Table of Contents

# 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, 2023**

**OR**

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

**For the transition period from to**
**Commission file number: 001-32979**

# MOLECULAR TEMPLATES, INC.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **94-3409596** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(IRS employer Identification number)** |
| **9301 Amberglen Blvd, Suite 100, Austin TX** | **78729** |
| **(Address of principal executive office)** | **(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** | **Trading Symbol** | **Name of Each Exchange On Which Registered** |
|---|---|---|
| **Common Stock, $0.001 Par Value Per Share** | **MTEM** | **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 | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| | | Emerging growth company | ☐ |

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 $7.20 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 $18.0 million. 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 25, 2024 there were 5,374,268 shares of the registrant's common stock outstanding.

Auditor Name: Ernst & Young LLP Auditor Firm ID: 42 Auditor Location: Austin, Texas

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement for the registrant's 2024 annual meeting of stockholders or an amendment to this Annual Report on Form 10-K to be filed pursuant to Regulation 14A within 120 days of the registrant's fiscal year ended December 31, 2023 are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

**Molecular Templates, Inc.**
**TABLE OF CONTENTS**

## PART I

### Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K, including the sections titled "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 continue to pursue development pathways and regulatory strategies for MT-6402, MT-8421, MT-0169 and other engineered toxin body ("ETB") biologic candidates;
- our utilization of a de-immunized ETB scaffold that has been designed to reduce or eliminate the propensity for innate immunity, including capillary leak syndrome ("CLS"); via de-immunization of the Shiga-like Toxin A subunit ("SLTA") as well as chemistry, manufacturing, and controls improvements;
- the timing and our ability to advance the development of our biologic candidates;
- our plans to pursue discussions with regulatory authorities, and the anticipated timing, scope and outcome of related regulatory actions or guidance;
- our ability to establish and maintain potential new partnering or collaboration arrangements for the development and commercialization of ETB biologic candidates;
- our ability to obtain the benefits we anticipate from partnering, collaboration, or supply agreements that we may enter into;
- our financial condition, including our ability to obtain the funding necessary to advance the development of our biologic candidates, any statements indicating whether or not the closing of the amended and restated second tranche of our July 2023 Private Placement (as defined below) will occur, and our ability to continue as a going concern;
- our ability to comply with the terms of our Convertible Secured Contingent Value Right Agreement pursuant to which our obligations are secured, subject to certain limited exceptions, by substantially all of our assets;
- our ability to comply with applicable listing standards within the one-year monitoring period that commenced on August 2, 2023 and to maintain the listing of shares of our common stock on the Nasdaq Capital Market;
- the ongoing effect of the reverse stock split of our common stock that we completed in August 2023 on the price or trading of our common stock; including potential continued adverse impacts on the liquidity of our common stock;
- the anticipated progress of our biologic candidate development programs, including whether our ongoing and potential future clinical trials will achieve clinically relevant results;
- our ability to generate data and conduct analyses to support the regulatory approval of our biologic candidates;
- our ability to establish and maintain intellectual property rights for our biologic candidates;

- whether any biologic candidates that we are able to commercialize are safer or more effective than other marketed products, treatments or therapies;
- our ability to discover and develop additional biologic candidates suitable for clinical testing;
- our ability to identify, in-license or otherwise acquire additional biologic candidates and development programs;
- our anticipated research and development activities and projected expenditures;
- our ability to complete preclinical and clinical testing successfully for new drug or biologic candidates that we may develop or license;
- our ability to have manufactured active pharmaceutical ingredient and biologic product that meet required release and stability specifications;
- our ability to have manufactured sufficient supplies of drug product for clinical testing and commercialization;
- our ability to obtain licenses to any necessary third-party intellectual property;
- our anticipated use of proceeds from any financing activities;
- potential uncertainty regarding the outcome of our exploration of strategic alternatives, and the impacts that it may have on our business;
- the expected cost savings from our strategic restructuring that we completed in 2023;
- the extent to which global economic and political developments, including the indirect and/or long-term impact of inflation, will affect our business operations, clinical trials, or financial condition;
- the impact of laws and regulations;
- our projected financial performance;
- the sufficiency of our cash resources; and
- other risks and uncertainties, including those listed under Part I, Item 1A, “Risk Factors.”

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

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

As used in this 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 subsidiary.

## ITEM 1. BUSINESS

### Overview

Molecular Templates, Inc. is a clinical-stage biopharmaceutical company focused on the discovery and development of differentiated, targeted, biologic therapeutics for cancer. Molecular utilizes its proprietary biologic drug platform to design and generate 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 SLTA, a ribosome inactivating bacterial protein. In its wild-type form, SLTA 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 ("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 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.

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 a reduced propensity for triggering innate immunogenicity and attendant toxicities like CLS. Of the over 100 patients treated across Molecular's three clinical programs utilizing Molecular's de-immunized scaffold to date, there has been no instance of CLS or other manifestations of innate immunity observed. The vast majority of toxicities observed to date appear to be target mediated with only an occasional infusion related reaction that may be related to the underlying scaffold.

ETBs have relatively predictable pharmacokinetic ("PK") 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 ("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 tolerability in multiple animal models as well as a generally favorable tolerability profile 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 tolerability profile provide opportunities for the clinical development of these agents to address multiple cancer types.

