairperson of the JAC from the Effective Date until the end of Calendar Year 2020, Vertex will designate the chairperson of the JAC from the start of Calendar Year 2021 until the end of Calendar Year 2021, and the JAC chairperson will alternate between the Parties annually thereafter. The chairperson of the JAC will be responsible for setting the agenda for meetings of the JAC with input from the other members of the JAC, and for conducting the meetings of the JAC. The JAC will conduct its responsibilities hereunder in good faith and with reasonable care and diligence.

3.1.2. **Responsibilities.** In addition to its overall responsibility to provide oversight and to facilitate information sharing between the Parties with respect to the Research Activities and, if applicable, the Follow-On Research, the JAC will:

- (a) review, discuss, and approve amendments or updates to the Research Plan;
- (b) review and discuss all material Research Activities undertaken by or on behalf of Company under the Research Plan, including the exchange and review of data and information generated pursuant to the Research Plan;
- (c) determine whether to designate as a Development Candidate for a Collaboration Program any ETB directed against the Collaboration Target with respect to such Collaboration Program that has not otherwise satisfied the applicable criteria for a Development Candidate set forth in the Research Plan;
- (d) determine the final Development Candidate under a Collaboration Program;
- (e) discuss Company's progress toward preparation of each Option Exercise Data Package;
- (f) oversee the transfer of Licensed Know-How to Vertex in accordance with Section 5.3;
- (g) discuss and oversee any Follow-On Research that is mutually agreed by the Parties with respect to a Vertex Target; and
- (h) perform such other duties as are specifically assigned to the JAC under this Agreement or as may be otherwise mutually agreed by the Parties from time to time.

3.1.3. **Meetings; Minutes.**

(a) The JAC will meet in person or by teleconference at least [***] on such dates and at such times and places as agreed to by the members of the JAC; *provided* that at least [***] shall be in person unless the Parties agree otherwise. Each Party will be responsible for its own expenses relating to attendance at, or participation in, JAC meetings.

(b) The responsibility for preparing the minutes of the JAC's meetings will alternate between the Alliance Managers on a meeting-by-meeting basis. The Alliance Manager responsible for the minutes will provide the other Alliance Manager and the members of the JAC with draft written minutes for the JAC's approval within [***] after each meeting setting forth, among other things, a description, in reasonable detail, of the discussions at the meeting and a list of any actions, decisions or determinations approved by the JAC. Such minutes will be effective only after being approved by both Parties. If the minutes of any meeting of the JAC are not unanimously approved by the JAC within [***] after such meeting, then the Party objecting to the approval of such minutes will append a notice of objection with the specific details of the objection to the proposed minutes.

3.1.4. **JAC Decision-Making.** The JAC will use reasonable, good faith efforts to reach unanimous agreement with respect to all matters within the JAC's authority, and no action or decision will be taken by the JAC without unanimous consent of the JAC's members. If the JAC is not able to reach agreement with respect to a matter at a duly called meeting of the JAC, either Party may refer such matter to the Executive Officers of the Parties by delivering written notice to the other Party, and the Executive Officers will confer in good faith on the resolution of the issue for a [***] period (or such other period of time as mutually agreed by the Executive Officers) following receipt of such written notice. If such matter is not resolved by the Executive Officers within such [***] period, then (a) Company will have the final decision-making authority with respect to [***], (b) the Parties will decide by mutual agreement whether [***], (c) the Parties will determine by mutual agreement [***], (d) the Parties will decide by mutual agreement any [***], and (e) Vertex will have the final decision-making authority [***]; *provided, however*, that neither Party may exercise final decision-making authority if such decision would [***] without the other Party's prior written consent. Notwithstanding any provision of this ARTICLE 3 to the contrary, the JAC will not have the authority to amend the terms or conditions of this Agreement, interpret this Agreement, or determine whether or not a Party has met its obligations under this Agreement or whether or not a breach of this Agreement has occurred.

3.1.5. **Discontinuation of the JAC.** The JAC will continue to exist until the first to occur of (a) the Parties mutually agreeing to terminate the JAC, (b) the completion or termination of the Research Plan (*provided* that Vertex may elect to reconstitute the JAC in the event of any Follow-On Research, and thereafter the JAC will continue to exist for the sole purpose of discussing and overseeing the Follow-On Research until the completion or termination of the Follow-On Research Plan), or (c) the expiration or termination of this Agreement for any reason.

3.2. **IP Committee.** Within [***] after the Effective Date, the Parties will form a committee (the "IP Committee"), composed of an equal number of representatives from each Party having relevant expertise, to coordinate the Prosecution and Maintenance of Licensed Patents. The IP Committee will meet in person or by means of telephone or video conference at least [***] during the Term. Each Party may replace its representatives on the IP Committee at any time by providing notice in writing to the other Party. The IP Committee will have no decision-making authority, but will act as a discussion forum between the Parties. In addition, each Party may invite a reasonable number of additional subject matter experts or relevant personnel of such Party to participate in discussions and meetings of the IP Committee. Each Party's representatives on the IP Committee and all other individuals attending or participating in discussions and

meetings of the IP Committee on behalf of a Party will be bound under written confidentiality and non-use obligations with respect to information disclosed at such meeting that are no less restrictive than the provision of ARTICLE 12.

3.3. **Other Committees.** The Parties may, by mutual agreement, form such other committees or working groups as may be necessary or desirable to facilitate activities under this Agreement.

3.4. **Alliance Managers.**

3.4.1. **Appointment.** Each Party will appoint a representative of such Party to act as its alliance manager under this Agreement (each, an “**Alliance Manager**”). Each Party may replace its Alliance Manager at any time upon notice to the other Party. The initial Alliance Managers will be:

For Vertex: [***]

For Company: [***]

3.4.2. **Specific Responsibilities.** The Alliance Managers will attend all meetings of the JAC, but may not be members of the JAC. The Alliance Managers will serve as the primary contact point between the Parties for the purpose of providing each Party with information regarding the other Party’s activities pursuant to this Agreement and will have the following responsibilities:

- 3.1.3(b); (a) schedule meetings of the JAC and circulate draft written minutes as provided in Section
- (b) oversee and facilitate the flow of information and otherwise promote communication, coordination and collaboration between the Parties;
- (c) provide a single point of communication for seeking consensus, both internally within the respective Party’s organization, and between the Parties regarding key strategy and planning issues; and
- (d) perform such other functions as requested by the JAC.

**ARTICLE 4.
EXCLUSIVE OPTIONS**

4.1. **Options.** On a Development Candidate-by-Development Candidate basis until the Option Deadline, Company hereby grants to Vertex an exclusive option to obtain the Exclusive License for the applicable Development Candidate and the corresponding Licensed ETBs and Licensed Products (each, an “**Option**”). For clarity, Vertex may exercise an Option with respect to more than one Development Candidate directed against a given Collaboration Target, and the failure to exercise an Option with respect to any given Development Candidate will not limit Vertex’s ability to exercise an Option with respect to any other Development Candidate.

4.1.1. **Option Exercise Data Package.** Within [***] after completion of the final study report for the last non-GLP NHP study conducted by Company with respect to a Development Candidate pursuant to the Research Plan, or otherwise upon Vertex's earlier written request, Company will deliver to Vertex the Option Exercise Data Package for such Development Candidate (or, in the case of Vertex's earlier request, Company will deliver all portions of the Option Exercise Data Package for such Development Candidate that are then available and in Company's possession). If Vertex reasonably determines that any Option Exercise Data Package is incomplete or otherwise does not conform to the requirements of this Agreement, then, within [***] after Vertex's receipt of such Option Exercise Data Package, Vertex may notify Company of the incomplete or non-conforming status of such Option Exercise Data Package, which notice shall specify the information required to be included in such Option Exercise Data Package which is incomplete or non-conforming (and, if the latter, how the information is non-conforming) ("**Incomplete Data Package Notice**"). Following Company's receipt of an Incomplete Data Package Notice, Company will promptly deliver to Vertex the additional information specified in the Incomplete Data Package Notice as needed to complete such Option Exercise Data Package and, within [***] of receipt of such additional information, Vertex will provide Company a written acknowledgement that the Option Exercise Data Package is complete or will provide another Incomplete Data Package Notice. If Vertex does not provide either such acknowledgement or another Incomplete Data Package Notice within such [***] period, the Option Exercise Data Package will be deemed complete. Following Company's delivery to Vertex of a complete Option Exercise Data Package, Vertex will have the right, prior to the Option Deadline, to reasonably request additional information relating to the applicable Development Candidate, and Company will respond to any such reasonable request promptly with any such additional information that is in its Control; *provided* that Company shall in no event be required to conduct any new or additional Research or other activities to generate any such additional information.

4.1.2. **Option Exercise.** Vertex may exercise its Options for one or more Development Candidates arising under a Collaboration Program by providing written notice to Company (the "**Option Exercise Notice**") at any time between the Effective Date and the date that is [***] after Company delivers to Vertex a complete Option Exercise Data Package for the final Development Candidate for such Collaboration Program as determined by the JAC (the "**Option Deadline**"). For clarity, the Option Deadline for the Development Candidates under each Collaboration Program will be calculated based on the date that Company delivers a complete Option Exercise Data Package for such final Development Candidate, and will not be calculated based on the date, if applicable, that Company delivers an Option Exercise Data Package for such final Development Candidate that is incomplete or otherwise does not conform to the requirements of this Agreement as evidenced by an Incomplete Data Package Notice. The Option Exercise Notice will specify the Development Candidate(s) with respect to which Vertex intends to exercise its Options. If Vertex delivers an Option Exercise Notice to Company with respect to one or more Development Candidates arising under a Collaboration Program prior to the Option Deadline, then Vertex will pay Company the Option Exercise Fee in accordance with Section 7.3 with respect to each such Development Candidate. On the License Effective Date for any such Development Candidate, (a) the applicable Collaboration Target will automatically become a "Vertex Target," and (b) Company will automatically grant to Vertex the Exclusive License for such Development Candidate and the corresponding Licensed ETBs and Licensed Products. On a Development

Candidate-by-Development Candidate basis, if Vertex fails to provide an Option Exercise Notice in accordance with this Section 4.1.2 with respect to a Development Candidate prior to the Option Deadline, then the Option for such Development Candidate will expire and be of no further force or effect and, for clarity: such Development Candidate shall not be a Licensed ETB; any Agreement Know-How pertaining solely to such Development Candidate shall not be deemed Product Agreement Know-How; and Vertex shall have no rights in or to such Development Candidate.

4.2. **HSR Compliance.**

4.2.1. **HSR Notice.** If Vertex determines in good faith upon advice of counsel that an HSR Filing is required to be made under the HSR Act as a result of Vertex's exercise of an Option and notifies Company of such determination in connection with Vertex's delivery of the applicable Option Exercise Notice, then (i) the Parties will file an HSR Filing in accordance with Section 4.2.2, and (ii) Vertex's election to exercise the applicable Option will not be effective (and Vertex will not be obligated to pay the applicable Option Exercise Fee) until the HSR Clearance Date, if any.

4.2.2. **HSR Filing.** If Vertex notifies Company pursuant to Section 4.2.1 that an HSR Filing is required for Vertex to exercise an Option, then each of Vertex and Company will, within [***] after such notice from Vertex (or such later time as may be agreed to in writing by the Parties), file with the U.S. Federal Trade Commission ("FTC") and the Antitrust Division of the U.S. Department of Justice ("DOJ") any HSR Filing required with respect to the transactions contemplated hereby. Each of the Parties agrees to cooperate in the antitrust clearance process, including by furnishing to the other Party such necessary information and reasonable assistance as the other Party may reasonably request in connection with its preparation of any filing or submission that is necessary under the HSR Act and other antitrust requirements, and to furnish promptly with the FTC, DOJ, and any other antitrust authority, any information requested by them in connection with such filings. Each Party shall furnish copies (subject to reasonable redactions for privilege or confidentiality concerns) of, and shall otherwise keep the other Party apprised of the status of any material communications with, and any inquiries or requests for additional information from, the FTC, DOJ and any other antitrust authority, and shall comply promptly with any such inquiry or request. Each Party shall give the other Party the opportunity to review in advance, and shall consider in good faith the other Party's reasonable comments in connection with, any proposed filing or communication with the FTC, DOJ or any other antitrust authority. Each Party shall consult with the other Party, to the extent practicable, in advance of participating in any substantive meeting or discussion with the FTC, the DOJ or any other antitrust authority with respect to any filings, investigation or inquiry and, to the extent permitted by such antitrust authority, give the other Party to the opportunity to attend and participate therein. Each Party will be responsible for its own costs and expenses (other than filing fees, which Vertex will pay) associated with any HSR Filing.

4.2.3. **HSR Clearance.** In furtherance of obtaining clearance for an HSR Filing filed pursuant to this Section 4.2, Company and Vertex will use their respective Commercially Reasonable Efforts (subject to this Section 4.2.3) to resolve as promptly as practicable any objections that may be asserted with respect to this Agreement or the transactions contemplated by this Agreement under any antitrust, competition or trade regulatory law. In connection with such clearance for an HSR Filing from the FTC, the DOJ or any other Governmental Authority, neither Party, nor its Affiliates will be required to (i) sell, divest (including through license or a reversion of licensed or assigned rights), hold separate, transfer or dispose of any assets, operations, rights, product lines, businesses or interest therein of such Party or any of its Affiliates (or consent to any of the foregoing actions); or (ii) litigate or otherwise formally oppose any determination (whether judicial or administrative in nature) by a Governmental Authority seeking to impose any of the restrictions referenced in clause (i) above.

ARTICLE 5.
LICENSE GRANTS; EXCLUSIVITY

5.1. **License Grants to Vertex.**

5.1.1. **Exclusive License.** On a Development Candidate-by-Development Candidate basis, effective upon the License Effective Date for the applicable Development Candidate, Company hereby grants to Vertex and its Affiliates an exclusive, royalty-bearing license, including the right to grant and authorize Sublicenses in accordance with Section 5.1.2, under Company's and its Affiliates' interests in the Licensed Technology, to Research, Develop, Manufacture, have Manufactured, Commercialize, use, keep, and otherwise exploit such Development Candidate and all corresponding Licensed ETBs and Licensed Products in the Field in the Territory (each, an "**Exclusive License**").

5.1.2. **Sublicensing.** Vertex and its Affiliates may grant Sublicenses of any Exclusive License through multiple tiers of Sublicenses to one or more Sublicensees. Each such Sublicense will be consistent with the terms of this Agreement and will require the Sublicensee to comply with the terms of this Agreement that are applicable to such Sublicense, including obligations of confidentiality and non-use at least as stringent as those set forth in ARTICLE 12, the reporting obligations set forth under Section 7.5.3 and Section 7.6.7, the record keeping and audit requirements set forth under Section 7.11, and the intellectual property assignment provisions set forth in Section 8.1.2. Vertex will, as soon as reasonably practicable (and in any event within [***] thereafter), provide Company with a copy of each executed Sublicense with a Third Party Sublicensee (which copy may be redacted to remove provisions which are not necessary to monitor compliance with this Section 5.1.2); *provided* that Vertex shall have no obligation to provide Company with any copy of any Subcontractor agreement. Notwithstanding any Sublicense, Vertex will not be relieved of any of its obligations under this Agreement and will remain primarily liable to Company for the performance of all of Vertex's obligations under this Agreement and for the acts or omissions of or breach of this Agreement by any Sublicensee.

5.1.3. **Retained Rights.** Other than those expressly set forth in this Agreement, no rights or licenses are granted to Vertex by Company hereunder. Company retains all right, title and interest in and to the Licensed Technology, subject to any Exclusive License granted by Company to Vertex pursuant to Section 5.1.1, and all rights not expressly granted by Company to Vertex hereunder are reserved and retained by Company. Notwithstanding any Exclusive License granted to Vertex pursuant to Section 5.1.1, Company will retain rights under the Licensed Technology to the extent necessary to perform its obligations under this Agreement, including to perform the Research Activities and any Follow-On Research as may be agreed by the Parties.

5.2. **License Grant to Company.**

5.2.1. **Research License.** Vertex hereby grants to Company and its Affiliates a non-exclusive, fully paid-up, non-transferable (except as provided in Section 13.1), royalty-free license in the Territory, with no right to grant sublicenses except to Subcontractors engaged in accordance with Section 2.6, under the Vertex Technology, solely to perform the Research Activities and, if applicable, the Follow-On Research. Such license shall terminate automatically upon completion of such Research Activities or, if applicable, such Follow-On Research.

5.2.2. **Antibody Agreement Technology License.** On a Terminated Target-by-Terminated Target basis for any Collaboration Target that becomes a Terminated Target, Vertex shall grant and hereby grants to Company and its Affiliates, effective as of the expiration of the Option Deadline for the final Development Candidate directed against such Terminated Target, an exclusive, royalty-free, irrevocable, perpetual, worldwide license, including the right to grant and authorize sublicenses through multiple tiers, under the Antibody Agreement Technology for such Terminated Target, to [***], subject to the terms and conditions of this Agreement and any relevant Third Party agreements with respect to such Antibody Agreement Technology.

5.3. **Technology Transfer after Option Exercise.**

5.3.1. **Licensed Know-How Transfer.** On a Development Candidate-by-Development Candidate basis, following the License Effective Date with respect to a Development Candidate, upon Vertex's request, which request will occur within [***] following the License Effective Date with respect to such Development Candidate, Company will promptly transfer to Vertex or its designated Affiliate a copy of all Licensed Know-How related to such Development Candidate (or the corresponding Licensed ETBs or Licensed Products) in its Control as of such License Effective Date, including any documentation (whether held in paper or electronic format) or similar removable media (including emails, documents, spreadsheets, copies of standard operating procedures or technical specifications), and will complete such transfer no later than [***] following Vertex's request. In addition, on a Development Candidate-by-Development Candidate basis, to the extent Company has performed Follow-On Research with respect to such Development Candidate, Company will promptly, following completion of such Follow-On Research, transfer to Vertex or its designated Affiliate a copy of all Licensed Know-How related to such Development Candidate (or the corresponding Licensed ETBs or Licensed Products) generated under the Follow-On Research in its possession as of such completion date, including any documentation (whether held in paper or electronic format) or similar removable media (including e-mails, documents, spreadsheets, copies of standard operating procedures or technical specifications), and will complete such transfer no later than [***] following completion of such Follow-On Research, in each case, to the extent not previously provided pursuant to this Section 5.3.1.

5.3.2. **Additional Transfers.** On a Development Candidate-by-Development Candidate basis, following the License Effective Date with respect to a Development Candidate and during [***], no more than once every [***] during the first [***] after the License Effective Date [***], Vertex may inform Company in writing of its [***] and Manufacturing activities with respect to Licensed Products. Upon such information being provided by Vertex, or otherwise upon a general request by Vertex, in either case no more than once every [***] during the first [***] after the License Effective Date [***], Company will, within [***] after receipt of such information or request, notify Vertex [***] that has come into Company's Control, including any [***] generated during any applicable Follow-On Research, in each case that, based upon such information provided by Vertex (if any), it reasonably determines would be necessary [***] to Vertex's [***] and Manufacturing activities with respect to Licensed Products, in each case, to the extent not previously provided by Company. Upon receipt of such notice from Company, Vertex may request a copy of [***] from Company, and Company will promptly transfer to Vertex or its designated Affiliate a copy of [***] in Company's Control, including any documentation (whether held in paper or electronic format) or similar removable media (including emails, documents, spreadsheets, copies of standard operating procedures or technical specifications), and will complete such transfer no later than [***] following Vertex's request. Additionally, if Vertex becomes aware of any [***] that comes into Company's Control, in each case to the extent not previously provided by Company, then Vertex may request a copy of such [***] from Company. Company will, promptly following such request [***] necessary [***] for Vertex's [***] or Manufacturing activities with respect to the Licensed Products, transfer to Vertex or its designated Affiliate a copy of such [***] in Company's Control, including any documentation (whether held in paper or electronic format) or similar removable media (including emails, documents, spreadsheets, copies of standard operating procedures or technical specifications), and will complete such transfer no later than [***] following Vertex's request. Notwithstanding the foregoing, with respect to any such [***] relating to the Manufacture of Licensed ETBs or Licensed Products, the obligations set forth in this Section 5.3.2 shall apply only to the extent that Vertex informs Company of the then-current Manufacturing process used by or on behalf of Vertex, its Affiliates or its Sublicensees for any such Licensed ETBs or Licensed Products and that such [***] constitutes an improvement, modification or enhancement to such Manufacturing process.

5.3.3. **No Transfers of Other Know-How.** For clarity, Company will not have any obligation under Section 5.3.1 or Section 5.3.2 to transfer any Know-How to the extent such Know-How is not within the scope of the Licensed Know-How.

5.3.4. **Assistance by Company Personnel.** To assist with the transfer of Licensed Know-How under this Section 5.3 and Vertex's exploitation thereof in accordance with the terms of this Agreement, Company will make its personnel reasonably available to Vertex during normal business hours to transfer such Licensed Know-How to Vertex and respond to Vertex's reasonable inquiries with respect thereto. Company will be responsible for [***] and Vertex will reimburse Company for (a) [***] and (b) [***], in each case within [***] after receiving Company's invoice therefor.

5.3.5. **Third Party Vendors or Subcontractors.** At Vertex's reasonable request following the License Effective Date with respect to a given Development Candidate, Company will use Commercially Reasonable Efforts to facilitate the establishment of a business relationship between Vertex and any Subcontractor that Company has engaged in the Research Activities or in the Manufacture of such Development Candidate (or the corresponding Licensed ETBs or Licensed Products), including by facilitating introductions with such Subcontractors, and will use Commercially Reasonable Efforts to assign to Vertex any agreements with any such Subcontractor that are solely related to such Development Candidate (or the corresponding Licensed ETBs or Licensed Products).

5.3.6. **Costs of Transfer.** Except as set forth in Section 5.3.4, each Party will bear its own costs and expenses in conducting the activities set forth in this Section 5.3.

5.4. **No Implied Licenses.** Except as expressly provided in this Agreement, no Party will be deemed by estoppel, implication or otherwise to have granted the other Party any license or other right with respect to any intellectual property.

5.5. **Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by a Party to the other are and will be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The Parties agree that the Parties will retain and may fully exercise all of their rights and elections under the Bankruptcy Code and any foreign equivalent thereto. The Parties further agree that if (x) a bankruptcy proceeding by or against a Party (the "**Bankrupt Party**") is commenced under the Bankruptcy Code, (y) this Agreement is rejected as provided in the Bankruptcy Code, and (z) the other Party (the "**Non-Bankrupt Party**") elects to retain its rights hereunder as provided in Section 365(n) of the Bankruptcy Code, the Non-Bankrupt Party will be entitled to a complete duplicate of, and complete access to (as the Non-Bankrupt Party deems appropriate), all such intellectual property and all embodiments of such intellectual property. Upon such election by the Non-Bankrupt Party, such intellectual property and all embodiments of such intellectual property will be promptly delivered to the Non-Bankrupt Party. The Bankrupt Party (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) agrees not to interfere with the exercise by the Non-Bankrupt Party of its rights and licenses to such intellectual property and such embodiments of intellectual property in accordance with this Agreement, and agrees to assist the Non-Bankrupt Party and its Affiliates in obtaining such intellectual property and such embodiments of intellectual property in the control of Third Parties. The foregoing provisions are without prejudice to any rights the Non-Bankrupt Party may have arising under the Bankruptcy Code or other Applicable Law.

5.6. **Exclusivity Covenants.**

5.6.1. [***], neither Company nor any of its Affiliates will work independently or for or with any Third Party (including the grant of any license to any Third Party) with respect to the research, development, manufacture or commercialization of any product directed against such [***].