Molecular has developed ETBs to various targets, including PD-L1, CTLA-4, and CD38. PD-L1 and CTLA-4 are key immune checkpoint pathways and are validated targets expressed in a variety of solid tumor cancers and immune cells. The differentiated mechanism of action of Molecular's ETBs allows for a novel approach to mediating anti-tumor T-cell activity against immuno-oncology targets by: (i) dismantling the tumor micro-environment ("TME"), through the depletion of immunosuppressive immune cells and (ii) delivering high avidity major histocompatibility complex-I ("MHC-I") antigens to the tumor to directly alter the tumor's immunophenotype. The altering of the tumor's immunophenotype is unique and leverages the intrinsic intracellular routing properties of ETBs through a mechanism Molecular calls Antigen Seeding.

MT-6402 (ETB targeting PD-L1) and MT-8421 (ETB targeting CTLA-4) are in Phase I stages of development. Molecular is currently negotiating an investigator-sponsored clinical trial ("IST") for MT -0169 and anticipate initiating a Phase 1 study at the 5 and 10 mcg/kg dose levels for CD38+ leukemia in mid-2024. Molecular expects to provide periodic updates on these studies throughout 2024.

Molecular also developed the proprietary process for manufacturing ETBs under Current Good Manufacturing Practice ("cGMP") regulatory standards and continues to make improvements to its manufacturing processes. Molecular has conducted multiple cGMP manufacturing runs with its compounds and believes this process is robust and could support commercial production with gross margins that are similar to those seen with antibodies.

On March 29, 2023 and June 16, 2023, Molecular implemented a strategic reprioritization and corresponding reduction in workforce, designed to focus on the clinical development programs for MT-6402, MT-8421 and MT-0169, and preclinical activities related to Molecular's collaboration with Bristol-Myers Squibb (the "Restructuring"). The Restructuring reduced Molecular's workforce by approximately 68%, ceased further development of Molecular's MT-5111 clinical development program, and refocused the majority of Molecular's pre-clinical efforts around activities related to the Bristol-Myers Squibb collaboration. Molecular incurred $0.3 million of costs in connection with the Restructuring related to severance pay and other related termination benefits. Molecular does not anticipate to incur additional costs related to the Restructuring.

On March 4, 2024, Molecular announced its continued efforts in the comprehensive evaluation of strategic alternatives, including consideration of a wide range of options including, among other things, a potential financing/recapitalization, sale, merger, or other strategic transaction. Molecular has not set a deadline or definitive timetable for the completion of the strategic review process, nor has it made any decisions relating to any strategic alternative at this time.

**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 biologic. These challenges include 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 relatively predictable PK 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.

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 treatment-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 compound, MT-6402, targets the PD-L1 protein, found on the surface of tumor and immune cells in the TME. PD-L1 is a validated target, as evidenced by the development of PD-1 and PD-L1 inhibitors, some of the most useful new therapies that the U.S. Food and Drug Administration (the "FDA") has approved over the past decade for treatment of patients with cancer. Destruction of PD-L1 expressing tumors and immune cells is also expected to be a tolerable strategy for patients, with immune-related adverse events anticipated to occur in a manner similar to the approved checkpoint inhibitors. PD-L1 expression is not ubiquitously found in the tumors of cancer patients, but it does not typically reduce over time in those where it is found and it appears to increase in response to other cancer therapies such as cytotoxic chemotherapy or radiation therapy. Molecular chose targeting of PD-L1 because of its relationship to modifying immune surveillance of tumors, its limited normal tissue expression, the known and manageable toxicity profile associated with checkpoint inhibition, and the persistence of PD-L1 expression even after prior treatment failure. Molecular used a similar rationale in the selection of Molecular's current pipeline, 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 target and select patients in the Phase I clinical trials that phenotypically match that ETB program*. Molecular can screen libraries of antibody-like

binding domains such as single chain variable fragments ("scFvs") or single domain VHH antibodies expressed in Molecular's ETB scaffold to a given target. The PK profile of these compounds is similar and relatively predictive in humans based on animal models. Once the lead is selected and Investigational New Drug ("IND") Application and 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 the candidate's safety as well as efficacy than is possible in many drug development programs.

**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 developing MT-6402 as a single agent therapy for relapsed and refractory solid tumors with confirmed PD-L1 expressing tumors or confirmed PD-L1 expression in the TME. The targeting of this checkpoint has been demonstrated to confer clinical benefit in a wide variety of settings. MT-6402's differentiated mechanism of action, safety, and pharmacological profile targeting PD-L1 may provide an advantage over other modalities. Given the unique mechanism of direct cell kill via ribosome inactivation and by sensitizing cytotoxic T lymphocytes to these PD-L1 cells by forcing expression of the pp65 CMV antigen, Molecular believes there is the potential for combination drug strategies, particularly with PD-1 inhibitors. Further, based on the safety data seen to date with ETBs, Molecular believes the different PK 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 therapy. 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 and is utilized in Molecular's clinical-stage ETBs. In addition, new approaches have been developed for the genetic fusion of the SLTA and antibody domain that enhance the potency of Molecular's ETBs. Molecular has also developed ETBs like MT-6402 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 biopharmaceutical company focused on compounds with unique and differentiated biology*. Molecular believes that differentiated mechanisms of action are crucial for improving outcomes in cancer. 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 scalable and economical manufacturing. If MT-6402, MT-8421, MT-0169, or any future drug candidates Molecular may develop are approved, Molecular will consider commercializing them itself in select markets.

**Molecular's 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, immuno-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 profiles and can be readily manufactured to cGMP standards. From a library of antibody-like targeting domains, Molecular's research and design platform allows for the comprehensive *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, absorption, distribution, metabolism and excretion, 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.

In all clinical-stage 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. 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, a differentiated approach to immuno-oncology. Molecular has integrated its Antigen Seeding Technology into the PD-L1 targeting ETB, MT-6402, and continues to build out animal models to further validate and screen additional 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.