5.6.2. [***], neither Company nor any of its Affiliates will work independently or for or with any Third Party (including the grant of any license to any Third Party) with respect to the research, development, manufacture or commercialization of any product directed against such [***].

5.6.3. [***] until the earlier of (a) [***] or (b) [***], neither Company nor any of its Affiliates will work independently or for or with any Third Party (including the grant of any license to any Third Party) to research, develop, manufacture or commercialize any product directed against the [***].

5.7. **Right of First Negotiation.** If, on a Terminated Target-by-Terminated Target basis, within [***] following the expiration of the Option Deadline for the final Development Candidate directed against such Terminated Target, [***] will provide written notice (the “**Terminated Target Notice**”) to [***] of the general nature of the proposed transaction. The Terminated Target Notice will include information similar in nature and scope, taking into account the applicable stage of research or development of such product, to the information that would be required to be included in [***] for such Terminated Target in the form and to the extent that any such information is then available (and in [***]) for such [***] (including [***], if applicable), and [***] will have an exclusive right of first negotiation to acquire or obtain an exclusive license to such [***]. [***] will have [***] after receipt of any Terminated Target Notice from [***] to provide [***] notice that [***] desires to exercise such exclusive right of first negotiation with respect to such [***] (“**Terminated Target Exercise Notice**”). If [***] provides a timely Terminated Target Exercise Notice, then the Parties will promptly commence exclusive good faith negotiations regarding the terms of an agreement providing for such acquisition or the grant of such exclusive license for a period of up to [***] unless extended by mutual written agreement of the Parties, during which period [***] will not engage in any discussions or negotiations with or permit diligence access to any Third Party regarding the acquisition or license of such [***]. In the event that [***] does not provide a timely Terminated Target Exercise Notice, or the Parties fail to reach agreement within such [***] period (or such longer period as the Parties may mutually agree in writing), then [***] may enter into an agreement with any of its Affiliates or a Third Party with respect to the acquisition or license of such [***].

ARTICLE 6.

DEVELOPMENT, MANUFACTURING AND COMMERCIALIZATION

6.1. **Development.**

6.1.1. **Generally.** Vertex will have sole and exclusive control, at its sole cost and expense, over all matters relating to the Development of Licensed ETBs and Licensed Products in the Field in the Territory.

6.1.2. **Development Plan.** On a Vertex Target-by-Vertex Target basis, within [***] after the License Effective Date with respect to any Development Candidate directed against the applicable Vertex Target, Vertex will provide the JAC, or the Company if the JAC has disbanded, with a high-level Development plan outlining key aspects of the Development of Licensed ETBs and Licensed Products directed against such Vertex Target for the ensuing [***] period (the “**Development Plan**”), for informational purposes only. After the initial Development Plan has been provided to Company, Vertex will update such Development Plan no less than [***] for so long as activities are taking place under such Development Plan and provide such updates to Company for informational purposes only. For the avoidance of doubt, Vertex may, in satisfaction of its obligations hereunder, undertake activities other than, or in lieu of, those set forth in the Development Plan and in that case, Vertex will provide updates to Company of such activities in accordance with Section 6.1.3.

6.1.3. **Reporting.** During the Term until [***], no later than [***], Vertex will provide Company with a high-level report regarding the status of Vertex’s Development of Licensed ETBs and Licensed Products directed against such Vertex Target and the results of such Development.

6.2. **Regulatory Matters.**

6.2.1. **Responsibilities.** Vertex will have the sole and exclusive right, at its sole cost and expense, to (a) prepare, file and maintain Regulatory Filings, each in its own name (including applications for Marketing Approval and Price Approval) for all Licensed Products in the Field in the Territory, and (b) communicate with Regulatory Authorities with respect to the Licensed Products in the Field in the Territory, both prior to and following Marketing Approval and Price Approval, including all communications and decisions with respect to (i) labeling of Licensed Products, and (ii) [***], in each case, either by itself or with or through one or more Affiliates or Third Parties.

6.2.2. **Ownership.** Ownership of all right in and to all Regulatory Filings, Marketing Approvals and Price Approvals for any Licensed Products in the Field in each country of the Territory will be held in the name of Vertex or its designated Affiliate or Sublicensee.

6.2.3. **Cooperation.** As and to the extent reasonably requested by Vertex, Company will, and will cause its Affiliates to, cooperate with Vertex with respect to all regulatory matters relating to any Licensed Products. Without limiting the foregoing, as reasonably requested by Vertex, Company will assist Vertex in preparing Regulatory Filings for Licensed Products and make information in the Control of Company available to Vertex to the extent necessary or useful for completion of such Regulatory Filings. Upon Vertex’s reasonable request, Company will support the Development of Licensed Products by providing Regulatory Authorities with access to, and the right to audit, any data or other Know-How and associated documents that are in Company’s Control and are relied on by Vertex in its Regulatory Filings for Licensed Products. All of Company’s cooperation, assistance and support under this Section 6.2.3 will be at Vertex’s expense, and Vertex will reimburse Company for its [***] incurred in connection with the same within [***] after receiving Company’s invoices therefor. Company will not make any submissions to any Regulatory Authority with respect to a Licensed ETB or Licensed Product.

6.2.4. **Right of Reference.** On a Vertex Target-by-Vertex Target basis, effective upon the License Effective Date with respect to any Development Candidate directed against the applicable Vertex Target, Company hereby grants Vertex, its Affiliates and Sublicensees a “Right of Reference,” as that term is defined in 21 C.F.R. § 314.3(b) and any foreign counterpart to such regulation, to any Regulatory Filings held by Company or its Affiliates to the extent necessary [***] for the submission, approval or maintenance of Marketing Approval of any Licensed Product directed against such Vertex Target in the Field in the Territory. If requested by Vertex, Company will provide a signed statement to this effect in accordance with 21 C.F.R. §314.50(g)(3) or any foreign counterpart to such regulation.

6.3. **Manufacturing.**

6.3.1. **General.** Vertex will have the sole and exclusive right, at its sole cost and expense, to Manufacture the Licensed ETBs and Licensed Product(s) in the Field in the Territory, either by itself or with or through one or more Affiliates or Third Parties selected by Vertex, in its sole discretion.

6.3.2. **R&D Supply Agreement.** Within [***] of the Effective Date (or such other time period as may be agreed upon by the Parties), the Parties will negotiate in good faith the terms of a supply agreement (and corresponding quality agreement) for the pre-clinical and clinical supply of Licensed Products by Company to Vertex following the License Effective Date with respect to one or more Development Candidates (the “**R&D Supply Agreement**”). The R&D Supply Agreement will include commercially reasonable terms customarily found in agreements for the pre-clinical and clinical supply of pharmaceutical products. Without limiting the foregoing, the R&D Supply Agreement will provide for the Parties to discuss the estimated Fully Burdened Manufacturing Cost in advance of Company incurring any such costs for the supply of Licensed Products and periodically during the course of such supply, and will require any increase to the Fully Burdened Manufacturing Cost of [***] or more during any Calendar Year to be documented by written evidence of the basis for such increase and subject to Vertex’s prior written approval. Subject to the foregoing, the supply price for such Licensed Products will equal [***]. The R&D Supply Agreement (a) will include customary rights of Vertex to audit Company’s and its Affiliates’ and CMOs’ books and records on a periodic basis for the purpose of verifying the calculation of Company’s Fully Burdened Manufacturing Cost for the Licensed Products and customary inspection rights of Vertex with respect to Company’s and its Affiliates’ and CMOs’ facilities used in the Manufacture of the Licensed Products, and (b) will provide that (i) Company will reasonably assist Vertex in putting together a chemistry, manufacturing and controls (CMC) package to be included in the submission of an IND for Licensed Products and (ii) Vertex will reimburse Company for its [***] incurred in connection with such assistance, *provided* that Company provides Vertex with written notice of such anticipated [***] prior to incurring such costs, and Vertex has agreed in writing to reimburse such costs up to the amounts set forth in such notice. Following the License Effective Date with respect to one or more Development Candidates, upon Vertex’s request, the Parties will enter into the R&D Supply Agreement.

6.3.3. **Manufacturing Technology Transfer.** Following the License Effective Date with respect to one or more Development Candidates, upon Vertex's written request, Company shall conduct a technology transfer of the Manufacturing process (including the transfer of the relevant quality control methods) for all steps of the Manufacturing supply chain for the Licensed Products (including starting material) from Company, its Affiliates and its CMOs to Vertex (or one or more Affiliates or CMOs designated by Vertex), and will provide the assistance reasonably necessary to effectuate such transfer and secure licensure of such CMOs' facilities, such assistance to include providing to or securing for Vertex, and requiring its Affiliates and using Commercially Reasonable Efforts to require its CMOs to provide to or secure for Vertex, such reasonably sufficient access to data, other information and the personnel of Company, its Affiliates and CMOs, as may be necessary or useful to enable Vertex or its Affiliates or CMOs to Manufacture the Licensed Products (the "**Manufacturing Technology Transfer**"). Such Manufacturing Technology Transfer will be conducted pursuant to a Manufacturing Technology Transfer plan (the "**Manufacturing Technology Transfer Plan**") and budget (the "**Manufacturing Technology Transfer Budget**") mutually agreed by the Parties. Vertex shall reimburse Company in accordance with Section 7.8 for Company's [***] incurred in conducting such Manufacturing Technology Transfer in accordance with the Manufacturing Technology Transfer Plan and Manufacturing Technology Transfer Budget, as the same may be amended from time to time in writing by the Parties. Without limiting the foregoing Manufacturing Technology Transfer obligations, upon Vertex's written request, Company will use Commercially Reasonable Efforts to facilitate the entry by Vertex into direct relationships with Company's CMOs with respect to the Manufacture of Licensed Products, including by providing introductions to such CMOs.

6.4. **Commercialization.**

6.4.1. **General.** Vertex will have sole and exclusive control, at its sole cost and expense, over all matters relating to the Commercialization of Licensed Products in the Field in the Territory, either by itself or with or through one or more Affiliates or Third Parties.

6.4.2. **Branding.** Vertex or its designated Affiliates or Sublicensees will select and own all trademarks used in connection with the Commercialization of any Licensed Product in the Field in the Territory. Company will not use nor seek to register, anywhere in the Territory, any trademark that is confusingly similar to any trademark used by or on behalf of Vertex, its Affiliates or Sublicensees in connection with any Licensed Product.

6.4.3. [***]. Vertex will provide Company with written notice promptly following submission of the first Approval Application for Marketing Approval of a Licensed Product in a Major Market Country. [***].

6.5. Diligence Obligations.

6.5.1. **Development Diligence.** On a Vertex Target-by-Vertex Target basis, after the License Effective Date with respect to any Development Candidate directed against the applicable Vertex Target, Vertex (acting directly or through one or more Affiliates or Sublicensees) will use Commercially Reasonable Efforts to Develop and seek Marketing Approval and Price Approval (if Price Approval is required for government reimbursement of commercial sale of a Licensed Product) for at least one Licensed Product directed against such Vertex Target in each Major Market Country [***].

6.5.2. **Commercial Diligence.** After receipt of Marketing Approval and Price Approval (if Price Approval is required for government reimbursement of commercial sale of a Licensed Product) (on terms deemed appropriate by Vertex in its sole discretion in any regulatory jurisdiction where Price Approval is required by Applicable Law) with respect to a Licensed Product in a Major Market Country, Vertex (acting directly or through one or more Affiliates or Sublicensees) will use Commercially Reasonable Efforts to Commercialize such Licensed Product in such Major Market Country.

6.6. **Applicable Laws.** Vertex will, and will require its Affiliates and Sublicensees to, comply with all Applicable Law in its and their Research, Development, Manufacture and Commercialization of Licensed ETBs and Licensed Products.

6.7. **Safety Data Exchange.** Upon either Party's request, the Parties will establish processes and procedures for sharing information regarding class effects relevant to ETBs as needed to support each Party's regulatory responsibilities and to comply with applicable regulatory pharmacovigilance requirements. Any such procedures will not be construed to restrict either Party's ability to take any action that it deems to be appropriate or required of it under the applicable regulatory requirements, if permitted by Applicable Laws. Without limiting the foregoing, (a) if Company determines or suspects that an Adverse Event related to any ETB Developed or Commercialized by Company or its Affiliates or licensees is related to a class effect or the ETB Platform and may reasonably impact the safety of a Licensed Product, Company will promptly disclose to Vertex in writing any information in Company's Control regarding the occurrence of such Adverse Event, and (b) if Vertex determines or suspects that an Adverse Event related to any Licensed Product is related to a class effect or the ETB Platform and may reasonably impact the safety of any ETB Developed or Commercialized by Company or its Affiliates or licensees, Vertex will promptly disclose to the Company in writing any information in Vertex's Control regarding the occurrence of such Adverse Event. Each of Company and Vertex will use good faith efforts to obtain Control of any such information.

ARTICLE 7.
FINANCIAL PROVISIONS

7.1. **Upfront Fee.** Within [***] following the Effective Date, Vertex will pay Company a one-time upfront fee of Twenty-Three Million Dollars (\$23,000,000).

7.2. **Equity Investment.** The Parties acknowledge that simultaneously with the execution of this Agreement, the Parties are entering into that certain Stock Purchase Agreement dated as of the Effective Date, pursuant to which Vertex (or its Affiliate) will purchase certain shares of the Company's common stock for an aggregate purchase price of Fifteen Million Dollars (\$15,000,000) on the terms and subject to the conditions set forth therein.

7.3. **Option Exercise Fee.** On a Development Candidate-by-Development Candidate basis for each Development Candidate for which Vertex exercises the Option, Vertex will pay Company a one-time Option exercise fee of [***] (the "**Option Exercise Fee**") within [***] after the later of (a) Vertex's delivery to Company of the applicable Option Exercise Notice or (b) if applicable, the HSR Clearance Date.

7.4. **Additional Target Option Exercise Fee.** Vertex will pay Company a one-time Additional Target Option exercise fee of (a) in the case of exercise of the Additional Target Option for ETBs directed against one Target or for [***], [***], or (b) in the case of exercise of the Additional Target Option [***], [***] (each of (a) or (b), as applicable, the "**Additional Target Option Exercise Fee**") within [***] after the later of (a) Vertex's delivery of the Additional Target Option Exercise Notice or (b) if applicable, the date that the Gatekeeper delivers the applicable Target Availability Notice.

7.5. **Milestone Payments.**

7.5.1. **Development Milestones.** On a Vertex Target-by-Vertex Target basis, Vertex will pay to Company the milestone payments set forth in this Section 7.5.1 (each a “**Development Milestone Payment**”) in accordance with the procedure set forth in Section 7.5.3 upon the first achievement of the relevant milestone event (each a “**Development Milestone Event**”) with respect to a Licensed Product of Vertex or any of its Affiliates or Sublicensees directed against such Vertex Target. Each Development Milestone Payment will be payable by Vertex only once with respect to each Vertex Target regardless of how many Licensed Products directed against such Vertex Target achieve the relevant Development Milestone Event. If any Development Milestone Event is achieved without the achievement of any earlier listed Milestone Event applicable to the same jurisdiction (or not specific to a jurisdiction), then Vertex will pay to Company the Development Milestone Payment applicable to such earlier Development Milestone Event at the same time as Vertex pays the applicable Development Milestone Payment in accordance with the procedure set forth in Section 7.5.3 due upon achievement of such Development Milestone Event. For example, if Development Milestone Event number 3 is achieved and Vertex has not previously made the Development Milestone Payment for Development Milestone Event number 2, Vertex will pay both the Development Milestone Payments for Development Milestone Event number 2 and Development Milestone Event number 3 at the same time (but, if Development Milestone Event number 6 is achieved and Vertex has not previously made the Development Milestone Payment for Development Milestone Event number 5, the achievement of Development Milestone Event number 6 will not give rise to any obligation of Vertex to make the Development Milestone Payment for Development Milestone Event number 5 (however, the Development Milestone Payment for Development Milestone Event number 5 will become payable upon achievement, if any, of Development Milestone Event number 5)). Additionally, if the [***] occurs, and Development Milestone Event number 2 has not yet been achieved with respect to the applicable Vertex Target at the time of such dosing, then Vertex will pay the Development Milestone Payment for Development Milestone Event number 2 for such Vertex Target in accordance with the procedure set forth in Section 7.5.3 upon [***].

| Milestone Number | Milestone Event | Milestone Payment |
|------------------|-----------------|-------------------|
| 1 | [***] | [***] |
| 2 | [***] | [***] |
| 3 | [***] | [***] |
| 4 | [***] | [***] |
| 5 | [***] | [***] |
| 6 | [***] | [***] |
| 7 | [***] | [***] |
| 8 | [***] | [***] |
| 9 | [***] | [***] |
| 10 | [***] | [***] |

7.5.2. **Sales Milestones.** On a Vertex Target-by-Vertex Target basis, Vertex will pay Company the milestone payments set forth in this Section 7.5.2 (each a “**Sales Milestone Payment**”, and, together with the Development Milestone Payments, the “**Milestone Payments**”) in accordance with the procedure set forth in Section 7.5.3 upon the first achievement of the relevant [***] threshold (each, a “**Sales Milestone Event**”, and, together with the Development Milestone Events, the “**Milestone Events**”) with respect to all Licensed Products of Vertex and its Affiliates and Sublicensees directed against such Vertex Target. Each Sales Milestone Payment will be payable by Vertex only once with respect to each Vertex Target regardless of how many times the Licensed Products directed against such Vertex Target achieve the relevant Sales Milestone Event.

| Milestone Number | Milestone Event | Milestone Payment |
|-------------------------|------------------------|--------------------------|
| 11 | [***] | [***] |
| 12 | [***] | [***] |

7.5.3. **Notice; Payment.** Each Milestone Payment will be earned upon achievement of the corresponding Milestone Event, and Vertex will provide Company with written notice upon the achievement of each Milestone Event, such written notice to be provided (a) with respect to any Development Milestone Event, within [***] after such achievement, and (b) with respect to any Sales Milestone Event, on or prior to the date of delivery of the royalty report under Section 7.6.7 for the [***] in which such Sales Milestone Event is achieved. Following receipt of such written notice, Company will promptly invoice Vertex for the applicable Milestone Payment, and Vertex will pay such Milestone Payment to Company within [***] after receipt of such invoice. The Sales Milestone Payments are additive, such that if, with respect to a Vertex Target, more than one Sales Milestone Event is achieved for the first time with respect to such Vertex Target in the same Calendar Year, then each corresponding Sales Milestone Payment for such event will be payable in accordance with this Section 7.5.3.

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

7.6. **Royalties.**

7.6.1. **Royalty Rates.** Subject to the remainder of this Section 7.6, Vertex will pay Company royalties on a Vertex Target-by-Vertex Target basis based on the aggregate Net Sales of all Licensed Products directed against such Vertex Target sold by Vertex or any of its Affiliates or Sublicensees in the Field in the Territory during a Calendar Year during the applicable Royalty Term at the rates set forth in the table below. The obligation to pay royalties will be imposed only once with respect to the same unit of a Licensed Product.

| Calendar Year Net Sales (in Dollars) for all Licensed Products directed against a given Vertex Target in the Territory | Royalty Rates as a Percentage (%) of Calendar Year Net Sales |
|--|--|
| Portion of Calendar Year Net Sales up to and including \$[***] | [***]% |
| Portion of Calendar Year Net Sales that exceeds \$[***] up to and including \$[***] | [***]% |
| Portion of Calendar Year Net Sales that exceeds \$[***] | [***]% |

The applicable royalty rate set forth in the table above will apply only to that portion of the Calendar Year Net Sales of the Licensed Products directed against a given Vertex Target during a given Calendar Year that falls within the indicated range. By way of example and without limitation of this Section 7.6.1, if Calendar Year Net Sales of the Licensed Products directed against a given Vertex Target by Vertex, its Affiliates and its Sublicensees were \$[***] for a given Calendar Year, then the royalties payable with respect to such Calendar Year Net Sales for such Licensed Products for such Calendar Year, subject to adjustment as set forth in this Section 7.6, would be: [***].

7.6.2. **Royalty Term.** Vertex will pay royalties to Company under this Section 7.6 on a Licensed Product-by-Licensed Product and a country-by-country basis during the Royalty Term for such Licensed Product in such country. Upon the expiration of the Royalty Term for a given Licensed Product in a given country, the Exclusive License granted to Vertex under Section 5.1 will become fully-paid, perpetual, irrevocable and royalty-free with respect to such Licensed Product in such country.

7.6.3. **Reduction for Lack of Patent Coverage and Regulatory Exclusivity.** Subject to Section 7.6.6, if, during any [***] within the applicable Royalty Term for a Licensed Product in a country, (a) no Valid Claim of any Licensed Patent exists that Covers such Licensed Product or the method of use of manufacture of such Licensed Product in such country, and (b) Regulatory Exclusivity, if any, has expired in such country with respect to such Licensed Product (the “**Reduction Circumstances**”), then, commencing the [***], Net Sales of such Licensed

Product in such country will be reduced by [***]% for purposes of calculating the royalty owed under Section 7.6.1; *provided* that, if either one of the Reduction Circumstances no longer exists with respect to such Licensed Product in such country during the Royalty Term for such Licensed Product in such country (e.g., if such Licensed Product or its method of use or manufacture subsequently becomes Covered by a Valid Claim of any Licensed Patent in such country during the Royalty Term for such Licensed Product in such country), then the Net Sales with respect to such Licensed Product in such country will no longer be subject to any reduction during any [***] in which either of the Reduction Circumstances no longer exists.

7.6.4. **Reduction for Competition.** Subject to Section 7.6.6, if during any [***] during the Royalty Term for a Licensed Product in a given country, the aggregate number of units of Competitive Products with respect to such Licensed Product sold during such [***] in such country exceeds [***]% of the aggregate units of the sum of all such Competitive Products and such Licensed Product sold in such [***] in such country (as determined by data obtained from a mutually agreed upon Third Party source), then Net Sales of such Licensed Product in such country in such [***] (after any applicable reduction pursuant to Section 7.6.3) will be reduced by [***]% for purposes of calculating the royalty owed under Section 7.6.1. For clarity, the reduction under this Section 7.6.4 shall only apply in the [***], if any, in which the aggregate number of units of Competitive Products with respect to a Licensed Product sold during the [***] in a country exceeds [***]% of the aggregate units of the sum of all such Competitive Products and such Licensed Product sold in such [***] in such country.

7.6.5. **Third Party Licenses.** Subject to Section 7.6.6, Vertex may deduct from the royalties payable to Company under this Section 7.6 with respect to a Licensed Product for a [***] [***]% of any Blocking Third Party Intellectual Property Costs actually paid by Vertex to the extent applicable to such Licensed Product during or prior to such [***]; *provided, however,* that in no event will the royalties that would otherwise be payable to Company with respect to Net Sales of Licensed Products pursuant to Section 7.6.1 (after any applicable reduction to such Net Sales pursuant to Section 7.6.3 and Section 7.6.4) be reduced by more than [***]% in any given [***] as a result of any deduction under this Section 7.6.5; and *provided further,* that Vertex will be entitled to carry forward to subsequent [***] any amounts with respect to which Vertex would have been entitled to make a deduction pursuant to this Section 7.6.5 but is unable to take such deduction pursuant to the first proviso in this Section 7.6.5.