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 have the ability to 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:

| | Target | Stage and Timeline | Differentiated MOA and Product Profile |
|---|---|---|---|
| MT-6402 | PD-L1 | Phase 1 Ongoing | • Depletion of PD-L1+ immunosuppressive immune cells and PD-L1+ tumor cells<br>• Delivery of CMV antigen to alter immunophenotype to redirect antigen specific T-cells to tumor (Antigen Seeding) |
| MT-8421 | CTLA-4 | Phase 1 Ongoing | • Depletion of Tregs via enzymatic direct-cell kill to dismantle TME<br>• No peripheral blockade effect to enhance tolerability |
| MT-0169 | CD38 | Phase 1 Ongoing | • Clearance of CD38 expressing cells via novel MOA of enzymatic direct cell kill |

***Immuno-Oncology ETBs***

**MT-6402 – ETB Targeting PD-L1**

***Overview***

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 complex 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.

MT-6402 is an ETB consisting of a scFv, with affinity for PD-L1, fused to the enzymatically active de-immunized SLTA and a HLA-A*02 class I antigen derived from the human cytomegalovirus ("HCMV") pp65 protein. MT-6402 was designed to induce potent anti-tumor effects via PD-L1 targeting through multiple mechanisms that may overcome the limitations of approved checkpoint inhibitors. In preclinical studies, MT-6402 specifically binds and kills both tumor and immune PD-L1 expressing cells in a manner consistent with SLTA mediated cellular cytotoxicity through ribosomal inactivation, independent of checkpoint inhibition. Additionally, MT-6402 alters the immunophenotype of targeted cells by delivering foreign class I antigen from CMV for presentation in complex with MHC class I, which may provoke a CMV-specific immune response against the targeted cells. Third, MT-6402 may rehabilitate the tumor microenvironment ("TME") and allow for immune recognition of tumors by destroying PD-L1-expressing immunosuppressive immune cells in the TME through ribosomal inactivation.

Molecular filed an IND application for MT-6402 in December 2020 and the IND was accepted in January 2021. A Phase I study of MT-6402 in relapsed/refractory patients with PD-L1 expressing tumors began in July 2021 at a starting dose of 16 mcg/kg. The Phase I study for MT-6402 is a multi-center, open-label, dose escalation and dose expansion trial. Patients with confirmed PD-L1 expressing tumors or confirmed PD-L1 expression in the TME are eligible for enrollment, irrespective of HLA genotype or CMV status. Following a review of the safety data from cohort 5 (63 mcg/kg), which was well tolerated, patient enrollment in cohort 6 initiated at a dose of 83 mcg/kg.

As of March 2024, 48 patients have been treated across seven dose escalation cohorts of 16 mcg/kg, 24 mcg/kg, 32 mcg/kg, 42 mcg/kg, 63 mcg/kg, 83 mcg/kg, and 100 mcg/kg in the MT-6402 study of patients with relapsed/refractory tumors that express PD-L1.

Molecular continues to observe pharmacodynamic ("PD") effects including the depletion of PD-L1+ monocytes, MDSCs, PD-L1+ dendritic cells, and regulatory T cells ("Tregs") as well as T cell activation, with the highest effects observed at the highest dose. MT-6402 dosing appears to affect peripheral vascular endothelial growth factor ("VEGF") levels particularly in patients with elevated VEGF at study entry. In these patients, VEGF levels appear to inversely correlate with MDSC depletion. These PD effects associated with immune activation were seen across the majority of patients irrespective of HLA genotype or level of tumor or immune cell PD-L1 staining. Additionally, these VEGF elevations occur at earlier timepoints with increasing dose levels.

One patient with high tumor PD-L1 expression who also had Antigen Seeding capability, demonstrated tumor regression. This patient, with non-small cell lung cancer ("NSCLC"), was treated in cohort 1 (16 mcg/kg) and demonstrated resolution of three osseous lesions and a reduction in uptake in the remaining lesion. This patient also experienced grade 2 cytokine release syndrome ("CRS") consistent with T-cell activation and was dose reduced to 8 mcg/kg. This patient had evaluable-only multiple sites of bone disease that appeared to have resolved on bone scan after 3-4 months on MT-6402 with only one remaining site which showed decreased uptake. To date, treatment-related adverse events ("AEs") including immune related AEs have been largely restricted to grade 1 or grade 2. Molecular has not observed any cases of clinically significant cardiotoxicity in human subjects who have been dosed with MT-6402.

The Part A dose escalation of the phase I study for MT-6402 was completed in September 2023. The 100 mcg/kg dose was deemed not tolerable based on two dose limiting toxicities ("DLTs") of grade 3 rash and a grade 1 high sensitivity troponin elevation without clinical sequalae that led to drug interruption for more than two weeks. Rash and high sensitivity troponin elevation are immune-related adverse events that have been documented with approved checkpoint therapies. The 63 and 83 mcg/kg doses will be further explored in the Part B dose expansion study.

In the Part A dose escalation, ten patients with heavily pre-treated (including immunotherapy) head neck squamous cell cancer ("HNSCC") were treated at doses of 63, 83, or 100 mcg/kg. Two of these patients were not evaluable for the cycle 1 DLT period or for efficacy because of early progression and came off study after receiving only one or two doses of MT-6402, respectively. Of the remaining eight head and neck cancer patients, the best responses observed were as follows: three patients had a partial response ("PR") (two unconfirmed) and a fourth patient had evidence of tumor regression. All four patients had progressed on their previous therapies after multiple lines of treatment including checkpoint antibodies. Additional details on each of these participant's clinical profile and response to the investigational treatment are provided below.

- One patient with a PD-L1 TPS of 2% who had progressed after chemotherapy, radiation therapy, and pembrolizumab had a confirmed PR with 70% tumor reduction and remains on study in cycle 18 (1 cycle = 4 weeks).

- One patient with a PD-L1 CPS of 10% who had progressed after three previous lines of therapy, including progression on Ipi/Nivo within four months, showed deepening tumor reduction over time of 3%, 9%, and 15% at the end of cycles 2, 4, and 6, respectively. At the end of cycle 8, the patient had an unconfirmed PR with a 37% reduction in tumor size. The patient remains on study in cycle 9.

- One patient with a cutaneous skin cancer of the head and neck region and a PD-L1 CPS of 5% who had progressed after six prior lines of therapy and was refractory to pembrolizumab received two doses of MT-6402 before discontinuing treatment due to the treating physician's concerns around an asymptomatic grade 1 high sensitivity troponin elevation and hyponatremia related to excessive alcohol intake. A CT scan assessed by the treating site determined the patient to be in stable disease ("SD"), but an external radiology review showed that the patient had a 36% tumor reduction (an unconfirmed PR).

- One patient with a PD-L1 CPS of 10% with pre-existing cardiac risk factors of hypertension, hyperlipidemia, and hypercholesterolemia received three doses of MT-6402 before presenting with asymptomatic grade 1 high sensitivity troponin elevation and dosing was held. A CT scan showed a 13% reduction in tumor size, but disease progression occurred during treatment interruption and patient discontinued at the end of cycle 6.

The three other HNSCC patients enrolled in the Part A dose escalation had SD of six, four, and two months, respectively, before disease progression or study discontinuation. One patient progressed at the end of cycle 2. Of these eight patients, only one patient (the patient with SD through six cycles) had a PD-L1 tumor proportion score ("TPS") greater than 50%.

The Part B dose expansion is currently enrolling. The 63 and 83 mcg/kg doses will be studied in the expansion in patients with >50% tumor expression of PD-L1, allowing for the potential of direct tumor cell-kill. Additionally, in patients with the HLA A*02 haplotype and who are CMV+, the antigen seeding mechanism of MT-6402 may be engaged.

In November 2021, MT-6402 was granted Fast Track Designation for the treatment of patients with advanced NSCLC expressing PD-L1. For MT-6402, dose escalation in the Phase I study continued as planned for 2023, with one expansion for patients with high PD-L1 tumor expression (≥ 50%) and the other expansion for patients with low (1-49%) PD-L1 tumor expression.

**MT-8421—ETB Targeting CTLA-4**

MT-8421, Molecular's ETB targeting CTLA-4, along with MT-6402, represent Molecular's unique approach to immuno-oncology based on dismantling the TME through direct cell-kill of tumor and immune cells and not only the blocking of ligand-ligand interactions seen with current antibody therapeutics. The ETB approach includes potent destruction of CTLA-4+ Tregs via enzymatic ribosome destruction, and the mechanism of cell kill is independent of TME. MT-8421 preferentially destroys high CTLA-4 expressing Tregs in the TME relative to peripheral Tregs which are lower CTLA-4 expressing. Preclinical data from MT-8421 shared at the Society for Immunotherapy of Cancer ("SITC") annual meeting in November 2022 showed that in a transgenic mouse model expressing human CTLA-4 and bearing syngeneic subcutaneous tumors, MT-8421 treatment depleted immune suppressive Tregs in the TME but not in the periphery. MT-8421 was well tolerated in a non-human GLP primate toxicology study and achieved serum levels well-above projected $IC_{50}$ concentrations for Tregs in the TME.

Molecular filed an IND for MT-8421 in February 2023 and the IND was accepted in March 2023. In November 2023, Molecular dosed its first patient in a multi-center open-label, dose-escalation, dose-expansion, and first-in-human Phase I clinical trial evaluating the safety, tolerability, PK, PD, and the preliminary efficacy of MT-8421. Approximately 24-30 patients are anticipated to enroll in part A dose escalation with a starting dose of 32 mcg/kg. The first cohort (32 mcg/kg) has been completed with no grade 3 or grade 4 drug-related toxicities observed. Enrollment is on-going in the 48 mcg/kg cohort. Early pharmacodynamic data demonstrate Treg clearance in the periphery and in the tumor microenvironment. The study enrolls adult patients with tumors where CTLA-4 inhibitors have been proven to provide benefit and in other select tumor types known to frequently have an immune rich TME. The first dose of 32 mcg/kg has been cleared with no grade 3 or grade 4 drug-related toxicities. Unique pharmacodynamic effects demonstrating potent Treg clearance in the periphery and the tumor microenvironment were observed at the first dose level. Enrollment in the second dose cohort (48 mcg/kg) is on-going.

Approximately 24-30 patients are anticipated to enroll in part A dose escalation with a starting dose of 32 mcg/kg.

***Hematologic Malignancy Targeted ETBs***

**MT-0169—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®), an anti-cancer drug originally developed by Genmab, 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.

MT-0169 had its IND filed in May 2019 and was accepted in June 2019. The Phase I study for MT-0169 in relapsed/refractory multiple myeloma initiated in the fourth quarter of 2019, with the first patient dosed in February 2020. In December 2019, the FDA granted Orphan Drug Designation to MT-0169 for the treatment of multiple myeloma.