7.6.6. **Cumulative Reductions Floor.** Notwithstanding anything to the contrary herein, in no event shall the cumulative effect of the adjustments in Section 7.6.3, Section 7.6.4 and Section 7.6.5 in any given [***] reduce the royalties payable to Company pursuant to Section 7.6.1 to less than [***]% of the amounts that otherwise would have been payable pursuant to Section 7.6.1 (without taking into consideration any such adjustments) in such [***].

7.6.7. **Royalty Reports.** On a Vertex Target-by-Vertex Target basis following the First Commercial Sale of a Licensed Product directed against a Vertex Target and continuing until the expiration of all Royalty Terms for Licensed Products directed against such Vertex Target, within [***] after the end of each [***], Vertex will deliver a report to Company specifying: (a) Net Sales of the Licensed Products directed against such Vertex Target by Vertex, its Affiliates and its Sublicensees in the relevant [***], (b) to the extent such Net Sales include sales not denoted in U.S. Dollars, a summary of the then-current exchange rate methodology used by Vertex, (c) royalties payable on such Net Sales, (d) the withholding taxes, if any, required by law to be deducted in respect of such royalties, (e) the amount and description of any reduction in royalties due to Blocking Third Party Intellectual Property Costs in the relevant [***], and (f) the date of the First Commercial Sale of each Licensed Product in each country in the Territory that has occurred during the corresponding [***]. All royalty payments due under Section 7.6.1 for each [***] will be due and payable within [***] after the end of each [***].

7.7. **Company In-License Agreements.**

7.7.1. **Proposed New Company Agreements.** Company may, during the Term, enter into one or more agreements to acquire or in-license rights to additional intellectual property that, if solely owned by Company, without any encumbrance or restriction on licensing, would constitute Company Background Technology. Any such agreement that [***] will be considered to be a “**Proposed New Company Agreement**”. Notwithstanding the foregoing, the following shall not be considered a Proposed New Company Agreement: (i) an [***], or (ii) [***] (each, a “**New Platform Agreement**”). For clarity, (x) the terms of this Section 7.7 shall not apply to any Antibody Agreement and (y) the terms of Section 7.7.1(a) shall not apply to (A) any New Platform Agreement or (B) [***] (y), an “**Other Company License Agreement**”); *provided* that (I) subject to Section 7.7.4, the intellectual property in-licensed under any Other Company License Agreement, to the extent it constitutes Company Background Technology, shall be included in the license grant to Vertex hereunder, (II) [***], and (III) any Other Company License Agreement that includes intellectual property [***].

(a) If Company [***] with any Third Party (a “**Grantor**”) regarding a Proposed New Company Agreement, [***]. Company shall provide Vertex with [***].

(b) Any Proposed New Company Agreement shall be licensable or sublicensable (as the case may be) to Vertex under this Agreement. Company shall use reasonable, good faith efforts to [***].

7.7.2. **New Company Agreements.** [***] following execution of a Proposed New Company Agreement, Company shall provide to Vertex [***] shall constitute notice by Company that Company proposes to make such Proposed New Company Agreement subject to Section 7.7.3 if Vertex elects to have such Proposed New Company Agreement become a New Company Agreement in accordance with this Section 7.7.2. Company and Vertex will discuss in good faith to determine whether Vertex will take a license or sublicense (as the case may be) under all or a portion of the intellectual property rights that are the subject of such Proposed New Company Agreement, and Vertex will provide Company with written notice of its decision with

respect thereto. Following such notice, subject to the terms of such Proposed New Company Agreement that are applicable to a Licensee thereunder, such intellectual property rights shall automatically be deemed included in the Company Background Technology (any such Proposed New Company Agreement with respect to such intellectual property rights that are included in the Company Background Technology pursuant to this sentence, a “**New Company Agreement**”). For clarity, any intellectual property rights in-licensed or acquired by Company pursuant to a Proposed New Company Agreement that is not a New Company Agreement (*i.e.*, under which Vertex does not agree to take a license or sublicense) shall not be included in Company Background Technology. Additionally, if Company later [***]; *provided that*, if Company does not propose to make such executed agreement subject to Section 7.7.3 (any such agreement, a “**Later Company License Agreement**”), then, (i) subject to Section 7.7.4, the intellectual property in-licensed under any Later Company License Agreement, to the extent it constitutes Company Background Technology, shall be included in the license grant to Vertex hereunder and (ii) if a Later Company License Agreement imposes obligations applicable to Vertex as a sublicensee thereunder, then, subject to Company’s obligations of confidentiality to Third Parties, if any, Company shall provide to Vertex [***]. To the extent that (x) any such executed agreement that Company proposes to make subject to Section 7.7.3 is not licensable or sublicensable (as the case may be) to Vertex or (y) any Later Company License Agreement that [***]. For the avoidance of doubt, nothing in this Section 7.7.2 obligates Company to terminate any such executed agreement or Later Company License Agreement with the Grantor.

7.7.3. **Payment Obligations under New Company Agreements.** Any payment obligations arising under any New Company Agreement directly as a result of the [***] by or on behalf of Company, Vertex or any of their respective Affiliates or Vertex’s Sublicensees, after application of all available reductions to and deductions from such payment obligations under the applicable New Company Agreement (but, for the avoidance of doubt, excluding any such payment obligations of Company with respect to licensing or sublicensing income (as the case may be) received by Company), will be paid by Company and reimbursed by Vertex in accordance with this Section 7.7.3. Except as expressly set forth in the preceding sentence, Company shall be responsible for all payment obligations under any New Company Agreement (including any such payment obligations with respect to licensing or sublicensing income (as the case may be) received by Company). Company shall provide Vertex with a reasonably detailed invoice for any reimbursable payments made by Company pursuant to this Section 7.7.3 within [***] in which any such payments were made by Company, and Vertex shall pay the undisputed portion of such invoices within [***] of receipt thereof. For clarity, Vertex and its Affiliates will be obligated to reimburse a given amount owed under a New Company Agreement one time only. The provisions of Section 7.9 shall apply to any such amounts paid or payable by Vertex, *mutatis mutandis*. Notwithstanding anything to the contrary in this Agreement, any amounts paid by Vertex pursuant to this Section 7.7.3, regardless of whether such amounts are paid to Company or directly to the applicable Third Party, shall constitute Blocking Third Party Intellectual Property Costs under this Agreement but solely to the extent such Third Party intellectual property rights are [***] and such amounts are paid by Vertex directly as a result of the [***], except where otherwise mutually agreed by the Parties in writing on a New Company Agreement-by-New Company Agreement basis.

7.7.4. **Termination of License under New Company Agreements, Other Company License Agreements and Later Company License Agreements.** Notwithstanding the foregoing, Vertex may, at its sole discretion, (a) notify Company that it elects to terminate its license or sublicense (as applicable) under the Company Background Technology acquired or licensed pursuant to a New Company Agreement, whereupon, (i) such New Company Agreement shall be deemed not to be a New Company Agreement under this Agreement, (ii) Vertex will have no further payment obligations under Section 7.7.3, if any, with respect to such New Company Agreement, and (iii) all intellectual property rights in-licensed or acquired by Company under such New Company Agreement shall no longer be included in Company Background Technology, or (b) notify Company that it elects to terminate its license or sublicense (as applicable) under the Company Background Technology acquired or licensed pursuant to an Other Company License Agreement or Later Company License Agreement, whereupon, (x) such Other Company License Agreement or Later Company License Agreement, as applicable, shall be deemed not to be an Other Company License Agreement or Later Company License Agreement, as applicable, under this Agreement and (y) all intellectual property rights in-licensed or acquired by Company under such Other Company License Agreement or Later Company License Agreement, as applicable, shall no longer be included in Company Background Technology.

7.8. **Research Funding for Follow-On Research.**

7.8.1. **Research Costs for Collaboration Program for Additional Target.** If Vertex exercises the Additional Target Option, Vertex will reimburse Company for its [***] actually incurred by Company or its Affiliates for the Research Activities under the Collaboration Program for the Additional Target performed in accordance with a Research Plan and Additional Target Research Budget, as the same may be updated or amended; *provided* that Vertex shall not reimburse Company for any [***] incurred during any Calendar Year in the conduct of such Research Activities in excess of [***] of the then-current Additional Target Research Budget for such Calendar Year and, subject to Section 2.2.3, Company shall be solely responsible for all such excess expenses above [***] of the Additional Target Research Budget incurred during such Calendar Year (as the same may be updated or amended), unless otherwise agreed in writing by Vertex.

7.8.2. **Research Costs for Follow-On Research.** Vertex will reimburse Company for its [***] actually incurred by Company or its Affiliates for the Follow-On Research performed in accordance with a Follow-On Research Plan and Follow-On Research Budget, as the same may be updated or amended; *provided* that Vertex shall not reimburse Company for any [***] incurred during any Calendar Year in the conduct of the Follow-On Research in excess of [***] of the then-current Follow-On Research Budget for such Calendar Year and, subject to Section 2.5, Company shall be solely responsible for all such excess expenses above [***] of the Follow-On Research Budget incurred during such Calendar Year (as the same may be updated or amended), unless otherwise agreed in writing by Vertex.

7.8.3. **Costs for Manufacturing Technology Transfer.** Vertex will reimburse Company for its [***] actually incurred by Company or its Affiliates for the Manufacturing Technology Transfer performed in accordance with the Manufacturing Technology Transfer Plan and Manufacturing Technology Transfer Budget; *provided* that Vertex shall not reimburse Company for any [***] incurred in the conduct of the Manufacturing Technology Transfer in excess of [***] of the then-current Manufacturing Technology Transfer Budget (as the same may be amended from time to time by the Parties) and Company shall be solely responsible for all such excess expenses above [***] of the Manufacturing Technology Transfer Budget (as may be amended), unless otherwise agreed in writing by Vertex.

7.8.4. **Payments.** Any payments to be made to Company by Vertex pursuant to Section 7.8.1, Section 7.8.2 and Section 7.8.3 shall be made [***] pursuant to invoices submitted by Company to Vertex within [***] for which such costs have been incurred; *provided* that Company shall provide a good faith estimate of any costs for which reimbursement is due under Section 7.8.1 within [***]. Each such invoice will be accompanied by reasonable supporting documentation evidencing the [***] incurred for, as applicable, the Follow-On Research or the Manufacturing Technology Transfer (such expenses to be itemized) during such [***]. Undisputed payments shall be due within [***] after Vertex receives such an invoice from Company.

7.9. **Payment Terms.**

7.9.1. **Currency; Payment Method.** All payments under this Agreement are expressed in U.S. Dollars and will be paid in U.S. Dollars, by wire transfer or Automated Clearing House (ACH) payment to an account designated by Company (which account Company may update from time to time in writing).

7.9.2. **Exchange.** If any amounts that are relevant to the determination of amounts to be paid under this Agreement or any calculations to be performed under this Agreement are denoted in a currency other than U.S. Dollars, such amounts will be converted to their U.S. Dollar equivalent using Vertex's then-current standard procedures and methodology, including its then-current standard exchange rate methodology for the translation of foreign currency expenses into U.S. Dollars or, in the case of Sublicensees, such similar methodology, consistently applied.

7.10. **Withholding Tax.** Where any sum due to be paid to Company hereunder is subject to any withholding or similar tax, Vertex will pay such withholding or similar tax to the appropriate Governmental Authority and deduct the amount paid from the amount then due to Company. Vertex will timely transmit to Company an official tax certificate or other evidence of such withholding sufficient to enable Company to claim such payment of taxes. The Parties will cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, Milestone Payments, and other payments made by Vertex to Company under this Agreement. Company will provide to Vertex any tax forms that may be reasonably necessary in order for Vertex not to withhold tax or to withhold tax at a reduced rate under an applicable income tax treaty. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.

7.11. **Records; Audits.** Vertex will and will cause its Affiliates and will use Commercially Reasonable Efforts to cause its Sublicensees to keep and maintain accurate and complete records regarding Net Sales during the [***]. Company will keep accurate and complete records regarding all [***] incurred in connection with its performance of the Follow-On Research, in sufficient detail to confirm the accuracy of any payments required under this Agreement, covering the [***]. Upon [***] prior written notice from the other Party (the “**Auditing Party**”), the Party required to maintain such records will permit (and Vertex will cause its Affiliates and use Commercially Reasonable Efforts to cause its Sublicensees to permit) (as applicable, the “**Audited Party**”) an independent certified public accounting firm of internationally recognized standing, selected by the Auditing Party and reasonably acceptable to the Audited Party, to examine the relevant books and records of the Audited Party and its Affiliates, as may be reasonably necessary to verify the sales milestone report under Section 7.5.3 and the royalty reports submitted by Vertex in accordance with Section 7.6.6 or the [***] reported by Company in accordance with Section 7.8, as applicable. An examination by the Auditing Party under this Section 7.11 will occur not more than [***] in any Calendar Year and will be limited to the pertinent books and records for any Calendar Year ending not more than [***] before the date of the request. No records will be audited more than once unless a discrepancy with respect to such records is discovered during a prior audit. The accounting firm will be provided access to such books and records at the Audited Party’s facility or facilities where such books and records are normally kept and such examination will be conducted during the Audited Party’s normal business hours. The Audited Party may require the accounting firm to sign a customary non-disclosure agreement before providing the accounting firm access to its facilities or records. Upon completion of the audit, the accounting firm will provide both Parties a written report disclosing whether the reports submitted by Vertex or the [***] submitted by Company, as applicable, are correct or incorrect and the specific details concerning any discrepancies. No other information will be provided to the Auditing Party. If the report or information submitted by the Audited Party results in an underpayment or overpayment, (a) the Party owing an underpaid amount will promptly pay the amount of such underpayment to the other Party, and (b) any such overpayment shall be creditable against future payments to the other Party hereunder. The costs and fees of any audit conducted by the Auditing Party under this Section 7.11 will be borne by the Auditing Party, unless such audit reveals an underpayment of amounts owed to the Auditing Party or overpayment of amounts owed to the Audited Party of more than [***] percent of the amount that was owed with respect to the relevant period, in which case, the Audited Party will reimburse the Auditing Party for the reasonable expense incurred by the Auditing Party in connection with the audit.

7.12. **Late Payment.** Any payments or portions thereof due hereunder that are not paid when due will accrue interest from the date due until paid at an annual rate equal to the [***].

ARTICLE 8.
INTELLECTUAL PROPERTY

8.1. Ownership; Assignment.

8.1.1. **Company Technology and Vertex Technology.** As between the Parties, Company will own and retain all of its rights, title and interest in and to the Company Background Technology, and Vertex will own and retain all of its rights, title and interest in and to any Vertex Background Technology, subject to any rights or licenses expressly granted by one Party to the other Party under this Agreement.

8.1.2. **Agreement Technology.**

(a) For purposes of determining ownership under this Section 8.1, where inventorship is relevant to such determination, inventorship will be determined in accordance with United States patent laws (regardless of where the applicable activities occurred).

(b) As between the Parties, Company will be the sole owner of any Agreement Know-How that [***] (the “**ETB Agreement Know-How**”) and all Patents that [***] any of the foregoing Know-How (the “**ETB Agreement Patents**”, and, collectively with the ETB Agreement Know-How, the “**ETB Agreement Technology**”), and will own and retain all rights, title and interests in and to the ETB Agreement Technology, subject to any rights or licenses expressly granted by Company to Vertex under this Agreement. For clarity, ETB Agreement Technology shall exclude any Product Agreement Technology.

(c) As between the Parties, Vertex will be the sole owner of any Agreement Know-How that [***] (i) [***], (ii) [***] or (iii) [***] ([***], such Know-How described in (i) through (iii), the “**Product Agreement Know-How**”) and all Patents that Cover the Product Agreement Know-How (the “**Product Agreement Patents**,” and, together with the Product Agreement Know-How, the “**Product Agreement Technology**”), and Vertex will own and retain all rights, title, and interests in and to the Product Agreement Technology, subject to any rights or licenses expressly granted by Vertex to Company under this Agreement. The Parties shall coordinate in good faith through the IP Committee to segregate claims Covering ETB Agreement Know-How and claims Covering Product Agreement Know-How into separate Patents (which may be related, e.g., as continuations or divisionals of one another). The Parties shall also coordinate in good faith through the IP Committee to segregate claims Covering an Antibody directed against a Collaboration Target and claims Covering [***] into separate Patents (which may be related, e.g., as continuations or divisionals of one another). The coordination referred to in the previous two sentences shall include, without limitation, collaboration in the form of sharing pre-filing disclosure and planned filing dates, at least [***] in advance of filing, to ensure [***]; in addition, each Party shall promptly notify the other Party of the date the applicable patent filing was made.

(d) Except as expressly set forth in Sections 8.1.2(b) and (c), as between the Parties, each Party will be the sole owner of any Agreement Know-How discovered, developed, invented or created solely by such Party or its Affiliates or Third Parties acting on its or their behalf, and all Patents that Cover any of the foregoing, and the Parties shall jointly own, on an equal and undivided basis, any Agreement Know-How discovered, developed, invented or created jointly by both (i) Vertex, its Affiliates or Third Parties acting on Vertex's behalf and (ii) Company, its Affiliates or Third Parties acting on Company's behalf, and all Patents that Cover any of the foregoing Know-How. Except as expressly provided in this Agreement, neither Party will have any obligation to account to the other Party for profits with respect to, or to obtain any consent of the other Party to license or exploit any such jointly owned Agreement Technology by reason of joint ownership thereof, and each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting.

(e) Each Party and its Affiliates will, and hereby does, assign to the other Party or one or more of its designated Affiliates, such first Party's and its Affiliates' rights, title and interest in any Agreement Technology as may be necessary to effectuate the allocation of ownership of Agreement Technology set forth in this Section 8.1. Without limiting the foregoing, promptly following the License Effective Date with respect to a Development Candidate, Company and its Affiliates will, [***]. The assigning Party will take all actions and provide the other Party with all reasonably requested assistance to [***] and will execute any and all documents necessary to [***].

(f) [***] following Company's or any of its Affiliates' receipt of an invention disclosure with respect to any invention discovered, developed, invented or created, solely or jointly, by Company or its Affiliates or Third Parties acting on its or their behalf that constitutes [***], Company will [***] disclose to Vertex in writing, and will cause its Affiliates to so disclose, the discovery, development, invention or creation of such [***]. Promptly following Vertex's or any of its Affiliate's receipt of an invention disclosure with respect to any invention that is discovered, developed, invented or created, solely or jointly, by Vertex or its Affiliates or Third Parties acting on its or their behalf that constitutes [***], Vertex will promptly disclose to Company in writing, and will cause its Affiliates to so disclose, the discovery, development, invention or creation of such [***].

8.2. Prosecution and Maintenance of Patents.

8.2.1. **Company Patents.** Except as expressly set forth in this Agreement, Company will control, be responsible and have the sole right (but not the obligation), at its own expense, for all aspects of the Prosecution and Maintenance of Company Background Patents and Company Agreement Patents.

8.2.2. **Vertex Patents.** Vertex will control and be responsible and have the sole right (but not the obligation), at its own expense, for all aspects of the Prosecution and Maintenance of all Vertex Background Patents and Vertex Agreement Patents.

8.2.3. **Joint Agreement Patents.** The Parties will discuss and agree upon an allocation of responsibility for the Prosecution and Maintenance of Joint Agreement Patents.

8.2.4. **Other Matters Pertaining to Prosecution and Maintenance of Patents.**

- (a) During the Term, each Party will keep the other Party informed through the IP Committee (or directly, if the IP Committee is disbanded) as to material developments with respect to the Prosecution and Maintenance of any Company Background Patents, Company Agreement Patents and Joint Agreement Patents, in each case, for which such Party has responsibility for Prosecution and Maintenance pursuant to this Section 8.2, including by providing copies of any patent office actions or patent office action responses or other correspondence that such Party provides to or receives from any patent office, including notice of all interferences, reissues, re-examinations, or oppositions, and all patent-related filings, and by providing the other Party the timely opportunity to have reasonable input into the strategic aspects of such Prosecution and Maintenance.
- (b) If, during the Term, Vertex intends to abandon any Joint Agreement Patent that Vertex is responsible for Prosecuting and Maintaining in a particular country, then Vertex will so notify Company of such intention at least [***] before such Patent will become abandoned, and Company will have the right, but not the obligation, to assume responsibility for the Prosecution and Maintenance thereof at its own expense with counsel of its own choice.
- (c) If, during the Term, Company intends to abandon (i) [***] or (ii) [***], then Company will notify Vertex of such intention at least [***] before such Patent will become abandoned, and Vertex will have the right, but not the obligation, to assume responsibility for the Prosecution and Maintenance thereof at its own expense with counsel of its own choice. For clarity, this Section 8.2.4(c) shall not apply to any Patent that solely Covers any ETB or Development Candidate directed against a Terminated Target. Notwithstanding the foregoing, Vertex will only have the right to assume responsibility for the Prosecution and Maintenance of a Company Background Patent under this Section 8.2.4(c) to the extent a Third Party licensee under any agreement entered into by Company prior to the Effective Date does not have the right to assume Prosecution and Maintenance of such Patent or waives its right or, if a time period is specified, fails to exercise its right within such specified time to assume Prosecution and Maintenance of such Patent, as the case may be; provided that, Company will not abandon any such Company Background Patent that Covers any ETB directed against a Collaboration Target (other than a Terminated Target), any Development Candidate (except for any Development Candidate directed against a Terminated Target), any Licensed ETB or any Licensed Product without the prior written consent of Vertex, such consent not to be unreasonably withheld, conditioned or delayed.

8.3. **Defense of Claims Brought by Third Parties.** If any Third Party brings a claim or otherwise asserts that any ETB directed against a Collaboration Target, any Development Candidate, any Licensed ETB or any Licensed Product infringes such Third Party's Patent or misappropriates such Third Party's Know-How (each, a "**Third Party Infringement Claim**"), the Party first having notice of the claim or assertion will promptly notify the other Party in writing. Prior to the applicable License Effective Date, Company will have the sole right to undertake and control the defense or settlement of any Third Party Infringement Claim using counsel of its choice, at its cost and expense and, following the applicable License Effective Date, Vertex will have the sole right to undertake and control the defense or settlement of any Third Party Infringement Claim using counsel of its choice, at its cost and expense (such Party having the right to control such defense, the "**Defending Party**"). If the Party not having the right to control such defense in accordance with the preceding sentence (the "**Non-Defending Party**") is named as a defendant in such suit, the Non-Defending Party will have the right to participate in such defense and settlement with its own counsel, at its cost. The Defending Party will not enter into any settlement of any Third Party Infringement Claim that is instituted or threatened to be instituted against the Non-Defending Party without the Non-Defending Party's prior written consent, which will not be unreasonably withheld, conditioned or delayed; *except that*, such consent will not be required if such settlement includes a release of all liability in favor of the Non-Defending Party or an assumption of any unreleased liability by the Defending Party. As requested by the Defending Party, the Non-Defending Party will provide reasonable cooperation and assistance to the Defending Party in connection with the Defending Party's control of the defense or settlement of a Third Party Infringement Claim. Such cooperation and assistance will include executing all necessary and proper documents and taking such actions as appropriate to allow the Defending Party to control the defense and settlement of such Third Party Infringement Claim. The Defending Party will reimburse the Non-Defending Party for the Out-of-Pocket Costs incurred by the Non-Defending Party in providing such assistance and cooperation; *except that* the Defending Party will have no obligation to reimburse the Non-Defending Party for any costs or expenses incurred if the Non-Defending Party exercises its right to participate in the defense and settlement of a Third Party Infringement Claim with its own counsel. The Defending Party will keep the Non-Defending Party reasonably informed of the progress of any Third Party Infringement Claim. Notwithstanding anything to the contrary in this Section 8.3, in the event of any Third Party Infringement Claim that is subject to a Party's indemnification obligations under ARTICLE 10, the applicable provisions of ARTICLE 10 shall control.

8.4. **Enforcement of Technology Against Competitive Infringement.**

8.4.1. **Duty to Notify of Competitive Infringement.** During the Term, if either Party learns of an infringement, unauthorized use, misappropriation or threatened infringement by a Third Party with respect to any Licensed Technology by reason of the making, using, offering to sell, selling or importing of an ETB (or pharmaceutical product containing an ETB) directed against a Collaboration Target or Vertex Target in the Field in the Territory (a "**Competitive Infringement**"), such Party will promptly notify the other Party in writing and will provide such other Party with all available information regarding such Competitive Infringement.

8.4.2. **Prior to Option Exercise.** As between the Parties, for any Competitive Infringement with respect to a Collaboration Target that is not a Vertex Target, Company will have the sole right, but not the obligation, to institute, prosecute, and control a Proceeding to enforce any Licensed Technology against such Competitive Infringement by counsel of its own choice. Vertex will have the right to engage counsel of its own choice in connection with such Proceeding at its own expense. Company will provide Vertex with prompt written notice of the commencement of any such Proceeding, and Company will keep Vertex apprised of the progress of such Proceeding.

8.4.3. **Following Option Exercise.** As between the Parties, for any Competitive Infringement with respect to a Vertex Target, Vertex will have the first right, but not the obligation, to institute, prosecute and control a Proceeding to enforce any Licensed Technology against such Competitive Infringement by counsel of its own choice at its own expense, and Company will have the right, at its own expense, to be represented in that action by counsel of its own choice. If Vertex fails to initiate such Proceeding within a period of [***] after written notice of such Competitive Infringement is first provided by a Party under Section 8.4.1, Company will have the right to initiate and control a Proceeding to enforce the Licensed Technology against such Competitive Infringement by counsel of its own choice at its own expense; *provided* that, if Vertex notifies Company during such [***] period that it is electing in good faith not to institute any Proceeding to enforce the Licensed Technology against such Competitive Infringement for strategic reasons intended to maintain the commercial value of the relevant Licensed Technology or any Licensed ETB or Licensed Product Covered thereby or relating thereto, Company will not have the right to initiate and control any Proceeding to enforce the Licensed Technology against such Competitive Infringement.

8.4.4. **Joinder.**

(a) If a Party initiates a Proceeding in accordance with this Section 8.4, the other Party agrees to be joined as a party plaintiff where necessary and to give the first Party reasonable assistance and authority to file and prosecute the Proceeding. Subject to Section 8.4.5, the costs and expenses of each Party incurred pursuant to this Section 8.4.4(a) will be borne by the Party initiating such Proceeding.

(b) If one Party initiates a Proceeding in accordance with this Section 8.4, the other Party may join such Proceeding as a party plaintiff where necessary for such other Party to seek lost profits with respect to such infringement.

8.4.5. **Share of Recoveries.**

(a) Any damages or other monetary awards recovered, prior to Vertex's exercise of the applicable Option, with respect to a Proceeding brought pursuant to this Section 8.4 will be shared as follows:

(i) [***]; and

(ii) [***].

(b) Any damages or other monetary awards recovered, following Vertex's exercise of the applicable Option, with respect to a Proceeding brought pursuant to this Section 8.4 will be shared as follows:

(i) [***];

(ii) [***]; and

(iii) [***].

8.4.6. **Settlement.** Notwithstanding anything to the contrary under this ARTICLE 8, neither Party may enter a settlement, consent judgment or other voluntary final disposition of a suit under this ARTICLE 8 that disclaims, limits the scope of, admits the invalidity or unenforceability of, or grants a license, covenant not to sue or similar immunity under a Patent owned or controlled by the other Party or its Affiliates without first obtaining the written consent of the Party that owns or controls the relevant Patent; *provided* that the foregoing restriction on granting a license or covenant not to sue will not apply with respect to any Sublicense granted by Vertex in accordance with Section 5.1.2.

8.5. **Other Infringement.**

8.5.1. **Joint Agreement Patents.** With respect to the infringement of a Joint Agreement Patent that is not a Competitive Infringement, neither Party shall enforce such Joint Agreement Patent unless mutually agreed by the Parties; *provided* that the Parties will cooperate in good faith to bring suit together against such infringing party or the Parties may decide to permit one Party to solely bring suit. Any damages or other monetary awards recovered with respect to a Proceeding brought pursuant to this Section 8.5.1 will be shared as follows: (a) [***]; and (b) any remaining proceeds will be allocated as follows: (i) [***]; and (ii) [***].

8.5.2. **Patents Solely Owned by Company.** Company will retain all rights to pursue an infringement of any Patent solely owned by Company that is not a Competitive Infringement, and Company will retain all recoveries with respect thereto.

8.5.3. **Patents Solely Owned by Vertex.** Vertex will retain all rights to pursue an infringement of any Patent solely owned by Vertex and Vertex will retain all recoveries with respect thereto.

8.6. **Patent Listing.** Vertex will have the sole right, but not the obligation, to submit to all applicable Regulatory Authorities patent information pertaining to the Licensed Products pursuant to 21 U.S.C. § 355(b)(1), 21 C.F.R. § 314.53, any similar statutory or regulatory requirement enacted in the future, or any similar statutory or regulatory requirement in any non-U.S. country or other regulatory jurisdiction.

8.7. **Common Ownership Under Joint Research Agreements.** (a) The Parties acknowledge and agree that this Agreement is a “joint research agreement” as defined in 35 U.S.C. § 100(h). (b) Notwithstanding anything to the contrary in this ARTICLE 8, neither Party will have the right to provide to a court or an agency a statement under 37 C.F.R. § 1.104(c)(4)(ii)(A) to disqualify, for purposes of 35 U.S.C. §§ 102(b)(2)(C) and 102(c), prior art under § 102(a)(2) by the other Party without the prior written consent of the other Party, which will not be unreasonably withheld, conditioned or delayed. With respect to any such permitted statement, the Parties shall coordinate their activities with respect to any submissions, filings or other activities in support thereof. (c) Notwithstanding the foregoing, the other Party’s consent under this Section 8.7 shall not be required to permit a Party to file with a court or agency a terminal disclaimer under 37 C.F.R. § 1.321(d) to overcome any obviousness-type double patenting in any patent application claiming a Licensed ETB, Licensed Product or one or more uses thereof.

8.8. **Patent Term Extension.** On a Licensed ETB-by-Licensed ETB basis, following the License Effective Date for such Licensed ETB, as between the Parties, Vertex will have the sole right and responsibility to obtain patent term extension in any country in the Territory under any statute or regulation equivalent or similar to 35 U.S.C. § 156, where applicable to the corresponding Licensed Products for such Licensed ETB. Vertex will determine the relevant Agreement Patents, if any, whose term will be extended (including, without limitation, by filing supplementary protection certificates and any other extensions that are now or in the future become available). Company will abide by Vertex’s determination and cooperate, as reasonably requested by Vertex, in connection with the foregoing (including by providing appropriate information and executing appropriate documents), at Vertex’s cost.

8.9. **Recording.** If Vertex deems it necessary or desirable to register or record this Agreement or evidence of this Agreement with any patent office or other appropriate Governmental Authority in one or more jurisdictions in the Territory, Company will reasonably cooperate to execute and deliver to Vertex any documents accurately reflecting or evidencing this Agreement that are necessary or desirable, in Vertex’s reasonable judgment, to complete such registration or recordation. If and after the license under 5.2.2 is effective, if Company deems it necessary or desirable to register or record this Agreement or evidence of this Agreement with any patent office or other appropriate Governmental Authority in one or more jurisdictions in the Territory, Vertex will reasonably cooperate to execute and deliver to Company any documents accurately reflecting or evidencing this Agreement that are necessary or desirable, in Company’s reasonable judgment, to complete such registration or recordation.

8.10. **Unitary Patent System.** Vertex will have the exclusive right to opt-in to or opt-out of the EU Unitary Patent System for any of the European Company Agreement Patents, European Vertex Agreement Patents and European Joint Agreement Patents. Without limiting the generality of the foregoing, unless a Party or its Affiliate has expressly opted in to the EU Unitary Patent System with respect to a given Patent, the other Party will not initiate any action under the EU Unitary Patent System without such Party's prior written approval, such approval to be granted or withheld in such Party's sole discretion.

8.11. **Trademarks.** Following Vertex's exercise of an Option with respect to a Development Candidate, all trademarks, trade dress and copyrights used in connection with the Commercialization of the corresponding Licensed Products in the Field in the Territory will be selected and owned exclusively by Vertex.

ARTICLE 9. REPRESENTATIONS AND WARRANTIES

9.1. **Representations and Warranties of Vertex.** Vertex hereby represents and warrants to Company, as of the Effective Date, that:

(a) Vertex is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization;

(b) Vertex (i) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (ii) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

(c) it has the requisite resources and expertise to perform its obligations hereunder;

(d) this Agreement has been duly executed and delivered on behalf of Vertex, and constitutes a legal, valid and binding obligation, enforceable against Vertex in accordance with the terms hereof, except to the extent that enforcement of the rights and remedies created hereby is subject to (i) bankruptcy, insolvency, reorganization, moratorium and other similar laws of general application affecting the rights and remedies of creditors, or (ii) laws governing specific performance, injunctive relief and other equitable remedies;

(e) the execution, delivery and performance of this Agreement by Vertex will not constitute a default under or conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, or violate any Applicable Law of any governmental body or administrative or other agency having jurisdiction over Vertex;

(f) Vertex has obtained all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons or entities required to be obtained by it in connection with the execution and delivery of this Agreement; and

(g) Vertex is an “accredited investor” within the meaning of Securities and Exchange Commission Rule 501 of Regulation D, as presently in effect, under the Securities Act of 1933.

9.2. **Representations and Warranties of Company.** Company hereby represents and warrants to Vertex, as of the Effective Date, that:

(a) it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization;

(b) it (i) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (ii) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

(c) it has the requisite resources and expertise to perform its obligations hereunder;

(d) this Agreement has been duly executed and delivered on behalf of Company, and constitutes a legal, valid and binding obligation, enforceable against it in accordance with the terms hereof, except to the extent that enforcement of the rights and remedies created hereby is subject to (i) bankruptcy, insolvency, reorganization, moratorium and other similar laws of general application affecting the rights and remedies of creditors, or (ii) laws governing specific performance, injunctive relief and other equitable remedies;

(e) the execution, delivery and performance of this Agreement by Company will not constitute a default under or conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, or violate any Applicable Law of any governmental body or administrative or other agency having jurisdiction over it;

(f) it has obtained all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons or entities required to be obtained by it in connection with the execution and delivery of this Agreement;

(g) except for those activities set forth in Schedule 9.2(g), Company is not conducting any internal research program (i.e., research activities conducted on behalf of Company or its Affiliates and not on behalf of any Third Party) whereby Company is actively pursuing or has committed in an approved budget or contract to pursue, using the ETB Platform, identification, development, synthesis, manufacture or optimization of [***];

(h) to Company’s Knowledge, the conduct of the Research Activities as contemplated by this Agreement as of the Effective Date will not (i) constitute misappropriation of any Know-How of any Third Party or (ii) infringe any Patent of any Third Party;

(i) to Company's Knowledge, Company Controls all Patents and Know-How owned or licensed by Company that are necessary [***] to research, develop, manufacture, commercialize, use, keep or otherwise exploit ETBs directed against the Initial Target as such activities are contemplated by this Agreement as of the Effective Date (such Patents, the "Existing Background Patents", such Know-How, the "Existing Background Know-How" and, collectively, the "Existing Background Technology" in each case existing as of the Effective Date);

(j) Company is the sole and exclusive owner of all Existing Background Technology, all of which is free and clear of any liens, charges and encumbrances (other than licenses or other rights granted to Third Parties, such as security liens, that would not adversely affect the options, rights and licenses (or sublicenses, as the case may be) granted to Vertex hereunder as of the Effective Date), and, as of the Effective Date, to Company's Knowledge, neither any license granted by Company or its Affiliates to any Third Party, nor any license granted by any Third Party to the Company or its Affiliates conflicts with the options, rights and licenses (or sublicenses, as the case may be) granted to Vertex hereunder as of the Effective Date, and Company is entitled to grant all options, rights and licenses (or sublicenses, as the case may be) under the Existing Background Technology that it purports to grant to Vertex under this Agreement;

(k) Schedule 1.81 sets forth a true, correct and complete list of all Existing Background Patents as of the Effective Date and indicates whether such Patent is owned by Company or licensed by Company from a Third Party and if so, identifies the licensor or sublicensor from which the Patent is licensed;

(l) all issued Patents within the Existing Background Patents are in full force and effect and, to Company's Knowledge, all Existing Background Patents have been Prosecuted and Maintained from the respective patent offices in accordance with Applicable Law. Company has not received any written claims that any issued Existing Background Patent is invalid or unenforceable;

(m) with respect to the Existing Background Patents, Company has obtained assignments from the inventors of all inventorship rights relating to such Patents, and all such assignments of inventorship rights relating to such Patents have been properly executed and recorded in the relevant U.S. patent offices;

(n) no Existing Background Technology is subject to any funding agreement with any government or governmental agency;

(o) to its Knowledge, the Research, Development, Manufacture, Commercialization or other exploitation of ETBs directed against the Initial Target by Vertex (or its Affiliates or Sublicensees) does not and will not infringe any issued Patent of any Third Party;

(p) there are no judgments or settlements against Company or any of its Affiliates, or any pending or, to Company's Knowledge, threatened claims or litigation, in each case in connection with the Existing Background Technology or relating to the transactions contemplated by this Agreement; and

(q) Company has not employed (and has not used a Subcontractor that has employed) any Person debarred by the FDA (or subject to a similar sanction of EMA or foreign equivalent), or any Person that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA or foreign equivalent), in any capacity in connection with this Agreement or the ETB Platform.

9.3. **Company Covenants**. Company hereby covenants to Vertex that, except as expressly permitted under this Agreement:

(a) Company will, and will require its Affiliates and Subcontractors to, comply with all Applicable Law in its and their conduct of the Research Activities and Follow-On Research, including where appropriate GMP, GCP and GLP (or similar standards);

(b) Company will maintain and not breach in a manner that could reasonably be expected to give rise to a termination right of the licensor party, and will cause its Affiliates to maintain and not breach in a manner that could reasonably be expected to give rise to a termination right of the licensor party, any New Company Agreement;

(c) Company will promptly notify Vertex in writing of any material breach by Company or its Affiliate or by the licensor party of any New Company Agreement, and in the event of a breach by Company or its Affiliate, will permit Vertex to cure such breach on Company's or its Affiliates behalf upon Vertex's request, subject to the terms of the applicable New Company Agreement;

(d) Company will not, and will cause its Affiliates not to, amend, modify or terminate any New Company Agreement in a manner that would adversely affect Vertex's rights under this Agreement or adversely affect Vertex's obligations under this Agreement, including those rights or obligations of Vertex resulting from Vertex being a sublicensee under any New Company Agreement, without first obtaining Vertex's written consent, which consent may be withheld in Vertex's sole discretion;

(e) neither Company nor any of its Affiliates will effect any corporate restructuring or enter into any new agreement or otherwise obligate itself to any Third Party, or amend an existing agreement with a Third Party, in each case, in a manner that conflicts with or otherwise adversely affects the options, rights and licenses (or sublicenses, as the case may be) granted to Vertex hereunder;

(f) Company will not, and will cause its Affiliates not to (i) license, sell, assign or otherwise transfer to any Person any [***] (or agree to do any of the foregoing) or (ii) incur or permit to exist, with respect to any [***], any lien, encumbrance, charge, security interest, mortgage, liability, grant of license to Third Parties or other restriction (including in connection with any indebtedness), in each case, that would conflict with, limit, impair, restrict or otherwise adversely affect the options, rights and licenses (or sublicenses, as the case may be) granted to Vertex hereunder, including [***];

(g) Company will require all employees and Subcontractors of Company and its Affiliates performing [***] hereunder on behalf of Company or its Affiliates to execute binding and enforceable agreements presently assigning to Company all right, title and interest in and to any inventions developed by them that constitute Agreement Technology, whether or not patentable, and will use Commercially Reasonable Efforts to enforce such agreements;

(h) Company will not engage directly or indirectly, in any capacity in connection with this Agreement any Person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any such similar sanction; and

(i) Company will inform Vertex in writing promptly if it or any Person engaged by Company or any of its Affiliates who is performing services under this Agreement or any ancillary agreements is debarred or is the subject of a conviction described in Section 306 of the FD&C Act, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to Company's knowledge, is threatened, relating to the debarment or conviction of Company, any of its Affiliates or any such Person performing services hereunder or thereunder.

9.4. **Vertex Covenant.** Vertex hereby covenants to Company that, except as expressly permitted under this Agreement:

(a) Vertex will, and will require its Affiliates, Sublicensees and Subcontractors to, comply with all Applicable Law in its and their conduct of Research, Development, Manufacture and Commercialization hereunder, including where appropriate GMP, GCP and GLP (or similar standards);

(b) Vertex will require all employees and Subcontractors of Vertex and its Affiliates performing Research, Development, Manufacture or Commercialization activities hereunder on behalf of Vertex or its Affiliates to execute binding and enforceable agreements presently assigning to Vertex all right, title and interest in and to any inventions developed by them that constitute ETB Agreement Technology, Joint Agreement Technology or Antibody Agreement Technology, in each case, whether or not patentable, and will use Commercially Reasonable Efforts to enforce such agreements;

(c) Vertex will not engage directly or indirectly, in any capacity in connection with this Agreement any Person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any such similar sanction; and

(d) Vertex will inform Company in writing promptly if it or any Person engaged by Vertex or any of its Affiliates who is performing services under this Agreement or any ancillary agreements is debarred or is the subject of a conviction described in Section 306 of the FD&C Act, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to Vertex's knowledge, is threatened, relating to the debarment or conviction of Vertex, any of its Affiliates or any such Person performing services hereunder or thereunder.

9.5. **Disclaimer.** EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED (AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES NOT EXPRESSLY PROVIDED IN THIS AGREEMENT), INCLUDING WITH RESPECT TO ANY PATENTS OR KNOW-HOW, INCLUDING WARRANTIES OF VALIDITY OR ENFORCEABILITY OF ANY PATENTS, TITLE, QUALITY, COMPLETENESS, ACCURACY, MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR PURPOSE, PERFORMANCE AND NONINFRINGEMENT OF ANY THIRD PARTY PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS. WITHOUT LIMITING THE FOREGOING, NEITHER PARTY MAKES ANY REPRESENTATION, WARRANTY OR GUARANTEE THAT ANY COLLABORATION PROGRAM WILL BE SUCCESSFUL, OR THAT ANY PARTICULAR RESULTS WILL BE ACHIEVED WITH RESPECT TO ANY COLLABORATION PROGRAM OR ANY LICENSED ETB OR LICENSED PRODUCT HEREUNDER.

ARTICLE 10.
INDEMNIFICATION; INSURANCE; LIMITATIONS

10.1. **Indemnification.**

10.1.1. **Indemnification by [***].** [***] will indemnify, defend and hold harmless [***], its Affiliates, and its and its Affiliates' employees, officers, directors and agents and their respective successors, heirs and assigns (each, a "[***] **Indemnified Party**") from and against any liability, loss, damage or expense (including reasonable attorneys' fees and expenses) (collectively, "**Liability**") that the [***] Indemnified Party may incur or otherwise be required to pay to one or more Third Parties in connection with any Third Party suit, investigation, claim or demand resulting from or arising out of:

(a) the Research, Development, Manufacture, Commercialization, use or other exploitation of any Licensed ETB or Licensed Product by, on behalf of, or under the authority of, [***] or its Affiliates or Sublicensees or Subcontractors (other than by any [***] Indemnified Party), other than claims by one or more Third Parties that the practice of the ETB Platform in accordance with this Agreement infringes or misappropriates any issued Patent or other intellectual property rights owned or controlled by such Third Party(ies);

(b) the use by [***] at [***]'s direction in accordance with this Agreement of any Antibody to which [***] has obtained rights by directly contracting with a Third Party pursuant to Section 2.4;

(c) the material breach by [***] of any of its representations, warranties or covenants set forth in this Agreement; or

(d) the negligence or intentional misconduct of [***] or any [***]Indemnified Party;

except, in each case ((a)–(d)), to the extent such claims fall within the scope of [***]'s indemnification obligations under Section 10.1.2 (or would have had the Third Party claim been made against [***] under this Agreement) as to which Liability each Party will indemnify the other to the extent of their respective liability.

10.1.2. **Indemnification by [***].** [***] will indemnify, defend and hold harmless [***], its Affiliates and its and its Affiliates' employees, officers, directors and agents and their respective successors, heirs and assigns (each, a "[***] **Indemnified Party**") from and against any Liability that the [***] Indemnified Party may incur or otherwise be required to pay to one or more Third Parties in connection with any Third Party suit, investigation, claim or demand resulting from or arising out of:

(a) any claim that the practice of the ETB Platform in accordance with this Agreement infringes or misappropriates any issued Patent or other intellectual property rights owned or controlled by any Third Party;

(b) [***]'s or any of its Affiliates' or Subcontractors' conduct of the Research Activities or the Follow-On Research, other than the use by [***] at [***]'s direction in accordance with this Agreement of any Antibody to which [***] has obtained rights by directly contracting with a Third Party pursuant to Section 2.4;

(c) the material breach by [***] of any of its representations, warranties or covenants set forth in this Agreement; or

(d) the negligence or intentional misconduct of [***] or any [***] Indemnified Party;

except, in each case ((a)–(d)), to the extent such claims fall within the scope of [***]'s indemnification obligations under Section 10.1.1 (or would have had the Third Party claim been made against [***] under this Agreement) as to which Liability each Party will indemnify the other to the extent of their respective liability.

10.1.3. **Procedure.** Each Party will notify the other Party in writing if it becomes aware of a claim for which such Party may seek indemnification hereunder. If any Proceeding (including any governmental investigation) is instituted against a Party with respect to which indemnity may be sought pursuant to Section 10.1.1 or 10.1.2, as applicable, such Party (the “**Indemnified Party**”) will give prompt written notice of the indemnity claim to the other Party (the “**Indemnifying Party**”) and provide the Indemnifying Party with a copy of any complaint, summons or other written notice that the Indemnified Party receives in connection with any such claim. An Indemnified Party's failure to deliver such written notice will relieve the Indemnifying Party of liability to the Indemnified Party under Section 10.1.1 or 10.1.2, as applicable, only to the extent such delay is prejudicial to the Indemnifying Party's ability to defend such claim and allow the Indemnifying Party to assume the defense of claim. *Provided* that the Indemnifying Party is not contesting the indemnity obligation, the Indemnified Party will permit the Indemnifying Party to control any litigation relating to such claim and the disposition of such claim by negotiated settlement or otherwise (subject to this Section 10.1) and any failure to contest such obligation prior to assuming control will be deemed to be an admission of the obligation to indemnify. The Indemnifying Party will act reasonably and in good faith with respect to all matters relating to such claim and will not settle or otherwise resolve such claim without the Indemnified Party's prior written consent, which will not be unreasonably withheld, conditioned or delayed; *provided* that such consent will not be required with respect to any settlement involving only the payment of monetary awards for which the Indemnifying Party will be fully responsible. The Indemnified Party will cooperate with the Indemnifying Party in the Indemnifying Party's defense of any claim for which indemnity is sought under this Agreement, at the Indemnifying Party's cost and expense.