The revised protocol for the ongoing Phase I study for MT-0169 in patients with relapsed/refractory multiple myeloma opened in January 2022. The revised protocol began at the lower dose of MT-0169 at 5 mcg/kg to reduce the risk of AEs observed at the initial dose level of 50 mcg/kg and to enable patients to continue MT-0169 therapy for a longer duration that may drive tumor benefit. Molecular opened new sites for the Phase I study and enrollment resumed in July 2022. Following a review of the safety data from cohorts 1 (5 mcg/kg) and 2 (10 mcg/kg) in which no cardiac AEs were observed, dose escalation continued in cohort 3 at 15 mcg/kg. In April 2023, the FDA placed the Phase I study for MT-0169 on a partial clinical hold based on previously disclosed cardiac AEs noted in two patients dosed at 50 mcg/kg that prompted the dose reduction to 5 mcg/kg in 2022. Under the partial clinical hold, current study participants could continue treatment, but no new patients were to be enrolled until the partial hold was lifted by the FDA. We submitted our response to the partial clinical hold to the FDA in May 2023, and the partial clinical hold was lifted by the FDA on May 31, 2023.

Molecular resumed screening and enrollment in cohort 3 at 15 mcg/kg in July 2023. One patient dosed at 15 mcg/kg showed a complete depletion of CD38+ NK cells. No toxicity ≥Grade 3 was noted at 15 mcg/kg, but, because complete CD38+ NK cell depletion may allow for MT-0169 targeting of CD38+ endothelial cells in the myocardium, the decision was made to move forward with doses of 5 or 10 mcg/kg. Of the patients treated at these doses, one patient with extramedullary IgA myeloma treated at 5 mcg/kg has had a marked reduction in IgA serum protein, conversion from immunofixation positive to negative and resolution of uptake on bone scan of skeletal lesions demonstrating a stringent complete response. The patient's disease was quad-agent refractory including CD38 targeting antibody, proteosome inhibitor, IMiD, and a B-cell maturation bispecific antibody.

Despite the early signals of activity, Molecular was not able to meet its enrollment goals after re-initiating the clinical study after the FDA's partial clinical hold was lifted on May 31, 2023. The approval of two new therapies for relapsed and/or refractory multiple myeloma in August 2023 added to the enrollment challenges of the MT-0169 Phase I study for relapsed and/or refractory multiple myeloma. As a result, Molecular decided to discontinue the Phase 1 study for relapse and/or refractory multiple myeloma and pursue alternative CD38+ hematological malignancies. Molecular is currently negotiating an investigator-sponsored trial ("IST") and anticipates initiating this Phase 1 study at the 5 and 10 mcg/kg dose levels for CD38+ leukemia in mid-2024. MT-0169 will continue to be studied in CD38+ hematologic malignancies.

We expect to provide periodic updates on MT-6402, MT-8421, and MT-0169 throughout 2024.

**ETB Research & Development Partnerships**

***Bristol-Myers Squibb Company***

On February 10, 2021, Molecular entered into the BMS Collaboration Agreement with Bristol-Myers Squibb, pursuant to which the parties agreed to enter into a strategic research collaboration leveraging Molecular's ETB technology platform to discover and develop novel products containing ETBs directed to multiple targets. On March 15, 2024, Molecular announced that following a corporate portfolio prioritization process, Bristol-Myers Squibb notified Molecular on March 13, 2024 that it does not intend to continue the research collaboration it entered into with the Company pursuant to the BMS Collaboration Agreement and would be terminating the BMS Collaboration Agreement in its entirety. The termination will be effective on June 13, 2024, or 90 days following Molecular's receipt of Bristol-Myers Squibb's written notice of termination.

Pursuant to the terms of the BMS Collaboration Agreement, Molecular granted Bristol-Myers Squibb a series of exclusive options to obtain one or more exclusive licenses under Molecular's intellectual property to exploit products containing ETBs directed against certain targets designated by Bristol-Myers Squibb.

Pursuant to the BMS Collaboration Agreement, Bristol-Myers Squibb paid Molecular an upfront payment of $70 million. In addition to the upfront payment, Molecular may have been eligible to receive near term and development and regulatory milestone payments of up to $874.5 million. Molecular would also have been eligible to receive up to an additional $450 million in payments upon the achievement of certain sales milestones, and subject to certain reductions, tiered royalties ranging from mid-single digits up to mid-teens as percentages of calendar year net sales, if any, on any licensed product.

Molecular was responsible for conducting the research activities through the designation, if any, of one or more development candidates. Upon the exercise of its option for a development candidate, Bristol-Myers Squibb would have been responsible for all development, manufacturing, regulatory and commercialization activities with respect to that development candidate, subject to the terms and conditions of the BMS Collaboration Agreement.

Unless earlier terminated, the BMS Collaboration Agreement would have expired (i) on a country-by-country basis and licensed product-by-licensed product basis, on the date of expiration of the royalty payment obligations under the BMS Collaboration Agreement with respect to such licensed product in such country and (ii) in its entirety upon the earlier of (a) the expiration of the royalty payment obligations under the BMS Collaboration Agreement with respect to all licensed products in all countries or (b) upon Bristol-Myers Squibb's decision not to exercise any option on or prior to the applicable option deadlines. Bristol-Myers Squibb had the right to terminate the BMS Collaboration Agreement for convenience upon prior written notice to Molecular. Either party had the right to terminate the BMS 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. Molecular had the right upon prior written notice to terminate the BMS Collaboration Agreement in the event that Bristol-Myers Squibb or any of its affiliates asserts a challenge against Molecular's patents.

On March 15, 2024, Molecular announced that following a corporate portfolio prioritization process, Bristol-Myers Squibb notified Molecular on March 13, 2024 that it does not intend to continue the research collaboration it entered into with the Company pursuant to BMS Collaboration Agreement and would be terminating the BMS Collaboration Agreement in its entirety. The termination will be effective on June 13, 2024, or 90 days following Molecular's receipt of Bristol-Myers Squibb's written notice of termination. Molecular will reduce costs associated with the BMS Collaboration Agreement and focus its resources exclusively on its wholly-owned clinical-stage programs.