10.2. **Insurance.** Throughout the Term, Company and Vertex will respectively, at their own cost and expense, obtain and maintain the insurance coverage listed on Schedule 10.2 from insurance carriers licensed to do business under the laws of the country, state, commonwealth, province, or territory in which such Party's obligations are provided, with insurers that carry a rating of at least an A- VII or better from A.M. Best. Each Party will furnish to the other Party evidence of such insurance upon request. Notwithstanding the foregoing, [***] may self-insure to the extent that it self-insures other activities similar to the activities under this Agreement.

10.3. **Limitation of Consequential Damages.** EXCEPT FOR (A) CLAIMS OF A THIRD PARTY THAT ARE SUBJECT TO INDEMNIFICATION UNDER THIS ARTICLE 10, (B) CLAIMS ARISING OUT OF A PARTY'S WILLFUL MISCONDUCT OR (C) A PARTY'S BREACH OF SECTION 5.6 OR ARTICLE 12, NEITHER PARTY NOR ANY OF ITS AFFILIATES WILL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE OR OTHER INDIRECT DAMAGES OR LOST OR IMPUTED PROFITS OR ROYALTIES, LOST DATA OR COST OF PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE.

**ARTICLE 11.
TERM; TERMINATION**

11.1. **Term; Expiration.** This Agreement is effective as of the Effective Date and, unless earlier terminated pursuant to the other provisions of this ARTICLE 11, will expire as follows (such period, the "Term"):

(a) on a country-by-country and Licensed Product-by-Licensed Product basis, on the date of expiration of all payment obligations under this Agreement with respect to such Licensed Product in such country; and

(b) in its entirety (i) upon the expiration of all payment obligations under this Agreement with respect to all Licensed Products in all countries pursuant to Section 11.1(a) or (ii) upon the termination of this Agreement with respect to all Collaboration Programs pursuant to Section 11.2.1.

11.2. **Termination of the Agreement.**

11.2.1. **Automatic Termination of Collaboration Program.** If, with respect to all Development Candidates arising under a Collaboration Program, Vertex does not exercise any Option under Section 4.1 on or prior to the applicable Option Deadline, then this Agreement shall automatically terminate with respect to such Collaboration Program, and, for clarity, the Collaboration Target for such Collaboration Program will automatically become a Terminated Target effective as of such Option Deadline with no further action by the Parties.

11.2.2. **Vertex's Termination for Convenience.** Vertex may terminate this Agreement, either in its entirety or on a Collaboration Program-by-Collaboration Program or Licensed Product-by-Licensed Product basis, for convenience by providing written notice of its intent to terminate to Company, in which case, such termination will be effective [***] after Company's receipt of such written notice.

11.2.3. **Termination for Material Breach.**

(a) **Vertex's Right to Terminate.** If Vertex believes that Company is in material breach of this Agreement, Vertex may deliver written notice of such material breach to Company. If the breach is curable, Company will have [***] following its receipt of such written notice to cure such breach. If Company fails to cure such breach within such [***] period or the breach is not subject to cure, subject to Section 11.2.4, (i) Vertex may terminate this Agreement, in its entirety or with respect to the particular Collaboration Target or Licensed Product to which the breach relates, by providing written notice to Company, in which case, this Agreement will terminate in its entirety or with respect to such Collaboration Target or Licensed Product, as applicable, on the date on which Company receives such written notice or (ii) Vertex may elect to exercise the alternative remedy set forth in Section 11.4; *provided, however*, that if (A) the relevant breach is curable, but not reasonably curable within [***], and (B) Company is making a *bona fide* effort to cure such breach, Vertex's right to terminate this Agreement or elect to exercise the alternative remedy set forth in Section 11.4 on account of such breach will be suspended for so long as Company is continuing to make such *bona fide* effort to cure such breach and if such breach is successfully cured, Vertex will no longer have the right to terminate this Agreement or elect to exercise the alternative remedy set forth in Section 11.4 on account of such breach.

(b) **Company's Right to Terminate.** If Company believes that Vertex is in material breach of this Agreement, Company may deliver written notice of such material breach to Vertex. If the breach is curable, Vertex will have [***] following its receipt of such written notice to cure such breach. If Vertex fails to cure such breach within such [***] period or the breach is not subject to cure, subject to Section 11.2.4, Company may terminate this Agreement, solely with respect to the particular Collaboration Programs or Licensed Product to which the breach relates (or, if such breach relates to all Collaboration Targets or all Licensed Products, with respect to this Agreement in its entirety), by providing written notice to Vertex, in which case, this Agreement will terminate with respect to the applicable Collaboration Target or Licensed Product (or, if applicable, in its entirety) on the date on which Vertex receives such written notice; *provided, however*, that if (i) the relevant breach is curable, but not reasonably curable within [***], and (ii) Vertex is making a *bona fide* effort to cure such breach, Company's right to terminate this Agreement on account of such breach will be suspended for so long as Vertex is continuing to make such *bona fide* effort to cure such breach and if such breach is successfully cured, Company will no longer have the right to terminate this Agreement on account of such breach.

11.2.4. **Disputes Regarding Material Breach.** Notwithstanding the foregoing, if the Breaching Party in Section 11.2.3 disputes in good faith the existence, materiality, or failure to cure of any breach, and provides written notice to the Non-Breaching Party of such dispute within the relevant cure period, the Non-Breaching Party will not have the right to terminate this Agreement in accordance with Section 11.2.3, or the right to exercise the alternative remedy provision of Section 11.4, as applicable, unless and until the relevant dispute has been resolved pursuant to Section 13.12. During the pendency of such dispute, the applicable cure period will be tolled, all the terms of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations hereunder.

11.2.5. **Termination for Insolvency.** If, at any time during the Term, either Party makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged within [***] after the filing thereof (each, an “**Insolvency Event**”), the other Party may terminate this Agreement in its entirety by providing written notice of its intent to terminate this Agreement to such Party, in which case, this Agreement will terminate on the date on which such Party receives such written notice.

11.3. **Termination by Company for Patent Challenge.** Company may terminate the license granted to Vertex under this Agreement with respect to any applicable Licensed Patent upon [***]’ prior written notice to Vertex, if Vertex or any of its Affiliates or Sublicensees, directly or indirectly, individually or in association with any other person or entity, challenges the patentability, validity, enforceability, term or scope of such Licensed Patent anywhere in the world (“**Patent Challenge**”); *provided* that, if a Patent Challenge is brought by a Sublicensee, Company will not have the right to terminate the license granted to Vertex under this Agreement with respect to the applicable Licensed Patent if Vertex terminates its Sublicense agreement with such Sublicensee within [***] of receipt of Company’s notice of termination under this Section 11.3. The foregoing right to terminate the license granted to Vertex under this Agreement with respect to a Licensed Patent that is the subject of a Patent Challenge shall not apply with respect to any Patent Challenge that is made by Vertex or any of its Affiliates or Sublicensees in response to and defense of an assertion by Company of the relevant Licensed Patent. As used herein, a Patent Challenge includes: (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any Licensed Patent; (b) filing, or joining in, a request under 35 U.S.C. § 302 for reexamination of any claim of any Licensed Patent; (c) filing, or joining in, a petition under 35 U.S.C. § 311 to institute inter partes review of any Licensed Patent; (d) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of any Licensed Patent or any portion thereof; (e) filing or commencing any opposition, nullity, or similar proceeding challenging the validity of any Licensed Patent in any country or region; or (f) filing or commencing an action under any foreign statute or regulation that is equivalent or similar to clause (a), (b), (c), (d) or (e).

11.4. **Alternative Remedy to Termination.**

11.4.1. **Alternative Remedy.** If Company commits a material breach of Section 5.6 or 9.3(f) of this Agreement or commits a material breach of any other provision of this Agreement arising out of Company’s willful misconduct, and Vertex has the right to terminate this Agreement in accordance with Section 11.2.3 (including expiration of any applicable cure periods thereunder) (a “**Company Breach Event**”), in lieu of exercising such termination right, Vertex may elect the alternative remedy of this Section 11.4 by providing written notice of such election to Company before the end of such applicable cure period, in which case, [***]. Notwithstanding the foregoing to the contrary, if the material breach of this Agreement relates solely to one Target, the alternative remedy contained in this Section 11.4 shall only apply with respect to Licensed Product applicable to such Target.

11.4.2. **Sole Remedy.** Following a Company Breach Event, if Vertex [***], and elects to exercise its rights under Section 11.4.1 [***], then, without limiting any other remedies available to Vertex under Section 13.12.6, such election by Vertex shall be its sole and exclusive remedy for such Company Breach Event. For clarity, Vertex may elect, following a Company Breach Event, (a) [***] or (b) [***], Vertex may exercise any other remedies available to it under this Agreement or at law or in equity.

11.5. Consequences of Expiration or Termination of the Agreement.

11.5.1. **In General.** If this Agreement expires or is terminated in its entirety or with respect to one or more Collaboration Programs or Licensed Products by a Party pursuant to Section 11.2, the following terms will apply to this Agreement, either in its entirety or with respect to the Collaboration Programs or Licensed Products that are the subject of such termination, as the case may be:

- (a) each Party will take all action required under Section 12.3;
- (b) termination or expiration of this Agreement for any reason will be without prejudice to any rights or financial compensation that will have accrued to the benefit of a Party prior to such expiration or termination. Such expiration or termination will not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement; and
- (c) the following provisions of this Agreement will survive the expiration or termination of this Agreement: ARTICLE 1 (to the extent the definitions or schedules are used in other surviving provisions), Section 5.4, Section 5.7 (for the applicable time period set forth therein), the last sentence of Section 7.6.2 (solely in the event of expiration of this Agreement but not any early termination), Sections 7.9 through 7.12 (inclusive, solely to the extent applicable with respect to an accrued obligation otherwise contemplated by Section 11.5.1(b)), Section 8.1, Section 8.2.3, Section 8.5 (provided that all references therein to “that is not a Competitive Infringement” will be deemed deleted), Section 9.5, Section 10.1, Section 10.3, this Section 11.5, Sections 12.1 through 12.5 (inclusive and for the time period set forth therein), and ARTICLE 13 (but excluding Section 13.2 and Section 13.6)..

11.5.2. **Effects of Termination.** If this Agreement is terminated in its entirety or with respect to one or more Collaboration Programs or Licensed Products by a Party pursuant to Section 11.2, the following terms will apply, as applicable:

- (a) if such termination is with respect to a Collaboration Program, then the Options granted to Vertex with respect to the Development Candidates arising under such Collaboration Program shall terminate;
- (b) if such termination is with respect to a Licensed Product, except as set forth in Section 11.5.2(d), the Exclusive License with respect to such Licensed Product will terminate;

(c) any permitted Sublicense of Vertex with respect to a terminated Licensed Product will, at the Sublicensee's option, survive such termination on the condition that the relevant Sublicensee is not in material breach of any of its obligations under such Sublicense and the Sublicensee's breach was not the cause of Vertex's breach hereunder. In order to effect this provision, at the request of the Sublicensee, Company will enter into a direct license with the Sublicensee on terms that are substantially the same terms as the applicable terms (including economic terms) of this Agreement; *provided* that (i) Company will not be required to undertake obligations in addition to those required by this Agreement and (ii) Company's rights under such direct license will be consistent with its rights under this Agreement, taking into account the scope of the license granted under such direct license;

(d) subject to patient and other ethical considerations, Vertex shall wind-down any ongoing Clinical Trials for any terminated Licensed Product in accordance with Applicable Law, at Vertex's cost; and

(e) if this Agreement is terminated by Vertex pursuant to Section 11.2.2 or by Company pursuant to Section 11.2.3 (as well as by Company pursuant to Section 11.3 if the applicable Patent Challenge is with respect to the last remaining Licensed Patent licensed by Company to Vertex under this Agreement), then notwithstanding the termination of the Exclusive License, to the extent Vertex, its Affiliates or Sublicensees can and do continue to Research, Develop, Manufacture or Commercialize any Licensed ETB or Licensed Product, Vertex shall remain obligated to pay amounts due to Company pursuant to Sections 7.5 and 7.6, and the terms of Sections 7.5, 7.6, 7.9, 7.10, 7.11 and 7.12 shall survive such termination; *provided, however*, that the Royalty Term as referred to in Section 7.6 shall mean, with respect to a Licensed Product in a country, the period commencing on the First Commercial Sale of such Licensed Product in such country and ending upon the latest of: (i) the expiration of the last Valid Claim of any Product Agreement Patent that Covers Agreement Know-How discovered, developed, invented or created by Company or its Affiliates or Third Parties acting on its behalf (whether solely or jointly with Vertex or its Affiliates or Third Parties acting on Vertex's behalf) and that Covers such Licensed Product or the method of use or manufacture of such Licensed Product in such country; (ii) [***] after the First Commercial Sale of such Licensed Product in such country; or (iii) expiration of Regulatory Exclusivity, if any, in such country with respect to such Licensed Product.

ARTICLE 12.
CONFIDENTIALITY

12.1. **Confidentiality.** During the Term and for [***] thereafter, each Party (the “**Receiving Party**”) receiving any Confidential Information of the other Party (the “**Disclosing Party**”) hereunder will: (a) keep the Disclosing Party’s Confidential Information confidential; (b) not publish, or allow to be published, and not otherwise disclose, or permit the disclosure of, the Disclosing Party’s Confidential Information to any Third Party; and (c) not use, or permit to be used, the Disclosing Party’s Confidential Information for any purpose, except, in each case, to the extent expressly permitted under this Agreement or otherwise agreed in writing. Without limiting the generality of the foregoing, to the extent that either Party provides the other Party any Confidential Information owned by any Third Party, the Receiving Party will handle such Confidential Information in accordance with the terms of this ARTICLE 12 applicable to a Receiving Party.

12.2. **Authorized Disclosure.** Notwithstanding Section 12.1, each Party may disclose the other Party’s Confidential Information to the extent such disclosure is reasonably necessary to:

- (a) file or prosecute patent applications as contemplated by this Agreement;
- (b) prosecute or defend litigation;
- (c) its actual or potential Sublicensees (in the case of Vertex and, in the case of Company, to its actual or potential sublicensees solely in connection with a sublicense of the rights granted to Company under Section 5.2.2) and actual or potential Subcontractors, in each case, in connection with the exercise of its rights and performance of its obligations under this Agreement; *provided* that such disclosure is covered by terms of confidentiality at least as restrictive as those set forth herein;
- (d) its advisors (including financial advisors, attorneys and accountants), actual or potential acquirers, financing sources or investors and underwriters on a need-to-know basis; *provided* that such disclosure is covered by terms of confidentiality at least as restrictive as those set forth herein (which may include professional ethical obligations); or
- (e) comply with Applicable Law (including to obtain and maintain Marketing Approvals for a Licensed Product).

If a Party deems it reasonably necessary to disclose Confidential Information belonging to the other Party pursuant to Sections 12.2(a), 12.2(b) or 12.2(e), then the Receiving Party will, to the extent possible, give reasonable advance notice of such disclosure to the Disclosing Party and take reasonable measures to ensure confidential treatment of such information.

Notwithstanding anything to the contrary herein, in no event may either Party, without the prior written consent of the other Party, disclose the other Party's Confidential Information to any Third Party (including any of such Party's Third Party investors, collaborators or licensees) engaged in the research, development, manufacture or commercialization of pharmaceutical products, other than to actual or potential Subcontractors or Sublicensees or to actual or potential acquirers or, in the case of Vertex, to actual or potential acquirers of Vertex's program with respect to the Licensed ETBs or Licensed Products, *provided* that in the case of actual or potential Subcontractors or Sublicensees, such disclosures are made in accordance with Section 12.2(c), and in the case of actual or potential acquirers, such disclosures are made (i) in accordance with Section 12.2(d), (ii) only to the extent necessary to evaluate, negotiate and potentially consummate the acquisition and (iii) only after the applicable Party has reached agreement on a *bona fide* term sheet or letter of intent regarding the terms of such acquisition with the actual or potential acquirer.

Notwithstanding anything to the contrary in this Agreement, in no event will Company be permitted to disclose to any Third Party the identity of any Collaboration Target or Reserved Target, except as otherwise expressly provided in clause (e) of this Section 12.2 or to a Third Party gatekeeper under conditions of strict confidentiality pursuant to a mechanism substantially equivalent to that set forth in Section 2.3.2 and the Gatekeeper Agreement.

12.3. **Expiration or Termination of this Agreement.** Following the expiration or termination of this Agreement, if requested by the Disclosing Party, at the Receiving Party's election, the Receiving Party will return or destroy, all data, files, records and other materials containing or comprising the Disclosing Party's Confidential Information, except to the extent such Confidential Information is necessary or useful to conduct surviving obligations or exercise surviving rights. Notwithstanding the foregoing, (a) the Receiving Party will be permitted to retain one copy of such data, files, records and other materials for archival and legal compliance purposes and (b) the Receiving Party will not be required to delete or destroy any electronic back-up tapes or other electronic back-up files that have been created solely by the Receiving Party's automatic or routine archiving and back-up procedures, to the extent created and retained in a manner consistent with its standard archiving and back-up procedures.

12.4. **SEC Filings and Other Disclosures.** Either Party may disclose the terms of this Agreement to the extent required to comply with Applicable Law, including the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory; *provided* that such Party will provide the other Party a reasonable opportunity to review such disclosure and reasonably consider the other Party's comments regarding confidential treatment sought for such disclosure.

12.5. **Residual Knowledge Exception.** Notwithstanding any provision of this Agreement to the contrary, a Receiving Party may use any Residual Knowledge for any purpose; *provided* that, for clarity, this right to use Residual Knowledge does not represent a license to any Patents owned or Controlled by the Disclosing Party. Any use made by the Receiving Party of Residual Knowledge is on an "as is, where is" basis, with all faults and all representations and warranties disclaimed at the Receiving Party's sole risk.

12.6. Public Announcements; Publications.

12.6.1. **Announcements.** On a date to be determined mutually by the Parties, which date shall be within [***] of the Effective Date, the Parties will jointly issue a press release regarding the signing of this Agreement in a mutually agreed form. Except (a) as set forth in the preceding sentence, (b) as required to comply with Applicable Law (including the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory in accordance with Section 12.4), or (c) as may be expressly permitted under Section 12.4 or Section 8.9, neither Party will make any public announcement regarding this Agreement without the prior written approval of the other Party. Notwithstanding the foregoing, subject to Section 12.6.2, Vertex may make scientific publications or public announcements concerning its Research, Development, Manufacture or Commercialization activities with respect to any Licensed ETB or Licensed Product under this Agreement without Company's prior written approval; *provided, however*, that except as permitted under Section 12.2, Vertex will not disclose any of Company's Confidential Information in any such publication or announcement without obtaining Company's prior written consent to do so.

12.6.2. Publications.

(a) **Publications Prior to License Effective Date.** During the Term prior to the License Effective Date with respect to a Development Candidate, neither Party will make any academic, scientific or medical publication or academic, scientific or medical public presentation related to such Development Candidate, the applicable Collaboration Target or any activities conducted pursuant to this Agreement with respect to such Collaboration Target, in each case, without the other Party's prior written consent.

(b) **Publications Following License Effective Date.** During the Term following the License Effective Date with respect to a Development Candidate, Vertex will submit to Company for review any proposed academic, scientific or medical publication or academic, scientific or medical public presentation related to such Development Candidate, any corresponding Licensed ETB or Licensed Product, the applicable Vertex Target or any activities conducted pursuant to this Agreement with respect to such Vertex Target, no later than [***] before submission for publication or presentation (or [***] in advance in the case of an abstract). Company will review such publication or presentation for purposes of determining whether any portion of the proposed publication or presentation contains Company's Confidential Information and will provide its comments with respect to such publications and presentations within [***] after its receipt of such written copy (or [***] in the case of an abstract). If requested by Company, Vertex will redact Company's Confidential Information from any such proposed publication or presentation. Vertex will comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication. Notwithstanding the foregoing, Vertex's obligation to submit any publication to Company for review and approval under this Section 12.6.2(b) will not apply to any publication that does not contain Company's Confidential Information. During the Term following the License Effective Date with respect to a Development Candidate, Company will not make any academic, scientific or medical publication or academic, scientific or medical public presentation related to such Development Candidate, any corresponding Licensed ETB or Licensed Product, the applicable Vertex Target or any activities conducted pursuant to this Agreement with respect to such Vertex Target, without the prior written consent of Vertex.

(c) **Publications Regarding ETB Platform.** Company may, at any time during the Term, make academic, scientific or medical publications or academic, scientific or medical public presentations related to the ETB Platform; *provided* that such academic, scientific or medical publications or academic, scientific or medical public presentations do not disclose any information related to any Development Candidate, any Collaboration Target or Vertex Target, any Licensed ETB or Licensed Product or any activities conducted pursuant to this Agreement with respect to a Collaboration Target or Vertex Target, without the prior written consent of Vertex, except that Company may make academic, scientific or medical publications or academic, scientific or medical public presentations related to any Terminated Target and any Development Candidate directed against such Terminated Target.

12.7. **Vertex Information Rights.** If Vertex determines in good faith upon advice of its independent financial auditor that Company is an entity that is subject to financial consolidation with Vertex for the purposes of its quarterly and annual financial statements (or otherwise requires such information in order to comply with GAAP), Company will make available to Vertex:

12.7.1. as soon as practicable, but in any event within [***] (i) an unaudited balance sheet as of the end of such Calendar Quarter, (ii) unaudited statements of income and cash flows for such Calendar Quarter, (iii) an unaudited statement of stockholders' equity for such period, and (iv) a detailed trial balance as of the end of such Calendar Quarter, all prepared in accordance with GAAP (except that such financial statements may (x) be subject to year-end audit adjustments and (y) not contain all notes thereto that may be required in accordance with GAAP);

12.7.2. as soon as practicable, but in any event within [***] (i) an audited balance sheet as of the end of such Calendar Year, (ii) audited statements of income and cash flows for such Calendar Year, (iii) an audited statement of stockholders' equity for such Calendar Year and (iv) a detailed trial balance as of the end of such Calendar Year, together with related footnotes all prepared in accordance with GAAP and audited and certified by a nationally recognized independent public accounting firm;

12.7.3. on or prior to [***], Company will perform a 409A analysis of the fair value of Company's stock as of December 1 of such year as prepared by an independent valuation expert; and

12.7.4. any other information or agreements requested by Vertex and reasonably necessary for the purposes of its quarterly and annual financial statements.

**ARTICLE 13.
MISCELLANEOUS**

13.1. **Assignment.** This Agreement will not be assignable by any Party to any Third Party without the written consent of the non-assigning Party. Notwithstanding the foregoing, either Party may, subject to the terms of this Agreement (including Section 13.2), assign this Agreement or its rights and obligations under this Agreement, without the written consent of the other Party, to an Affiliate or to a Third Party that acquires all or substantially all of the business or assets of such Party to which this Agreement relates (whether by merger, reorganization, acquisition, sale or otherwise), and agrees in writing to be bound by the terms of this Agreement. The assigning Party will promptly notify the other Party in writing of any permitted assignment or transfer under the provisions of this Section 13.1. This Agreement will be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein will be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 13.1 will be void.

13.2. **Change of Control.**

13.2.1. **Notification.** Each Party will notify the other Party in writing promptly (and in any event within [***]) following the closing of a Change of Control of such Party.

13.2.2. **Effects of Change of Control.** If, during the Term, either Party undergoes a Change of Control, from and after the effective date of such Change of Control, such acquired Party and its Preexisting Affiliates, on the one hand, and the acquirer and its Affiliates (other than such acquired Party and its Preexisting Affiliates), on the other hand, shall establish and enforce internal processes, policies, procedures and systems to segregate the other Party's Confidential Information, including the Research Plan and reports pursuant to Section 6.1, such that the acquirer and its Affiliates (other than such acquired Party and its Preexisting Affiliates) do not obtain access to Confidential Information of the other Party. In addition, from and after any Change of Control of Company, (a) notwithstanding the provisions of Section 3.1.4, Vertex shall have final decision-making authority at the JAC over all matters that are subject to the JAC's

authority, (b) Company will devote the same level and quality of FTEs and other resources to the Research Activities for each Collaboration Program and Follow-On Research, as applicable, and will use the same level of effort, which in no case will be less than Commercially Reasonable Efforts, to progress such activities, in each case, as were dedicated to such activities prior to such Change of Control, and (c) as requested by Vertex, Company will promptly provide to Vertex written reports of Company's progress under the Research Plan for the applicable Collaboration Program or Follow-On Research, as applicable, which reports will include the information set forth in Section 2.7.2 and any other information that Vertex may reasonably request to ensure that Company is in compliance with this Section 13.2.2.

13.3. **Force Majeure.** Each Party will be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented or delayed by Force Majeure and the nonperforming Party promptly provides written notice of the Force Majeure to the other Party. Such excuse will continue for so long as the condition constituting a Force Majeure continues, on the condition that the nonperforming Party continues to use Commercially Reasonable Efforts to remove or mitigate the Force Majeure and resume performance of its obligations under this Agreement.

13.4. **Representation by Legal Counsel.** Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, no presumption will exist or be implied against the Party that drafted such terms and provisions.

13.5. **Notices.** All notices that are required or permitted hereunder will be in writing and sufficient if delivered personally or sent by nationally-recognized overnight courier, addressed as follows:

If to Vertex:

Vertex Pharmaceuticals Incorporated
Attn: Business Development
50 Northern Avenue
Boston, Massachusetts 02210

with a copy (which will not constitute notice) to:

Vertex Pharmaceuticals Incorporated
Attn: Corporate Legal
50 Northern Avenue
Boston, Massachusetts 02210

and a copy (which will not constitute notice) to:

Ropes & Gray LLP
Attn: Marc Rubenstein

Prudential Tower
800 Boylston Street
Boston, Massachusetts 02199

If to Company:

Molecular Templates, Inc.
Attn: President and COO
9301 Amberglen Blvd #100
Austin, Texas 78729

with a copy (which will not constitute notice) to:

Molecular Templates, Inc.
Attn: Legal Counsel
9301 Amberglen Blvd #100
Austin, Texas 78729

with a copy (which will not constitute notice) to:

Cooley LLP
Attn: Alison Freeman-Gleason
1700 Seventh Avenue, Suite 1900
Seattle, Washington 98101-1355

or to such other address as the Party to whom written notice is to be given may have furnished to the other Party in writing in accordance herewith. In addition, each Party will deliver a courtesy copy to the other Party's Alliance Manager concurrently with such notice. Any such written notice will be deemed to have been given and received by the other Party: (a) when delivered if personally delivered; or (b) on receipt if sent by overnight courier.

13.6. **Amendment.** No amendment, modification or supplement of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each of Vertex and Company.

13.7. **Waiver.** No provision of this Agreement will be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either Party of any breach of any provision hereof by the other Party will not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

13.8. **Severability.** If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same will not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement will be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement will be construed as if such clause or portion thereof had never been contained in this Agreement, and there will be deemed substituted therefor such provision as

will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by Applicable Law.

13.9. **Descriptive Headings.** The descriptive headings of this Agreement are for convenience only and will be of no force or effect in construing or interpreting any of the provisions of this Agreement.

13.10. **Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed upon or related to Company or Vertex from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate Governmental Authority.

13.11. **Governing Law.** This Agreement, and all claims arising under or in connection herewith, will be governed by and interpreted in accordance with the substantive laws of the Commonwealth of Massachusetts, without regard to conflict of law principles thereof.

13.12. **Dispute Resolution.** Subject to Section 13.12.4 regarding the resolution of certain Patent-related disputes and 13.12.5 regarding the resolution of any disputes with respect to the calculation of “Net Sales” with respect to any Combination Product, if a dispute arises between the Parties in connection with or relating to this Agreement (a “**Dispute**”), it will be resolved pursuant to Sections 13.12.1, 13.12.2, and 13.12.3.

13.12.1. **Escalation to Executive Officers.** Either Party may refer any Dispute to the Executive Officers of the Parties, who will confer in good faith on the resolution of the issue, by delivering written notice to the other Party.

13.12.2. **Mediation.** If the Executive Officers are unable to agree on the resolution of any such Dispute within [***] (or such other period of time as mutually agreed by the Executive Officers) after such Dispute was first referred to them, then within [***] after the end of such [***] period or such other mutually-agreed period of time, either Party may serve notice to the other Party referring the matter to confidential mediation administered by the American Arbitration Association (“**AAA**”) under its Mediation Procedures (subject to this Section 13.12.2) before resorting to arbitration pursuant to Section 13.12.3.

If the Parties are unable to agree on a mediator within [***] after service of the mediation notice, a mediator shall be appointed by the AAA. The mediation session shall last for at least [***] before any Party has the option to withdraw from the process. The Parties may agree to continue the mediation process beyond one day, until there is a settlement agreement, or one Party or the mediator states that there is no reason to continue. The Parties agree to have their respective principals participate in the mediation process, including being present throughout the mediation session(s). Any period of limitations that would otherwise expire between the reference of the Disputes to the Executive Officers of the Parties and the conclusion of the mediation shall be extended until [***] after the conclusion of mediation.

13.12.3. **Arbitration.** If the Dispute is not resolved through mediation within [***] after service of the mediation notice pursuant to Section 13.12.2, such Dispute shall be settled by binding arbitration in accordance with the Commercial Arbitration Rules of the AAA (the “**Rules**”). For clarity, the Parties may only resort to arbitration to resolve a Dispute after the Parties have escalated the Dispute to the Executive Officers pursuant to Section 13.12.1 and attempted to mediate the Dispute pursuant to Section 13.12.2. The Parties will follow the following procedures to resolve such Dispute under arbitration:

(a) **Arbitrators.** The number of arbitrators shall be three. The arbitrators shall be neutral and bound by The Code of Ethics for Arbitrators in Commercial Disputes. Each arbitrator shall have at least [***] of relevant experience in the pharmaceutical industry (and the field of pharmaceutical development, commercialization or any other relevant area, as applicable). Each Party shall select one arbitrator within [***] after the date the demand for arbitration (the “**Demand for Arbitration**”) is served upon the respondent, and the third, who will act as chairperson of the arbitral tribunal, shall be selected by the Party-selected arbitrators within [***] of their appointment, or, failing agreement by the Party-selected arbitrators, by the AAA in accordance with the Rules. If, at the time of the arbitration, the Parties agree in writing to submit the Dispute to a single arbitrator, said single arbitrator will (i) have at least [***] of relevant experience in the pharmaceutical industry (and the field of pharmaceutical development, commercialization or any other relevant area, as applicable) and (ii) be appointed by agreement of the Parties within [***] after the Demand for Arbitration, or, failing such agreement, by the AAA in accordance with the Rules. In no case shall any arbitrator have participated in a prior mediation involving either Party unless explicitly agreed to in writing by the Parties.

(b) **Seat of arbitration; language.** The seat, or legal place, of arbitration shall be Boston, MA, U.S.A. All arbitration proceedings will be conducted in the English language.

(c) **Limited Discovery.** Documentary discovery may be conducted at the discretion of the arbitrator(s), *provided* that any such discovery will (i) be limited to documents directly relating and material to the Dispute, (ii) be conducted pursuant to document discovery procedures as set forth under the laws of the International Bar Association Rules on the Taking of Evidence in International Arbitration, and (iii) be conducted subject to the schedule stipulated by the Parties, or in the absence of stipulation, the schedule ordered by the arbitrator(s). At the request of a Party, the arbitrator(s) may at their discretion order the deposition of witnesses. Depositions shall be limited to a maximum of [***] depositions per Party, each of a maximum of [***] duration, unless the arbitrator(s) otherwise determine. Notwithstanding any provision of this Section 13.12.3 to the contrary, all discovery must be completed within [***] after the appointment of the arbitrator(s).

(d) **Awards and Fees.** The arbitrator(s) may only issue awards of direct monetary damages and other damages to the extent set forth in Section 10.3 and will not under any circumstances have the authority or power to grant equitable relief or orders for specific performance. The allocation of expenses of the arbitration, including reasonable attorney’s fees, will be determined by the arbitrator(s), or, in the absence of such determination, each Party will pay its own expenses, including attorney’s fees.

(e) **Rulings.** All arbitration proceedings must be completed within [***] of the appointment of the chairperson or the single arbitrator. The Parties hereby agree that, subject to the provisions of this Section 13.12.3, the arbitrator(s) has authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrator(s) deem reasonable and necessary with or without petition therefor by the Parties as well as the final award. The final award will be issued no more than [***] after the final submissions of the Parties, unless the Parties jointly request an extension or the arbitrator(s) determine(s), in a reasoned decision, that the interest of justice or the complexity of the case requires an extension. All rulings by the arbitrator(s) will be final and binding on the Parties. The arbitrator(s) shall issue a reasoned decision that accompanies the final award.

(f) **Enforcement.** The arbitration award shall be final and binding on the Parties, and the Parties undertake to carry out any arbitration award without delay. Judgment on the award may be entered in any court of competent jurisdiction.

(g) **Confidentiality.** All activities undertaken by the arbitrator(s) or the Parties pursuant to this Section 13.12.3 will be conducted subject to obligations of confidentiality no less restrictive than those set forth in ARTICLE 12. Further, the Parties acknowledge and agree that their respective conduct during the course of the arbitration, their respective statements and all information exchanged in connection with the arbitration, and the conduct of the arbitration and any information produced thereunder is Confidential Information under this Agreement and subject to the provisions of ARTICLE 12.

(h) **Federal Arbitration Act.** The Parties agree that this Agreement evidences a transaction involving interstate commerce. Notwithstanding the provision in Section 13.11 with respect to applicable substantive law, any arbitration conducted pursuant to the terms of this Agreement shall be governed by the Federal Arbitration Act (9 U.S.C. § 1 et. seq.).

13.12.4. **Patent Disputes.** Notwithstanding the foregoing in this Section 13.12, if a dispute arises between the Parties under this Agreement with respect to the interpretation, scope, validity, enforceability, applicability or term of any Patent, then such dispute shall not be resolved pursuant to Sections 13.12.1 through 13.12.3, but instead may be brought by either Party in the federal courts in the Commonwealth of Massachusetts.

13.12.5. **Expert Determination.** For any disagreement between the Parties regarding the calculation of “Net Sales” with respect to any Combination Product, such matter will be resolved by expert determination rather than pursuant to the foregoing procedures under this Section 13.12. The Parties hereby agree that such decision shall be conducted expeditiously by an independent expert selected unanimously by the Parties, which expert shall have relevant expertise and experience in the pharmaceutical industry, including with respect to the pricing of pharmaceutical and biologic products. If the Parties are unable to agree upon an expert within [***] after receipt of the notice of request for an expert determination, then, the AAA shall appoint such expert in accordance with the Rules. The expert, once appointed, shall have no ex parte communications with either Party concerning the expert determination or the underlying dispute. The Parties agree to cooperate fully in the expeditious conduct of such expert determination and to provide the expert with a written report including supporting documentation in connection with

such Party's oral testimony if requested by the expert. At the conclusion of the arbitration hearings, each Party shall submit one (1) proposal to the expert. The expert shall accept only one (1) of the proposals submitted by the Parties (without making any changes to such proposal) and render such proposal as the expert's final decision. Notwithstanding anything to the contrary in this Agreement, the expert shall not have the authority to render any decision other than selecting one (1) of the proposals submitted by a Party pursuant to this Section 13.12.5. The expert shall endeavor to resolve the dispute within [***] (but no later than [***]) after his or her appointment, taking into account the circumstances requiring an expeditious resolution of the matter in dispute. The expert's decision shall be final and binding on the Parties. The costs of the expert determination shall be shared by the Parties, regardless of the outcome of the determination. All activities undertaken by the expert or the Parties pursuant to this Section 13.12.5 will be conducted subject to obligations of confidentiality no less restrictive than those set forth in ARTICLE 12. Further, the Parties acknowledge and agree that their respective conduct during the course of the expert proceedings, their respective proposals and all information exchanged in connection with the expert proceedings, and the conduct of such proceedings and any information produced thereunder is Confidential Information under this Agreement and subject to the provisions of ARTICLE 12.

13.12.6. **Equitable Relief.** Notwithstanding the foregoing in this Section 13.12, nothing contained in this Agreement will in any way limit or preclude a Party from, at any time, seeking or obtaining equitable relief hereunder, whether preliminary or permanent, including a temporary or permanent restraining order, preliminary or permanent injunction, specific performance or any other form of equitable relief, from any United States court of competent jurisdiction if necessary to protect the interests of such Party. Each Party agrees that its unauthorized release of the other Party's Confidential Information or its breach of Section 5.6 of this Agreement will cause irreparable damage to other Party for which recovery of damages would be inadequate, and that such other Party will be entitled to obtain timely injunctive relief with respect to such breach, without the need to show irreparable harm or the inadequacy of monetary damages as a remedy, and without the requirement of having to post bond or other security, as well as any further relief that may be granted by a court of competent jurisdiction.

13.13. **Entire Agreement.** This Agreement constitutes and contains the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof, including the CDA, which is hereby superseded and replaced in its entirety as of the Effective Date. All information shared by the Parties pursuant to the CDA will be Confidential Information under this Agreement from and after the Effective Date, and the use and disclosure thereof will be governed by ARTICLE 12.

13.14. **Independent Contractors.** Both Parties are independent contractors under this Agreement. Nothing contained herein will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

13.15. **Interpretation.** Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words “include,” “includes” and “including” will be deemed to be followed by the phrase “without limitation,” (c) the word “will” will be construed to have the same meaning and effect as the word “shall,” (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any Person will be construed to include the Person’s successors and assigns, (f) the words “herein,” “hereof” and “hereunder,” and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Schedules will be construed to refer to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto, (h) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent” or “approve” or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (i) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (j) any action or occurrence deemed to be effective as of a particular date will be deemed to be effective as of 11:59 PM ET on such date and (k) the term “or” will be interpreted in the inclusive sense commonly associated with the term “and/or.”

13.16. **No Third Party Rights or Obligations.** No provision of this Agreement will be deemed or construed in any way to result in the creation of any rights or obligations in any Person not a Party to this Agreement.

13.17. **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

13.18. **Counterparts.** This Agreement may be executed in two counterparts, each of which will be an original and both of which will constitute together the same document. Counterparts may be signed and delivered by digital transmission (e.g., .pdf), each of which will be binding when received by the applicable Party.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their representatives thereunto duly authorized as of the Effective Date.

**VERTEX PHARMACEUTICALS
INCORPORATED**

MOLECULAR TEMPLATES, INC.

By: /s/ Jeffrey Leiden

By: /s/ Eric Poma

Name: Jeffrey Leiden

Name: Eric Poma

Title: Chairman, President and Chief Executive Officer

Title: CEO & CSO

[Signature Page to Master Collaboration Agreement]

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

Schedule 1.149

Option Exercise Data Package

[***]

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

Schedule 1.177

Research Plan

[***]

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

Schedule 2.3.2

Gatekeeper Agreement

[***]

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

Schedule 9.29.2(g)

Reference is made to Company's internal research programs directed against the following Targets: [***]

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

Schedule 10.2

Insurance

| INSURANCE TYPE | MINIMUM LIMITS | MINIMUM COVERAGE | RESPECTIVELY MUST BE MAINTAINED BY |
|----------------|----------------|------------------|------------------------------------|
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*****] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

SHARE PURCHASE AGREEMENT

This SHARE PURCHASE AGREEMENT (this "Agreement") dated as of November 18, 2019 (the "Effective Date") is made by and between Molecular Templates, Inc., a Delaware corporation (the "Company"), and Vertex Pharmaceuticals Incorporated, a corporation organized under the laws of the Commonwealth of Massachusetts (the "Purchaser").

WHEREAS, the Company and the Purchaser are executing and delivering this Agreement in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), and Rule 506 of Regulation D as promulgated by the United States Securities and Exchange Commission (the "Commission") under the Securities Act;

WHEREAS, the Company and Purchaser have entered into a Master Collaboration Agreement of even date herewith (the "Collaboration Agreement"); and

WHEREAS, Purchaser desires to purchase from the Company, and the Company desires to sell and issue to Purchaser, shares of the common stock of the Company, par value \$0.001 per share, ("Common Stock"), subject to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the mutual representations, warranties, covenants and agreements contained in this Agreement, and for other good and valuable consideration, the parties hereby agree as follows:

1. Purchase and Sale of Shares. Subject to the terms and conditions of this Agreement, the Company agrees to issue and sell to Purchaser, and Purchaser agrees to purchase at the Closing (as defined below), 1,666,666 shares of Common Stock (the "Shares") at a purchase price per share of \$9.00 for an aggregate purchase price of Fourteen Million Nine Hundred Ninety-Nine Thousand Nine Hundred Ninety-Four Dollars (\$14,999,994) (the "Purchase Amount").

2. Closing; Deliveries.

(a) Closing. The closing of the sale and purchase of the Shares (the "Closing") shall take place on the Effective Date, remotely via the exchange of documents and signatures, or at such other date or location as may be agreed upon by the Company and Purchaser. The date the Closing occurs is hereinafter referred to as the "Closing Date".

(b) Deliveries.

(i) At the Closing, Purchaser will deliver to the Company the Purchase Amount by wire transfer of immediately available funds to a bank account designated by the Company. Purchaser will also deliver to Company at the Closing: (A) a duly executed cross receipt in form and substance reasonably satisfactory to each party (the "Cross Receipt"); and (B) a certificate in form and substance reasonably satisfactory to the Company duly executed by an authorized executive officer of Purchaser certifying that the conditions to Closing set forth in Section 5(b) of this Agreement have been fulfilled.

(ii) At the Closing, the Company will instruct the transfer agent for the shares of Common Stock (the “Transfer Agent”) to register the issuance of the Shares to the Purchaser via book-entry or, upon the request of the Purchaser, the Company will instruct the Transfer Agent to deliver stock certificates to the Purchaser representing the Shares. The Company will also deliver to Purchaser at the Closing: (A) a duly executed Cross Receipt; (B) a certificate in form and substance reasonably satisfactory to Purchaser and duly executed on behalf of the Company by an authorized executive officer of the Company, certifying that the conditions to Closing set forth in Section 5(a) of this Agreement have been fulfilled; (C) a legal opinion of Company’s counsel in form and substance reasonably satisfactory to Purchaser; and (D) a certificate of the secretary of the Company dated as of the Closing Date certifying that attached thereto is a true and complete copy of all resolutions adopted by the Board of Directors of the Company authorizing the execution, delivery and performance of the Transaction Agreements and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated by the Transaction Agreements as of the Closing Date.

3. Representations and Warranties of the Company. The Company represents and warrants to Purchaser that the statements contained in this Section 3 are true and complete as of the Effective Date and the Closing Date:

(a) Organization; Qualification and Good Standing.

(i) The Company is a public company duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to own, lease and operate (as applicable) its properties, to carry on its business as presently conducted and as proposed to be conducted in the Company’s SEC Reports (as defined below), to enter into this Agreement and the Collaboration Agreement (collectively, the “Transaction Agreements”), to issue and sell the Shares and to carry out the transactions contemplated by the Transaction Agreements. The Company is duly qualified to transact business as a foreign entity and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except to the extent that any failure to be so qualified or in good standing would not (x) have or be reasonably likely to have, singularly or in the aggregate, a material adverse effect on the business (as presently conducted or as proposed to be conducted in the Company’s SEC Reports), properties, assets, liabilities, management, financial condition, stockholders’ equity, results of operations or prospects of the Company and its subsidiaries taken as a whole, or (y) impair in any material respect the ability of the Company to perform its obligations under the Transaction Agreements or to consummate any transactions contemplated by the Transaction Agreements (any such effect as described in clauses (x) or (y), a “Material Adverse Effect”).

(ii) The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in the Company’s SEC Reports. Each of the Company’s “subsidiaries” (for purposes of this Agreement, as defined in Rule 405 under the Securities Act) has been duly incorporated or organized, as the case may be, and is validly existing as a corporation or company in good standing under the laws of the jurisdiction of its incorporation or organization and has all requisite power and authority (corporate or other) to own, lease and operate (as applicable) its properties and to carry on its business as presently conducted and as proposed to be conducted in the Company’s SEC Reports. Each of the Company’s subsidiaries is duly qualified as a foreign corporation or company to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except to the extent that any failure to be so qualified or in good standing would not have or be reasonably likely to have a Material Adverse Effect or a material adverse effect on the business, properties, assets, liabilities, management, financial condition, stockholders’ equity, results of operations or prospects of any of the Company’s subsidiaries.

(b) No Violation or Default. Neither the Company nor any of its subsidiaries is (i) in violation of its charter or by-laws (or analogous governing instrument, as applicable), (ii) in default in any respect in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement, lease or other agreement or instrument, whether written or oral, to which it is a party or by which it is bound or to which any of its property or assets is subject or (iii) in violation in any respect of any law, statute, rule, regulation, ordinance, writ, injunction, Permit (as defined below), judgment, order or decree of any court or governmental or regulatory agency or body, domestic or foreign, having jurisdiction over the Company or any of its subsidiaries or any of their properties or assets (including, without limitation, the United States Food and Drug Administration of the U.S. Department of Health and Human Services (“FDA”) or any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA) (collectively, “Laws”) except, in the case of clauses (ii) and (iii) above, for any such violation or default that would not, singularly or in the aggregate, have or be reasonably likely to have a Material Adverse Effect. To the knowledge of the Company, there exists no condition, event or act which after notice, lapse of time, or both, would constitute a default or violation by the Company under any of the foregoing, except, in the case of clauses (ii) and (iii) as would not have or be reasonably likely to have a Material Adverse Effect.

(c) Absence of Certain Events. Since December 31, 2018, there have been no events, occurrences or developments, or any binding commitment by the Company or its subsidiaries to cause any of the foregoing, that have had, or would reasonably be expected to have, a Material Adverse Effect. Except as set forth in the SEC Reports filed prior to the Effective Date, since December 31, 2018, the Company has not (i) declared or paid any dividends, or authorized or made any distribution upon or with respect to any class or series of its capital stock, or (ii) sold, exchanged or otherwise disposed of any of its material assets or rights. Since December 31, 2018, the Company has not admitted in writing its inability to pay its debts generally as they become due, filed or consented to the filing against it of a petition in bankruptcy or a petition to take advantage of any insolvency act, made an assignment for the benefit of creditors, consented to the appointment of a receiver for itself or for the whole or any substantial part of its property, or had a petition in bankruptcy filed against it, been adjudicated a bankrupt, or filed a petition or answer seeking reorganization or arrangement under the federal bankruptcy laws or any other Laws of the United States or any other jurisdiction.