***Previous Agreements***

In September 2018, Molecular entered into a Development Collaboration and Exclusive License Agreement, as amended (the "Takeda Development and License Agreement") with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda") for the development and commercialization of products incorporating or comprised of one or more CD38 SLTA fusion proteins ("Licensed Products") for the treatment of patients with diseases such as multiple myeloma.

In April 2021, Molecular received a notice of termination from Takeda for the Takeda Development and License Agreement. Following receipt of the termination notice from Takeda, Molecular notified Takeda of its intent to assume full rights to MT-0169, a second-generation ETB targeting CD38, by entering into an agreement for such rights pursuant to the termination provisions of the Takeda Development and License Agreement. The termination of the Takeda Development and License Agreement was effective in August 2021. As of the same date, Molecular assumed full rights to MT-0169, including full control of MT-0169 clinical development, per the terms of the terminated Takeda Development and License Agreement. Following the transfer of the full MT-0169 rights to Molecular, Molecular may owe low-single digit royalties on future net sales of MT-0169 to Takeda as well as to certain third-party licensors. Molecular may also owe certain third-party licensors potential aggregate clinical and regulatory milestone payments of up to $22.25 million.

In June 2017, Molecular entered into a Multi-Target Collaboration and License Agreement with Takeda (the "Takeda Multi-Target Agreement"), pursuant to which Molecular agreed to collaborate with Takeda to identify, generate and evaluate ETBs, against certain targets designated by Takeda. In March 2022, following Molecular's request to bring the agreement to an end, Molecular and Takeda mutually agreed to terminate the Takeda Multi-Target Agreement. As a

result of the termination, Molecular regained full rights to pursue the targets worked on under the Takeda Multi-Target Agreement. There are no ongoing activities or economic obligations in connection with the Takeda Multi-Target Agreement.

*Other Research & Development Collaborations*

**CPRIT Grant**

In September 2018, Molecular entered into a Cancer Research Grant Contract (the "CD38 CPRIT Agreement") with the Cancer Prevention Research Institute of Texas ("CPRIT"), which was extended in September 2022 and further extended in September 2023 to May 31, 2024, in connection with a grant of approximately $15.2 million awarded by CPRIT to Molecular 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, Molecular 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 Molecular's progress towards achievement of specified milestones, among other contractual requirements.

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 Molecular, its 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, Molecular 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.

Molecular 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 it by CPRIT under the CD38 CPRIT Agreement. If Molecular is required to obtain a license from a third party to sell any such product, the revenue sharing percentages may be reduced. In addition, once Molecular pays CPRIT 400% of the monies it has received under the CD38 CPRIT Agreement, Molecular 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) May 31, 2024 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 Molecular, (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 Molecular for convenience. CPRIT may approve a no cost extension for the CD38 CPRIT Agreement for a period of six months or twelve 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.

**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 ("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-6402, MT-8421, and MT-0169, have been developed by Molecular's biopharmaceutical development and manufacturing staff. Once a process is developed and defined for an ETB, it may be 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 regulations, 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 ("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 are 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 and early phase clinical research.

As part of its manufacturing process, Molecular endeavors to utilize cGMP grade materials and reagents, if commercially available; however, certain critical materials and reagents are currently qualified for research use only. Additionally, Molecular obtains key components required for the manufacture of its investigational products from third-party manufacturers and suppliers, which include, in some instances, sole source manufacturers and suppliers. Molecular does not currently have long-term commitments or supply agreements in place to obtain certain key components used in the manufacture of its 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 SLTA construct is associated, directly or indirectly, to immunoglobulin-like domains directed to a 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 SLTA constructs engineered to have reduced innate and adaptive immunogenicity, including by disruption of B-cell epitopes and T-cell epitopes.

Molecular has 7 patent families that cover its proprietary platform technologies, together covering about 190 patents and pending U.S. and foreign applications worldwide, including over 135 granted U.S. and foreign patents and over 50 pending patent applications in the U.S., Europe and in thirteen other jurisdictions outside of the U.S. and Europe (such as, *e.g.*, Australia, Canada, China, Hong Kong, Israel, India, Japan, Mexico, and South Korea). Patents have been granted in each of these seven patent families, including in Australia, China, Europe, Hong Kong, Israel, Japan, Mexico, South Korea, and the U.S. These U.S. and foreign patents are expected to expire from 2035 to 2038.

Molecular has 8 patent families covering ETBs in its product pipeline, including ETBs which target PD-L1, CTLA-4 and CD38. These 8 patent families include over 54 patents and pending U.S and foreign applications worldwide, including over 10 granted U.S. and foreign patents and over 40 pending patent applications in the U.S., Europe, and in other jurisdictions outside of the U.S. and Europe (such as, e.g., Australia, Canada, China, Hong Kong, Israel, India, Japan, Mexico, and South Korea). Patents have been granted from five of these patent families, including in Australia, China, Europe, Hong Kong, Israel, Japan, Mexico, South Korea, and the U.S. These U.S. and foreign patents are expected to expire from 2034 to 2043.

In certain circumstances, Molecular's patents may be eligible for adjustment of patent term due to patent office delay, or extension of patent term to compensate for loss of patent term during drug development and regulatory review. The expected expiration dates referenced above do not include these adjustments or extensions.