(d) Capitalization. The Company has the issued and outstanding capitalization described in the SEC Reports (except for subsequent issuances, if any, pursuant to reservations, agreements or employee benefit plans or pursuant to the exercise of convertible securities or options, in each case, described or reflected in the SEC Reports). All of the issued and outstanding capital shares of the Company have been duly authorized and validly issued and are fully paid and nonassessable. All of the Company’s options, warrants and other rights to purchase or exchange any securities for shares of the Company’s capital stock have been duly authorized and validly issued and were issued in compliance with federal and state securities laws. None of the outstanding shares of the Company’s capital stock was issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. Except as described in the SEC Reports (as defined below), as of the Effective Date there are no authorized or outstanding shares of capital stock, options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company or any of its subsidiaries. All of the authorized shares of Common Stock are entitled to one (1) vote per share.

(e) Capitalization of Subsidiaries. Except as described in the SEC Reports (as defined below), all the outstanding shares of capital stock (if any) of each subsidiary of the Company have been duly authorized and validly issued, are fully paid and nonassessable and are owned by the Company directly or indirectly through one or more wholly-owned subsidiaries, free and clear of any pledge, claim, lien, encumbrance, mortgage, security interest, restriction upon voting or transfer or any other claim, including any statutory or contractual preemptive rights, resale rights, rights of first refusal or other similar rights.

(f) Authorization of Shares. The Shares, when issued and delivered in accordance with the terms of this Agreement against payment of the Purchase Amount as provided herein, will be duly and validly authorized and issued and fully paid and nonassessable, free and clear of any pledge, claim, lien, encumbrance, mortgage, security interest, restriction upon voting or transfer or any other claim, including any statutory or contractual preemptive rights, resale rights, rights of first refusal or other similar rights.

(g) Authorization; Due Execution; Enforceability. The Company has full legal right, power and authority to enter into the Transaction Agreements and perform the transactions contemplated hereby and thereby. All requisite corporate action on the part of the Company and its subsidiaries, and their respective directors and shareholders required by applicable Laws for the authorization, execution and delivery by the Company and its subsidiaries of the Transaction Agreements and the performance of all obligations of the Company and its subsidiaries hereunder and thereunder, including the authorization, issuance and delivery of the Shares, has been taken. The Transaction Agreements have been duly authorized, executed and delivered by the Company and are legal, valid and binding agreements of the Company enforceable in accordance with their respective terms, except to the extent that enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally and by general equitable principles. No stop order or suspension of trading of the Common Stock has been imposed by The Nasdaq Stock Market LLC, the Commission or any other governmental authority and remains in effect.

(h) SEC Reports.

(i) The Company has timely filed all forms, reports and documents required to be filed by it with the Commission. All such required forms, reports and documents are referred to in this Agreement as the "SEC Reports." As of their respective filing dates, each of the SEC Reports (i) complied in all material respects with the requirements of the Securities Act, and the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations of the Commission thereunder applicable to such SEC Reports and (ii) did not at the time they were filed, declared effective or mailed, as applicable (or if subsequently amended or superseded by a filing prior to the Effective Date, then on the date of such subsequent filing), contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. As of the Effective Date, there are no outstanding or unresolved comments in comment letters received from the Commission or its staff.

(ii) The financial statements of the Company included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and in its quarterly reports on Form 10-Q for the quarterly periods ended September 30, 2019, June 30, 2019 and March 31, 2019 comply as to form in all material respects with applicable accounting requirements and the published rules and regulations of the Commission with respect thereto, have been prepared in accordance with U.S. generally accepted accounting principles applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto) and fairly present in all material respects the financial position of the Company as of the dates thereof and the results of its operations and cash flows for the periods then ended. Except (i) as set forth in the SEC Reports or (ii) for liabilities incurred in the ordinary course of business consistent with past practice since September 30, 2019, the Company has no material liabilities, whether absolute or accrued, contingent or otherwise.

(i) No Consents. No authorization, consent, approval or other order of, declaration to, or filing with, any governmental agency or body or securities exchange or any other third party is required to be made or obtained by the Company in connection with the consummation of the transactions contemplated by the Transaction Agreements, or with the authorization, issuance and sale by the Company of the Shares, except such filings as may be required to be made with the Commission and with any state blue sky or securities regulatory authority, which filings shall be made in a timely manner in accordance with all applicable Laws.

(j) No Conflicts. The execution, delivery and performance of the Transaction Agreements by the Company, the offering or sale of the Shares by the Company and the consummation of the transactions contemplated by the Transaction Agreements will not (with or without notice or lapse of time or both) (i) conflict with or result in a breach or violation of any of the terms or provisions of, constitute a default or a Debt Repayment Triggering Event (as defined below) under, or result in the creation or imposition of any lien, encumbrance, security interest, claim or charge upon any property or assets of the Company or any subsidiary pursuant to, any indenture, mortgage, deed of trust, loan agreement, lease or other agreement, arrangement or instrument, whether written or oral, to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the property or assets of the Company or any of its subsidiaries is subject, (ii) result in any violation of the provisions of the charter or by-laws (or analogous governing instruments, as applicable) of the Company or any of its subsidiaries or (iii) result in the violation of any Laws, except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation or default that would not, individually or in the aggregate, have or be reasonably likely to have a Material Adverse Effect. A “Debt Repayment Triggering Event” means any event or condition that gives, or with the giving of notice or lapse of time would give the holder of any note, debenture or other evidence of indebtedness (or any Person (as defined below) acting on such holder’s behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company of any of its subsidiaries.

(k) No Right of First Refusal; Voting Rights. No party has any right of first refusal, right of first offer, right of co-sale, pre-emptive right or other similar right regarding the securities of the Company or other agreements pursuant to which the Company is or may become obligated to issue, sell or repurchase any shares of its capital stock or any other securities of the Company. Except as described in the SEC Reports, no party has any registration rights regarding the securities of the Company. There are no provisions of the Company’s Certificate of Incorporation, and no contracts, other than this Agreement, that (a) may affect or restrict the voting rights of Purchaser with respect to the Shares in its capacity as a shareholder of the Company, (b) restrict the ability of Purchaser, or any successor thereto or assignee or transferee thereof, to transfer the Shares, (c) would adversely affect the Company’s or Purchaser’s right or ability to consummate the transactions contemplated by the Transaction Agreements, or (d) require the vote of more than a majority of the Company’s issued and outstanding shares of Common Stock to take or prevent any corporate action, other than those matters requiring a different vote under Delaware law and that are described in the SEC Reports. There are no restrictions on the transfer of shares of the Company’s capital stock other than pursuant to state and federal securities laws. The Company is not a party to or subject to any agreement or understanding relating to the voting of shares of the Company’s capital stock or the giving of written consents by a shareholder or director of the Company.

(l) Independent Auditors. Ernst & Young LLP and BDO USA, LLP, who have audited and certified certain financial statements of the Company and its subsidiaries included or incorporated by reference in the SEC Reports are each independent registered public accounting firms with respect to the Company and its subsidiaries within the meaning of Article 2-01 of Regulation S-X and the Public Company Accounting Oversight Board (United States).

(m) Absence of Litigation. There is no claim, action, suit, arbitration or similar proceeding or, to the knowledge of the Company, investigation, pending against, or to the knowledge of the Company, threatened against or affecting, the Company, any of its subsidiaries, or any of their respective properties or, to the knowledge of the Company, any of their respective officers or directors, including any such claim, action, suit, arbitration or similar proceeding, or investigation that questions the validity of the Transaction Agreements or the right of the Company to consummate the transactions contemplated in the Transaction Agreements.

(n) Intellectual Property. Except as described in the SEC Reports, the Company or its subsidiaries own or possess the lawful right to use all (i) valid and enforceable patents, patent applications, trademarks, trademark registrations, service marks, service mark registrations, Internet domain name registrations, copyrights, copyright registrations, licenses, trade secret rights (“Intellectual Property Rights”) and (ii) inventions, software, works of authorships, trademarks, service marks, trade names, databases, formulae, know how, Internet domain names and other intellectual property (including trade secrets and other unpatented and/or unpatentable proprietary confidential information, systems, or procedures) (collectively, “Intellectual Property Assets”) necessary to conduct their respective businesses as currently conducted, and as proposed to be conducted in the Company’s SEC Reports. The Company and its subsidiaries have not received any opinion from their legal counsel concluding that any activities of their respective businesses infringe, misappropriate, or otherwise violate, valid and enforceable Intellectual Property Rights of any other person, and have not received written notice of any challenge, which is to their knowledge still pending, by any other person to the rights of the Company and its subsidiaries with respect to any Intellectual Property Rights or Intellectual Property Assets owned or used by the Company or its subsidiaries. To the Company’s knowledge, the Company and its subsidiaries’ respective businesses as now conducted do not give rise to any infringement of, any misappropriation of, or other violation of, any valid and enforceable Intellectual Property Rights of any other person. All licenses for the use of the Intellectual Property Rights are valid, binding upon, and enforceable by or against the parties thereto in accordance to its terms. The Company has complied in all material respects with, and is not in breach nor has received any asserted or threatened claim of breach of any license for the use of Intellectual Property Rights, and the Company has no knowledge of any breach or anticipated breach by any other person to any license for the use of Intellectual Property Rights. No claim has been made against the Company alleging the infringement by the Company of any patent, trademark, service mark, trade name, copyright, trade secret, license in or other intellectual property right or franchise right of any person. The Company has taken all reasonable steps to protect, maintain and safeguard its Intellectual Property Rights and Intellectual Property Assets, including the execution of appropriate nondisclosure and confidentiality agreements. The consummation of the transactions contemplated by the Transaction Agreements will not result in the loss or impairment of or payment of any additional amounts with respect to, nor require the consent of any other person in respect of, the Company’s right to own, use, or hold for use any of the Intellectual Property Rights or Intellectual Property Assets as owned, used or held for use in the conduct of the business as currently conducted.

(o) Taxes. The Company and its subsidiaries each (i) have timely filed all necessary federal, state, local and foreign tax returns, and all such returns were true, complete and correct, (ii) have paid all federal, state, local and foreign taxes due and payable, for which it is liable, including, without limitation, all sales and use taxes and all taxes which the Company or any of its subsidiaries is obligated to withhold from amounts owing to employees, creditors and third parties, and (iii) do not have any tax deficiency or claims outstanding or assessed or, to its knowledge, proposed against any of them, except those, in each of the cases described in clauses (i), (ii) and (iii) above, that would not, singularly or in the aggregate, have or be reasonably likely to have a Material Adverse Effect.

(p) Environmental Laws and Hazardous Materials. The Company and its subsidiaries are in compliance with all foreign, federal, state and local rules, laws and regulations relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of health and safety or the environment which are applicable to their businesses ("Environmental Laws"). There has been no storage, generation, transportation, handling, treatment, disposal, discharge, emission, or other release of any kind of toxic or other wastes or other hazardous substances by, due to, or caused by the Company or any of its subsidiaries (or, to the Company's knowledge, any other entity for whose acts or omissions the Company or any of its subsidiaries is or may otherwise be liable) upon any of the property now or previously owned or leased by the Company or any of its subsidiaries, or upon any other property, in violation of any Laws or giving rise to any liability; and there has been no disposal, discharge, emission or other release of any kind onto such property or into the environment surrounding such property of any toxic or other wastes or other hazardous substances with respect to which the Company or any of its subsidiaries has knowledge.

(q) No Undisclosed Material Liabilities. There are no liabilities of the Company (including its subsidiaries) of the type required to be disclosed on a balance sheet prepared in accordance with U.S. generally accepted accounting principles, other than liabilities: (i) reflected in the financial statements (including footnotes thereto) included in the SEC Reports, (ii) created under, or incurred in connection with, this Agreement or (iii) incurred in the ordinary course consistent with past practice.

(r) Finder's Fees. Neither the Company nor any of the subsidiaries has incurred any liability for any finder's fees, brokerage commissions or similar payments in connection with the transactions contemplated under the Transaction Agreements.

(s) Listing. The Company is subject to and in compliance in all material respects with the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act and is listed on The Nasdaq Global Market, and the Company has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from The Nasdaq Global Market, nor has the Company received any notification that the Commission, the Financial Industry Regulatory Authority or The Nasdaq Stock Market LLC is contemplating terminating such registration or listing.

(t) No Integrated Offering. The Company has not, directly or through any agent, sold, offered for sale or solicited offers to buy any "security" (as defined in the Securities Act), or negotiated in respect of any of the foregoing, under any circumstances that would cause the offering of the Shares to be integrated with prior offerings by the Company for purposes of any applicable Laws or shareholder approval provisions.

(u) Private Placement. Assuming the accuracy of the representations and warranties of the Purchaser set forth in Section 4, and in reliance thereon, the offer, sale and issuance of the Shares to the Purchaser as contemplated hereby is exempt from the registration requirements of the Securities Act and from the qualification or registration requirements of applicable state securities laws. Neither the Company, nor its subsidiaries nor any Person acting on behalf of the Company or its subsidiaries, has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under any circumstances that would require registration of the Shares under the Securities Act, and neither the Company, nor its subsidiaries nor any Person acting on behalf of the Company or its subsidiaries will take any such action.

(v) Investment Company. The Company is not, and immediately after receipt of payment for the Shares, will not be an “investment company” within the meaning of the Investment Company Act of 1940, as amended.

(w) Licenses and Other Rights; Compliance with Laws. The Company and its subsidiaries (as applicable) have all franchises, permits, licenses and other rights and privileges (“Permits”) necessary to permit them to own or lease their properties and to conduct their business as presently conducted and are in compliance thereunder, except where the failure to be in compliance does not and would not have or be reasonably likely to have a Material Adverse Effect. To the Company’s knowledge, neither the Company nor its subsidiaries have taken any action that would interfere with the Company’s or its subsidiaries’ ability to renew all such Permit(s), except where the failure to renew such Permit(s) would not have or be reasonably likely to have a Material Adverse Effect. The Company and its subsidiaries are and have been in compliance with all Laws applicable to their business, properties and assets, and to the products and services sold by them, except where the failure to be in compliance does not and would not have or be reasonably likely to have a Material Adverse Effect.

(x) Compliance with Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with all applicable financial recordkeeping and reporting requirements, including those of the U.S. Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), the Currency and Foreign Transactions Reporting Act of 1970, as amended and the applicable anti-money laundering statutes of jurisdictions where the Company and its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the “Anti-Money Laundering Laws”), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(y) Insurance. The Company and each of its subsidiaries carry, or are covered by, insurance in such amounts and covering such risks as is adequate for the conduct of their respective businesses and the value of their respective properties. Neither the Company nor any of its subsidiaries has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a Material Adverse Effect. Neither the Company nor any of its subsidiaries has received written notice from any insurer, agent of such insurer or the broker of the Company or any of its subsidiaries that any material capital improvements or any other material expenditures (other than premium payments) are required or necessary to be made in order to continue such insurance.

(z) No Unlawful Payments. Neither the Company nor any of its subsidiaries nor, to the Company’s knowledge, any of its controlled Affiliates (as defined below) or subsidiaries or any director, officer, manager, employee, agent, affiliate, representative or other Person acting on behalf of the Company or any controlled Affiliate or subsidiary (collectively, “Representatives”), has (i) used any corporate funds for unlawful contributions, gifts, entertainment or other unlawful expenses relating to political activity, (ii) made any direct or indirect unlawful payment to foreign or domestic government officials or employees, political parties or campaigns, political party officials, or candidates for political office from corporate funds, (iii) promised, authorized, made any payment to, or otherwise contributed any item of value to, directly or indirectly, any non-U.S. government official, in each case, in violation of the U.S. Foreign Corrupt Practices Act (“FCPA”) or any other applicable anti-bribery or anti-corruption law or (iv) made any other unlawful bribe, rebate, payoff, influence payment, kickback, or other unlawful payment to any Person.

(aa) Compliance with OFAC.

(i) Neither the Company nor any of its subsidiaries, nor, to the Company's knowledge, any director, officer, employee, agent, affiliate, representative or other person acting on behalf of the Company or any of its subsidiaries, is an individual or entity ("Person") that is, or is owned or controlled by a Person that is: (i) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control ("OFAC"), the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, "Sanctions"), nor (ii) located, organized or resident in a country or territory that is the subject of a U.S. government embargo (including, without limitation, Cuba, Iran, North Korea, Syria and the Crimea).

(ii) The Company will not, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person: (i) to fund or facilitate any activities or business of or with any Person that, at the time of such funding or facilitation, is the subject of Sanctions, or in any country or territory that, at the time of such funding or facilitation, is the subject of a U.S. government embargo; or (ii) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering, whether as underwriter, advisor, investor or otherwise).

(iii) For the past five (5) years, the Company and its subsidiaries have not knowingly engaged in, are not now knowingly engaged in, and will not engage in, any direct or indirect dealings or transactions with any Person that at the time of the dealing or transaction is or was the subject of Sanctions or any country or territory that, at the time of the dealing or transaction is or was the subject of a U.S. government embargo.

(bb) Related Party Transactions. The Company has not entered into any agreements with any shareholders or any transactions with "affiliates" (as defined in Rule 12b-2 under the Exchange Act) ("Affiliates"), except as specifically disclosed in the SEC Reports.

4. Representations and Warranties of Purchaser. Purchaser represents and warrants to the Company that the statements contained in this Section 4 are true and complete as of the Effective Date and the Closing Date:

(a) Organization and Good Standing. Purchaser is a corporation duly organized, validly existing and in good standing under the laws of the Commonwealth of Massachusetts and has all requisite corporate power and authority to carry on its business as presently conducted, to enter into the Transaction Agreements and to carry out the transactions contemplated by the Transaction Agreements.

(b) Authorization; Due Execution; Enforceability. Purchaser has full legal right, power and authority to enter into the Transaction Agreements and perform the transactions contemplated hereby and thereby. All requisite corporate action on the part of Purchaser and its directors and shareholders required by applicable Laws for the authorization, execution and delivery by Purchaser of the Transaction Agreements and the performance of all obligations of Purchaser hereunder and thereunder has been taken. The Transaction Agreements have been duly authorized, executed and delivered by Purchaser and are legal, valid and binding agreements of Purchaser enforceable in accordance with their respective terms, except to the extent that enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally and by general equitable principles.

(c) No Current Ownership in the Company. Other than the Shares acquired under this Agreement, none of Purchaser or any of its direct or indirect subsidiaries owns any shares of Common Stock or other securities of the Company or any direct or indirect rights or options to acquire any such securities or any securities convertible into such securities (collectively, “Company Securities”), provided that Purchaser or its direct or indirect subsidiaries may own shares or other ownership interests in Company indirectly through holdings in mutual funds or similar entities for which Purchaser and its direct and indirect subsidiaries do not exercise control over the management or policies, which mutual funds or similar entities own shares of Common Stock or other securities of the Company.

(d) Accredited Investor. Purchaser is an “accredited investor” as such term is defined in Rule 501 promulgated under the Securities Act.

(e) Purchase for Investment. Purchaser is acquiring the Shares for its own account, for investment and not for, with a view to, or in connection with, any distribution or public offering thereof within the meaning of the Securities Act. Purchaser has not been organized solely for purposes of acquiring the Shares.

(f) Knowledge and Experience; Economic Risk. Purchaser has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares to be purchased hereunder, is capable of protecting its interest in connection with the transactions contemplated by this Agreement and is able to bear the economic risk of the investment in the Shares, including a complete loss of the investment.

(g) Access to Information. Purchaser acknowledges that it has had the opportunity to review the SEC Reports and has been afforded (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, the Company concerning the terms and conditions of the offering of the Shares and the merits and risks of investing in the Shares and (ii) access to information about the Company and its financial condition, results of operations, business, properties and management sufficient to enable Purchaser to evaluate its investment. In evaluating the suitability of its investment in the Company, the Purchaser has not relied upon any representations (whether oral or written) other than as set forth in the Transaction Agreements.

5. Conditions to Closing.

(a) Purchaser’s Conditions to Closing. Purchaser’s obligation to purchase the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by Purchaser):

(i) Each of the representations and warranties of the Company contained in Section 3 shall be true and accurate in all respects.

(ii) All covenants and agreements contained in this Agreement to be performed or complied with by the Company on or prior to the Closing Date shall have been performed or complied with in all material respects.

(iii) The Company shall have duly executed and delivered to Purchaser the Collaboration Agreement, and there shall have been no termination of the Collaboration Agreement that, as of the Closing, has been delivered or is effective.

(iv) From and after the Effective Date until the Closing Date (if later), there shall have occurred no event that has caused or would reasonably be expected to cause a Material Adverse Effect.

(v) All closing deliverables as required under Section 2(b)(ii) shall have been delivered to Purchaser.

(b) The Company's Conditions to Closing. The Company's obligation to issue and sell the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Company):

(i) Each of the representations and warranties of Purchaser contained in Section 4 shall be true and accurate in all respects.

(ii) All covenants and agreements contained in this Agreement to be performed or complied with by Purchaser on or prior to the Closing Date shall have been performed or complied with in all material respects.

(iii) Purchaser shall have duly executed and delivered to the Company the Collaboration Agreement, and there shall have been no termination of the Collaboration Agreement that, as of the Closing, has been delivered or is effective.

(iv) All closing deliverables as required under Section 2(b)(i) shall have been delivered to the Company.

6. Additional Covenants and Agreements of the Company and Purchaser.

(a) Standstill.

(i) During the period starting on the Effective Date and ending on the earlier of (x) the termination of the Collaboration Agreement (other than by Purchaser pursuant to Section 11.2.2 of the Collaboration Agreement) or (y) the date that is eighteen (18) months from the Effective Date (the "Restricted Period"), except as expressly approved or invited in writing by the Company, none of Purchaser or any of its controlled Affiliates (the "Standstill Parties") shall, and Purchaser shall not authorize, instruct or facilitate any Standstill Party to:

(A) except with respect to the Shares, acquire, seek, propose or agree to acquire, directly or indirectly, by purchase or otherwise, ownership (including, but not limited to, beneficial ownership as defined in Rule 13d-3 under the Exchange Act) of, or make a tender, exchange or other offer to acquire any Company Securities;

(B) "solicit" or knowingly encourage any other entity or person to solicit "proxies" (as such terms are defined in Regulation 14A under the Exchange Act) with respect to any matter subject to a vote of the stockholders the Company or its nominees for directors, including, but not limited to, any tender offer for Company Securities or any Acquisition Transaction;

(C) except with respect to proxies executed in connection with shareholders' meetings of the Company, deposit any Company Securities in any voting trust or subject them to any voting agreement or other agreement of similar effect;

(D) join or form any partnership, limited partnership, syndicate, or other group within the meaning of Section 13(d)(3) of the Exchange Act or advise or knowingly assist or encourage any third party for the purpose of taking any action prohibited by this Section 6(a);

(E) make, effect, cause, initiate or participate in any Acquisition Transaction (as defined below) with respect to the Company; or

(F) make any public proposals to the Company or any of its Affiliates, directors, officers, employees, agents, representatives, successors or security holders concerning, or announcing any intention to effect or participate in any Acquisition Transaction relating to the Company or any Affiliate or successor of the Company or take any action that would require the Company to make a public announcement regarding the possibility of an Acquisition Transaction with Purchaser or any of its Affiliates.

Notwithstanding the foregoing, the restrictions set forth in this Section 6(a) shall not restrict Purchaser from making a confidential, non-public offer or proposal to the Company's Chief Executive Officer and/or its Board of Directors with respect to an Acquisition Transaction by and between any of the Standstill Parties and the Company; provided, that the making thereof would not reasonably be expected to require public disclosure by the Company.

“Acquisition Transaction” means any transaction involving: (i) any sale, license, lease, exchange, transfer or other disposition of the assets of the Company or any subsidiary of the Company constituting more than fifty percent (50%) of the consolidated assets of the Company or accounting for more than fifty percent (50%) of the consolidated revenues of the Company in any one transaction or in a series of related transactions; (ii) any offer to purchase, tender offer, exchange offer or any similar transaction or series of related transactions made by any Person whereby such Person would become the beneficial owner of more than fifty percent (50%) of the then-outstanding voting securities of the Company; or (iii) any merger, consolidation, business combination, share exchange, reorganization or similar transaction or series of related transactions involving the Company or any subsidiary of the Company whereby the holders of voting securities of the Company immediately prior to any such transaction hold less than fifty percent (50%) of the voting securities of the Company or the surviving company (or its parent company) immediately after the consummation of any such transaction.

(ii) Notwithstanding Section 6(a)(i), Purchaser and its Affiliates may own (and may acquire shares or other ownership interests in) any mutual fund or similar entity that owns Company Securities provided that Purchaser and its Affiliates own, in the aggregate, less than 5% of such mutual fund or similar entity and do not exercise control over the management or policies of such entity. The provisions set forth in Section 6(a)(i) shall not prohibit passive investments by a pension or employee benefit plan or trust for Purchaser's or its Affiliates' employees so long as such investments are directed by independent trustees, administrators or employees.

(iii) Notwithstanding anything to the contrary in this Agreement, the Company agrees that the Standstill Parties will immediately be released from all of their obligations under this Section 6(a) if (1) any party unaffiliated with Purchaser initiates a tender or exchange offer for a majority of the outstanding shares of the Company's Common Stock (or publicly announces an intention to acquire by way of merger, tender or otherwise a majority of the outstanding shares of the Company's Common Stock), or (2) the Company publicly announces entering into a definitive agreement with a third party for a transaction involving more than 50% of the Company's voting equity securities or all or substantially all of the Company's and its subsidiaries' assets (taken as a whole) (whether by merger, business combination, tender or exchange offer, sale or otherwise), provided that the restrictions set forth in this Section 6(a) shall be automatically reinstated if and when (x) in the case of clause (1), such tender or exchange offer is withdrawn or terminated without such party acquiring such 50% ownership level and (y) in the case of clause (2), such definitive agreement is terminated prior to the consummation of the transaction.

(iv) The Company agrees that it will not assert that this Agreement or any other agreement between Purchaser or its Affiliates, on the one hand, and the Company or its Affiliates, on the other hand, restricts any of the actions contemplated by this Section 6(a) after the expiration or termination of the Restricted Period or the earlier release of the Standstill Parties from their obligations under this Section 6(a) pursuant to the provisions of Section 6(a)(iii) above.

(b) Lock-Up.

(i) Subject to Section 6(b)(ii), during the twelve (12)-month period after the Effective Date, Purchaser shall not dispose of (i) the Shares (together with any shares of Common Stock issued in respect thereof as a result of any share split, exchange or replacement, or merger, consolidation or similar recapitalization) or (ii) any shares of Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to the shares of Common Stock described in clause (i) of this sentence (the “Dividend Shares”); provided, however, that the foregoing shall not prohibit Purchaser from (x) transferring Shares to an Affiliate of Purchaser, provided that such Affiliate, prior to or simultaneously with such transfer, shall have agreed in writing to be subject to and bound by all the restrictions and obligations set forth in this Agreement as though it were Purchaser hereunder or (y) selling Shares or Dividend Shares in connection with any tender offer for Company Securities or any Acquisition Transaction.

“Dispose of” means any (A) offer, pledge (other than pledges in connection with bona fide debt financing transactions involving a general lien on assets of an investor), sale, contract to sell, sale of any option or contract to purchase, purchase of any option or contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any Company Securities, including, without limitation, any “short sale” or similar arrangement, or (B) swap, hedge, derivative instrument, or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of shares of Common Stock, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.

(ii) Notwithstanding Section 6(b)(i), fifty percent (50%) of the Shares referenced in Section 6(b)(i) (the “Lock-up Shares”) shall no longer be subject to the lock-up restrictions set forth in Section 6(b)(i) from and after the date that is six (6) months after the Effective Date, and the remaining fifty percent (50%) of the Lock-up Shares shall no longer be subject to such restrictions beginning on the first anniversary of the Effective Date. Dividend Shares will be released from the lock-up restrictions set forth in Section 6(b)(i) on a *pro rata* basis as if all such shares had been issued on the Effective Date.

(c) Restrictions on Transfer.

(i) In addition to those certain restrictions set forth in Section 6(b), Purchaser acknowledges and agrees that (A) the issuance and sale of the Shares has not been, and will not be, registered under the Securities Act or any state securities law, by reason of their issuance in a transaction exempt from the registration requirements of the Securities Act and such rules and regulations thereunder, (B) the Shares may be disposed of only pursuant to an effective registration statement under, and in compliance with the requirements of, the Securities Act, or pursuant to an available exemption from, or in a transaction not subject to, the registration requirements of the Securities Act, and in compliance with any applicable state and federal securities laws, and (C) the certificate(s) for the Shares shall bear a legend as set forth in Section 6(c)(ii) (unless and until such legend is removed in accordance with Section 6(c)(iii)), and (D) appropriate stop transfer instructions may be issued against any transfer of the certificate(s) for the Shares in violation of this Section 6(c). Purchaser further understands that such exemption depends upon, among other things, the *bona fide* nature of Purchaser’s investment intent expressed in this Agreement.

(ii) It is understood that the certificate(s) or book-entry position evidencing the Shares shall bear the following legend (or substantially similar legends) or stop order instructions, in the case of a book-entry position, until the time set forth in Section 6(c) (iii):

“THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 OR THE “BLUE SKY” LAWS OF ANY JURISDICTION. SUCH SECURITIES MAY NOT BE SOLD, TRANSFERRED, PLEDGED OR HYPOTHECATED UNLESS THE REGISTRATION, QUALIFICATION AND FILING REQUIREMENTS OF ALL APPLICABLE JURISDICTIONS HAVE BEEN SATISFIED OR THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE COMPANY THAT THE PROPOSED TRANSACTION WILL BE EXEMPT FROM REGISTRATION, QUALIFICATION, AND FILINGS IN ALL SUCH JURISDICTIONS.”

“THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO RESTRICTIONS ON TRANSFER AND MAY NOT BE SOLD, EXCHANGED, TRANSFERRED, PLEDGED, HYPOTHECATED OR OTHERWISE DISPOSED OF EXCEPT IN ACCORDANCE WITH AND SUBJECT TO ALL THE TERMS AND CONDITIONS OF A CERTAIN SHARE PURCHASE AGREEMENT DATED AS OF NOVEMBER 15, 2019, A COPY OF WHICH THE COMPANY WILL FURNISH TO THE HOLDER OF THIS CERTIFICATE UPON REQUEST AND WITHOUT CHARGE.”

(iii) The Company shall authorize the removal of the restrictive legends and stop transfer instructions described in Section 6(c)(ii) (A) if there is in effect a registration statement under the Securities Act covering the Shares or (B) promptly following receipt by the Company of a written request by Purchaser (the “Legend Removal Request”) accompanied by such customary representations, notices and other documentation (including, but not limited to, a legal opinion from securities counsel to Purchaser) as are requested by the Company or its transfer agent, so as to enable the sale of any Shares in a transaction registered under the Securities Act or pursuant to Rule 144 under the Securities Act, or otherwise in connection with a transaction exempt from registration under the Securities Act; provided, in each case, that such sale is otherwise permitted by this Agreement. Any such Legend Removal Request shall be delivered not less than two (2) business days prior to the date on which the proposed sale is to be effected.

(iv) For the avoidance of doubt, for purposes of this Agreement, none of the Company or its Affiliates shall be deemed an Affiliate of Purchaser or its Affiliates and no Person shall be deemed an Affiliate of another Person solely by virtue of the transactions contemplated by the Collaboration Agreement.

(d) FCPA Compliance. The Company shall not, and shall not permit any of its controlled Affiliates or subsidiaries or any of its or their respective Representatives to, promise, authorize or make any payment to, or otherwise contribute any item of value to, directly or indirectly, any non-U.S. government official, in each case, in violation of the FCPA or any other applicable anti-bribery or anti-corruption law. The Company shall, and shall cause each of its controlled Affiliates and subsidiaries to, cease all of its or their respective activities, as well as remediate any actions taken by the Company, its controlled Affiliates or any of its or their respective Representatives, in violation of the FCPA or any other applicable anti-bribery or anti-corruption law. The Company shall, and shall cause each of its controlled Affiliates and subsidiaries to, maintain systems or internal controls (including, but not limited to, accounting systems, purchasing systems and billing systems) to ensure compliance with the FCPA or any other applicable anti-bribery or anti-corruption law.

7. Miscellaneous.

(a) Fees and Expenses. Each party to this Agreement shall bear all of its own fees and expenses incurred in connection with the preparation, negotiation, execution and delivery of this Agreement and the consummation of the transactions contemplated hereby, including all fees of such party's legal counsel.

(b) Survival. The representations and warranties of the parties contained in this Agreement shall survive the Closing for a period of three (3) years.

(c) Entire Agreement. This Agreement and the Collaboration Agreement contain the entire agreement among the parties with respect to the transactions contemplated hereby and thereby and supersede all prior negotiations, commitments, agreements and understandings among them, whether written or oral, with respect thereto.

(d) Notices. All notices, requests, consents and other communications hereunder to any party shall be contained in a written instrument addressed to such party at the address set forth below or such other address as may hereafter be designated in writing by the addressee to the addressor, and shall be deemed given (i) when delivered in person or duly sent by fax showing confirmation of receipt, (ii) five (5) days after being duly sent by first class mail postage prepaid, or (iii) the next business day after being duly sent by Federal Express or other recognized express international courier service:

if to the Company, to:

Molecular Templates, Inc.
Attn: Jason Kim, President & Chief Operating Officer
9301 Amberglen Blvd., Suite 100
Austin, Texas 78729

with a copy (which shall not constitute notice) to:

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111
Attn: William C. Hicks Esq. and Mathew J. Gardella Esq.
Fax: (617) 542-2241

if to Purchaser, to:

Vertex Pharmaceuticals Incorporated
Attn: Business Development
50 Northern Avenue
Boston, Massachusetts 02210

with a copy (which will not constitute notice) to:

Vertex Pharmaceuticals Incorporated
Attn: Corporate Legal
50 Northern Avenue
Boston, Massachusetts 02210

and a copy (which will not constitute notice) to:

Ropes & Gray LLP
Attn: Marc Rubenstein
Prudential Tower
800 Boylston Street
Boston, Massachusetts 02199

(e) Amendments; Waivers. This Agreement may be amended, and compliance with the provisions of this Agreement may be omitted or waived, only by a written agreement executed by an authorized representative of each of the Company and Purchaser. Waiver by a party of a breach hereunder by the other party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such party.

(f) Counterparts. This Agreement may be executed in any number of counterparts, each such counterpart shall be deemed to be an original instrument, and all such counterparts together shall constitute but one agreement. Any such counterpart may contain one or more signature pages. This Agreement may be executed and delivered by facsimile, or by email in portable document format (.pdf), and upon such delivery of the signature page by such method will be deemed to have the same effect as if the original signature had been delivered to the other party.

(g) Headings; Interpretation. The headings of the various sections of this Agreement have been inserted for convenience of reference only and shall not be deemed to be a part of this Agreement. Except where the context expressly requires otherwise, (i) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (ii) the words “include,” “includes” and “including” will be deemed to be followed by the phrase “without limitation,” (iii) the word “will” will be construed to have the same meaning and effect as the word “shall,” (iv) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (v) any reference herein to any Person will be construed to include the Person’s successors and assigns, (vi) the words “herein,” “hereof” and “hereunder,” and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (vii) all references herein to Sections or Schedules will be construed to refer to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto, (viii) provisions that require that a party or the parties “agree,” “consent” or “approve” or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (ix) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (x) any action or occurrence deemed to be effective as of a particular date will be deemed to be effective as of 11:59 PM ET on such date and (xi) the term “or” will be interpreted in the inclusive sense commonly associated with the term “and/or.”

(h) Governing Law. This Agreement shall be governed by, and construed and enforced in accordance with, the substantive laws of the State of Delaware without regard to its principles of conflicts of laws.

(i) Assignment. Neither this Agreement nor any of the rights or obligations hereunder may be assigned by either party without the prior written consent of the non-assigning party; provided, however, that Purchaser may assign this Agreement without the Company's consent to an Affiliate of Purchaser, provided that such Affiliate agrees in writing to be bound by the terms of this Agreement.

(j) Successors and Assigns. This Agreement shall be binding upon, and inure to the benefit of, each of the successors and assigns of the parties and, except as otherwise expressly provided in this Agreement, each other Person who shall become a registered holder named in a certificate evidencing Shares transferred to such holder by Purchaser or its permitted transferees, and (except as aforesaid) its legal representatives, successors and assigns.

(k) Severability. Any provision of this Agreement that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. In such event, the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

(l) Disclaimer. Except as expressly set forth in this Agreement and the Collaboration Agreement, neither party makes any representation or warranty to the other party of any nature, express or implied.

(m) No Third Party Rights or Obligations. No provision of this Agreement will be deemed or construed in any way to result in the creation of any rights or obligations in any Person not a party to this Agreement.

(n) Further Actions. Each party hereto agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

[Signature page follows]

IN WITNESS WHEREOF, the parties have executed this Share Purchase Agreement as of the Effective Date.

MOLECULAR TEMPLATES, INC.

By: /s/ Eric E. Poma, Ph.D.
Name: Eric E. Poma Ph.D.
Title: Chief Executive Officer and Chief Scientific Officer

VERTEX PHARMACEUTICALS INCORPORATED

By: /s/ Jeffrey Leiden
Name: Jeffrey Leiden
Title: Chairman, President and Chief Executive Officer

[Signature Page to Share Purchase Agreement]



January 3, 2019

Roger J. Waltzman, MD, MBA
425 West 50th Apt. 11F
New York, NY 10019

Dear Dr. Waltzman,

On behalf of Molecular Templates (“MTEM” or the “Company”), I am pleased to offer you the position of Chief Medical Officer, reporting directly to me.

Total Rewards

Annual Salary

Your salary will be paid at the rate of \$33,333.33 per month (\$400,000.00 annualized) less payroll deductions and all required withholdings. Your salary will be paid in 24 installments annually or under such similar payroll procedure.

Target Bonus

You will be eligible to receive a target discretionary annual bonus of 40% of your base salary. Actual bonus awards may be above or below the targeted amount based on the Company’s performance and your individual performance, subject to MTEM’s policy for paying annual bonuses set forth in MTEM’s Employee Handbook, as may be amended from time to time. Your 2019 bonus, if any, will be prorated based on your start date of February 18, 2019.

Whether the Company awards bonuses for any given year, the allocation of the bonuses for Company and individual performance, and the amounts of such bonuses, if awarded, will be in the sole discretion of the Company as determined by its Compensation Committee of the Board of Directors (the “Committee”). If the Committee approves payment of bonuses for any given year, the bonus amounts generally will be determined and paid within the first calendar quarter of the year based on the prior year’s performance. To incentivize you to remain employed with MTEM, you must be employed on the date any bonus is paid in order to earn the bonus. If your employment terminates for any reason prior to the payment of the bonus, then you will not have earned the bonus and will not receive any portion of it. Notwithstanding the foregoing, if MTEM terminates your employment without “Cause” (as defined in MTEM’s 2014 Equity Incentive Plan) after the close of the fiscal year and prior to payment of the bonus, the Company will pay you any bonus awarded by the Compensation Committee on or before March 15.

Equity Incentives

Subject to approval by the Committee, you will be granted an initial new hire option to purchase 175,000 shares of the Company’s common stock, subject to the terms and conditions of MTEM’s 2014 Equity Incentive Plan and a stock option grant notice and

agreement that will be provided to you. The grant agreement will include a four (4) year vesting schedule, such that 25% of the shares will vest on the first anniversary of the commencement of your employment, with the balance vesting in equal monthly installments over the subsequent thirty-six (36) months, until either your option shares are fully vested or your employment ends, whichever occurs first. The stock option award vesting is subject to acceleration in certain circumstances following a Change in Control, as set forth below under “Termination Without Cause in Connection With a Change in Control”.

Annually, you will be eligible to participate in any long-term incentive plan in effect at a level commensurate with your position and role with MTEM under such plan’s terms and conditions.

Benefits

You will be eligible to receive MTEM’s complete package of wellness and insurance benefits. MTEM may, in its sole discretion, discontinue or modify any such plans, programs or practices at any time, with or without notice. Details about these benefit plans will be made available for your review.

Paid Time Off

Vacation. You are eligible for three weeks of paid vacation during each fiscal year at times that are mutually convenient for you and the Company.

Holidays. You are eligible for paid holidays. These holidays are listed in our employee handbook.

At-Will Employment; Termination; Severance

Acknowledgement. Your employment with MTEM is “at will,” which means you may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying MTEM, and likewise, MTEM may terminate your employment at any time and for any reason whatsoever, with or without cause or advance notice. This at-will employment relationship cannot be changed except in a writing signed by a Company officer.

Termination in General. In the event your employment with MTEM terminates for any reason, you will receive (i) your base salary through the date of termination; (ii) reimbursement of all expenses for which you are entitled to be reimbursed, but for which you have not yet been reimbursed; and (iii) if you participate in MTEM’s group health plans, the right to continue health care benefits under COBRA, at your cost, to the extent required and available by law.

Termination Without Cause. In the event MTEM terminates your employment without “Cause” (as defined in MTEM’s 2014 Equity Incentive Plan) in addition to (i), (ii) and (iii) above, provided you execute, deliver to MTEM and do not revoke a separation agreement and general release within 60 days following your last date of employment, the Company will pay you severance pay at a rate equal to 100% of your base salary, (less applicable withholding), for a period of nine months from the date of such termination, to be paid periodically in accordance with MTEM’s normal payroll practices. Payments will commence on the next payroll period following the date the separation agreement becomes

enforceable, provided that if the 60-day period to sign the separation agreement extends into the following calendar year, the payments will begin in the new calendar year. The first payment will include all amounts due to you under this paragraph through that date.

Termination Without Cause in Connection With a Change in Control. In the event that a Change in Control (as defined in MTEM's 2014 Equity Incentive Plan) occurs during your employment with us and MTEM terminates your employment without Cause (as defined in MTEM's 2014 Equity Incentive Plan) three months prior to or twelve months after the Change in Control, provided you execute, deliver to MTEM and do not revoke a separation agreement and general release within 60 days following your last date of employment, the Company will (i) pay you in lieu of the severance benefit described in the preceding paragraph, a lump sum amount equal to one times (1x) the sum of your current base salary and your annual target bonus, and (ii) accelerate your vesting in all Company time-based equity awards that you then hold. All stock options then held by you shall immediately become exercisable in full and any other stock awards held by you will become free of restrictions. MTEM will pay you the lump sum severance payment on the next payroll period following the date the separation agreement becomes enforceable, provided that if the 60-day period to sign the separation agreement extends into the following calendar year, the lump sum payment will be made in the new calendar year.

Confidentiality

As a MTEM employee, you will be expected to abide by Company rules and regulations and sign and comply with the Company's Proprietary Information and Inventions Agreement which prohibits unauthorized use or disclosure of company proprietary information.

In your work for the Company, you will be expected not to use or disclose any confidential information, including trade secrets, of any former employer or other person to whom you have an obligation of confidentiality. Rather, you will be expected to use only that information which is generally known and used by persons with training and experience comparable to your own, which is common knowledge in the industry or otherwise legally in the public domain, or which is otherwise provided or developed by the Company.

You agree that you will not bring onto Company premises any unpublished documents or property belonging to any former employer or other person to whom you have an obligation of confidentiality.

You represent that you are not a party to any agreement that would prohibit you from entering into employment with the Company and have otherwise brought to the Company's attention any agreement that purports to restrict the activities in which you can engage on behalf of the Company.

This letter, together with the Proprietary Information and Inventions Agreement, forms the complete and exclusive statement of your agreement with MTEM. The terms in this letter supersede any other agreements or promises made to you by anyone, whether oral or written. Changes in your agreement terms, other than those changes expressly reserved to the Company's discretion in this letter, require a written modification signed by an officer of the Company. As

required by law, this offer is subject to satisfactory proof of your right to work in the United States of America.

The Company reserves the right to conduct background investigations and/or reference checks on all of its potential employees. Your employment offer, therefore, is contingent upon a clearance of such a background investigation and/or reference check, if any.

The terms of this letter are governed by the laws of New Jersey without regard to its or any other state's conflict of law rules.

Please sign and date this letter and return it to the Company by Monday, January 14, 2019, if you wish to accept employment at MTEM under the terms described above.

We welcome you to the Molecular Templates team and look forward to your contribution to our success.

Sincerely,

/s/ Eric Poma PhD (MTEM Supervisor)
Eric Poma, PhD
Chief Executive Officer & Chief Scientific Officer

Accepted:

/s/ Roger J. Waltzman, MD

Date: January 5, 2019

SUBSIDIARIES OF MOLECULAR TEMPLATES, INC.

| Subsidiary | Jurisdiction |
|--------------------------------|----------------|
| Molecular Templates OpCo, Inc. | Delaware |
| THLD Enterprises (UK), Limited | 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. 333-195084) of Threshold Pharmaceuticals, Inc.,
6. Registration Statement (Form S-3 No. 333-174844) of Threshold Pharmaceuticals, Inc.,
7. Registration Statement (Form S-3 No. 333-169689) of Threshold Pharmaceuticals, Inc.,
8. Registration Statement (Form S-3 No. 333-162719) of Threshold Pharmaceuticals, Inc.,
9. Registration Statement (Form S-3 No. 333-153475) of Threshold Pharmaceuticals, Inc.,
10. Registration Statement (Form S-3 No. 333-202043) of Threshold Pharmaceuticals, Inc.,
11. Registration Statement (Form S-3 No. 333-217993) of Threshold Pharmaceuticals, Inc.,
12. Registration Statement (Form S-8 No. 333-225826) of Molecular Templates, Inc. pertaining to the Molecular Templates, Inc. 2018 Equity Incentive Plan,
13. 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,
14. Registration Statement (Form S-8 No. 333-210089) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Employee Stock Purchase Plan,
15. Registration Statement (Form S-8 No. 333-202476) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Employee Stock Purchase Plan,
16. 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,
17. 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,
18. 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,
19. 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,
20. Registration Statement (Form S-8 No. 333-167260) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Equity Incentive Plan,
21. 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,
22. Registration Statement (Form S-8 No. 333-156733) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Equity Incentive Plan,
23. Registration Statement (Form S-8 No. 333-143130) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Equity Incentive Plan,
24. 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
25. 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;
26. Registration Statement (Form S-8 No. 333-230617) of Molecular Templates, Inc. pertaining to the 2018 Equity Incentive Plan.,

of our reports dated March 13, 2020, with respect to the consolidated financial statements and the effectiveness of internal control over financial reporting of Molecular Templates, Inc. included in this Annual Report (Form

10-K) for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Austin, Texas
March 13, 2020

CERTIFICATIONS UNDER SECTION 302

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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 13, 2020

/s/ Eric E. Poma Ph.D.

Eric E. Poma, Ph.D.

Chief Executive Officer

CERTIFICATIONS UNDER SECTION 302

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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 13, 2020

/s/ Adam Cutler

Adam Cutler

Chief Financial Officer

CERTIFICATIONS UNDER SECTION 906

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

The Annual Report for the year ended December 31, 2019 (the “Form 10-K”) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 13, 2020

/s/ Eric E. Poma Ph.D.

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

Date: March 13, 2020

/s/ Adam Cutler

Adam Cutler
Chief Financial Officer