As of December 31, 2023, Molecular owned 19 U.S. and foreign patents relating to hypoxia-activated prodrugs. These U.S. and foreign patents are expected to expire from 2025 to 2031 (in each case, if all relevant maintenance fees or annuities are paid, and without accounting for any patent term extension ("PTE")).

**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 therapeutic biological products, such as MT-6402, MT-8421, MT-0169, and any future drug candidates. Generally, before a new 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 therapeutic biological products under the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Public Health Service Act ("PHSA") along with implementing regulations. 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.

As biological products, MT-6402, MT-8421, MT-0169, and any future ETB drug candidates we may develop must be approved by the FDA through a Biologics License Application ("BLA") before they may be legally marketed in the United States. The process generally involves the following:

- Completion of extensive nonclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice ("GLP") requirements;
- Submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- Approval by an independent institutional review board ("IRB") or ethics committee covering 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 ("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 a BLA for marketing approval, including payment of application user fees;
- A determination by the FDA within 60 days of its receipt of a BLA that the BLA is sufficiently complete to permit a substantial review, in which case the BLA is filed;
- Satisfactory completion of a FDA pre-approval inspection of the manufacturing facility or facilities where the biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality, purity, and potency;
- Potential FDA audit of the nonclinical studies and/or clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA, including consideration of the views of an FDA advisory committee, if one was involved, prior to any commercial marketing or sale of the 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-6402, MT-8421, MT-0169, and any future drug candidates will be granted on a timely basis, or at all. The data required to support a 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 potential studies to evaluate the molecule's 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, unless the consent requirement has been waived by an IRB. 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 on behalf of 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 to be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

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 a 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.

***Nonclinical Studies and IND***

Nonclinical 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 the investigational product's therapeutic use. The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended both the FDCA and PHSA to specify that nonclinical testing for investigational biologics may, but is not required to, include in vivo animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various in vitro assays (e.g., cell-based assays, organ chips, or microphysiological systems), in silico studies (i.e., computer modeling), other human or non-human biology-based tests (e.g., bioprinting), or in vivo animal tests. The conduct of nonclinical studies is subject to federal regulations and requirements, including GLP regulations. An IND sponsor must submit the results of the nonclinical 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 nonclinical 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 PK and PD 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 a 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 investigational 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. Congress also recently amended the FDCA to require sponsors of a Phase III clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Sponsors must submit a diversity action plan to the FDA by the time the sponsor submits the relevant clinical trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect Phase III trial planning and timing or what specific information FDA will expect in such plans, but if the FDA objects to a sponsor's diversity action plan or otherwise requires significant changes to be made, it could delay initiation of the relevant clinical trial.

In addition, an IRB must review and approve the plan for any clinical trial before it commences, 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 and form 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 ("NIH") for public dissemination on the ClinicalTrials.gov data registry. Information related to the investigational 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. The NIH's Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and the government has brought enforcement actions against clinical trial sponsors that fail to comply with such requirements.

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 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 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 a 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 biologic.

Concurrent with clinical trials, companies may perform additional nonclinical studies and develop additional information about the chemistry and physical characteristics of the 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 biological product. The PHSA also 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-6402, MT-8421, MT-0169, and any future therapeutic candidates do not undergo unacceptable deterioration over their respective labeled shelf lives.

***BLA Submission and FDA Review Process***

Following completion of the clinical trials, all of the data are analyzed to assess whether the investigational product is safe and effective for its proposed indicated use or uses. The results of nonclinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. In short, the BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of 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 or company-sponsored expanded access programs. 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 a BLA must be obtained before a biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, as amended ("PDUFA"), each BLA must be accompanied by a significant user fee, and the sponsor of an approved BLA is also subject to an annual program fee. The FDA typically adjusts these PDUFA user fees on an annual basis. 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 BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted 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 a 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 a 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 BLA. Under the goals and policies agreed to by the FDA under PDUFA, the

FDA has ten months, from the filing date, in which to complete its review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority 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 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 a 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 by each of the entities involved in the clinical trials, including clinical investigators and any third-party CROs.

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 final agency decisions on marketing 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 development of a risk evaluation and mitigation strategy ("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 product. 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 BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if one is required.

The approval process is lengthy and often difficult, and the FDA may refuse to approve a BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. 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 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 product 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 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, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may choose either to resubmit the 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 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, however, the FDA may ultimately decide that the 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 the applicant 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 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 a 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. Recent court cases have challenged the FDA's approach to determining the scope of orphan drug exclusivity; however, at this time the agency continues to apply its long-standing interpretation of the governing regulations and has stated that it does not plan to change any orphan drug implementing regulations. If a biological product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

In December 2019, the FDA granted Orphan Drug Designation to MT-0169 for the treatment of multiple myeloma.

***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. In addition, a recent oncology-specific program allows for so-called "real-time" review of data supporting a product candidate's marketing application.

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 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 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 BLA approval, but ideally no later than the pre-BLA meeting.

In November 2021, the FDA granted fast-track designation to MT-6402 for the treatment of patients with advanced NSCLC expressing PD-L1.

The FDA also may designate a product for priority review if it is a 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 from the date of filing.

Additionally, a 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.

Specific to oncology drug applications, FDA's Oncology Center of Excellence has developed a program called Real-Time Oncology Review ("RTOR"). RTOR facilitates earlier submission of topline results (i.e., efficacy and safety results from clinical studies before the study report is completed) and datasets, after database lock, to support an earlier start to the agency's review of a marketing application review. The intent of RTOR is to provide FDA reviewers earlier access to data, to identify data quality and potential review issues, and to potentially enable early feedback to the applicant, which can allow for a more streamlined and efficient review process for the product's BLA. Applicants can apply for review under RTOR when the database for a pivotal trial has been locked and the oncology product is eligible under FDA's criteria for the program. Eligibility requires (a) clinical evidence indicating that the drug may demonstrate substantial improvement on one or more clinically relevant endpoints over available therapies; (b) the use of straightforward study designs and easily interpreted clinical trial endpoints (e.g., overall survival, response rates); and (c) that no aspect of the BLA is likely to require a longer review time (e.g., requirement for new REMS or input from an advisory committee). In November 2023, the agency finalized guidance for industry on RTOR.

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, breakthrough therapy designation and ROTR 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 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 ("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 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. Biologics granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval. Further, all

promotional materials for products approved for marketing under the accelerated approval program are subject to prior review by the FDA.

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 product 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. In addition, as part of the Consolidated Appropriations Act for 2023, Congress provided the FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these recent amendments to the FDCA, the agency may require a sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports will be published on the FDA's website. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, allows the FDA to withdraw approval of the biologic. Congress also recently amended the law to give the FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product. Prior to the recent statutory amendments enacted by Congress, several oncology sponsors voluntarily withdrew specific indications for their drug products that were being marketed pursuant to accelerated approval, and the FDA's Oncology Center of Excellence launched an initiative called Project Confirm, aimed at promoting transparency in the area of accelerated approvals for oncology indications. Scrutiny of the accelerated approval pathway is likely to continue in the coming years and may lead to further legislative and/or administrative changes in the future.

***Pediatric Information***

Under the Pediatric Research Equity Act ("PREA") amendments to the FDCA, a BLA or supplement to a 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. Any 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 is required to submit an initial Pediatric Study Plan ("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 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 BLA or 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 a REMS plan to assure the safe use of the product. A REMS plan 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 before any product is approved and commercial products can be manufactured or distributed. Molecular relies in part, and expects to continue to rely in part, 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, or on the manufacturer or holder of an approved BLA, including recall or product seizure.

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 BLAs or supplements to approved 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;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; and/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 ("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 ("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 mandated phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors and dispensers over a 10-year period that culminated in November 2023. However, FDA announced a one-year stabilization period, until November 2024, to give entities subject to the DSCSA additional time to finalize interoperable tracking systems and to ensure supply chain continuity. 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. For example, the FDA released proposed regulations in February 2022 to amend the national standards for licensing of wholesale drug distributors by the states; establish new minimum standards for state licensing third-party logistics providers; and create a federal system for licensure for use in the absence of a state program, each of which is mandated by the DSCSA. 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 therapeutic product candidates may depend, in part, on the development and commercialization of either a companion diagnostic or complementary diagnostic. Companion diagnostics and complementary diagnostics can identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics and complementary diagnostics are regulated as medical devices by the FDA. The level of risk 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 FDA's approval of the therapeutic product. The use of the companion diagnostic device will be stipulated in the labeling of the therapeutic product, and vice versa.

***U.S. Patent Term Extension***

Depending upon the timing, duration and specifics of FDA approval of MT-6402, MT-8421, MT-0169 (if any) and any future product candidates, some of Molecular's U.S. patents may be eligible for limited PTE 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 extension of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. PTE, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The PTE period is generally one-half the time between the effective date of an IND, or the issue date of the patent, if the patent is issued after the IND

effective date, and the submission date of a BLA plus the time between the submission date of a 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 biological product 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 ("USPTO") in consultation with the FDA, reviews and approves the application for any PTE or restoration. In the future, Molecular may apply for extension 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 BLA.

***Reference Product Exclusivity for Biological Products***

In March 2010, the Patient Protection and Affordable Care Act ("ACA") was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009 ("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.

Since that time, the FDA has approved approximately 45 biosimilars, including the first interchangeable biosimilars in 2021. The FDA has also issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biosimilars. It has also created a public database that contains information on all FDA-licensed biological products, including biosimilars, called the Purple Book.

Biosimilarity requires that the follow-on 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 follow-on product and the reference product in terms of safety, purity and potency. The biosimilar applicant must demonstrate that its product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) toxicity assessments; 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. 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 twelve 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. As part of the Consolidated Appropriations Act for 2023, Congress amended the PHSA in order to permit multiple interchangeable products approved on the same day to receive and benefit from this one-year exclusivity period. 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 continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. As a result, the ultimate impact, implementation and meaning of the BPCIA continue to be subject to 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 a 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 PTE, 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 seven-year orphan drug exclusivity period, as may be applicable to the FDA-approved therapeutic product.

***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 ("HHS"), the Department of Justice, the Drug Enforcement Administration, the Federal Trade Commission ("FTC"), the Occupational Safety and Health Administration, the Environmental Protection Agency and state and local governments.

For example, in the United States, sales and marketing for prescription biopharmaceutical products 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 imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, the ACA, among other things, amended 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 ("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. State and federal consumer protection laws, including the Federal Trade Commission Act, govern the collection, use, disclosure and protection of health and other personal information and could apply to our operations and the operations of our collaborators.

Moreover, the government may now 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 companies 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, divert Molecular's management's attention from the operation of Molecular's business and harm Molecular's reputation. 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 in Europe as medicinal products, can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained. Whether or not Molecular obtains FDA approval for a product candidate, Molecular must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before Molecular may commence clinical trials or market products in those countries or areas.

In April 2023, the European Commission issued a proposal that will revise and replace the existing general pharmaceutical legislation. If adopted and implemented as currently proposed, these revisions will significantly change several aspects of drug development and approval in the European Union.

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 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 transposed and applied the provisions of the Directive differently. This led to significant variations in the member state regimes. Under the previous regime, before a clinical trial could be initiated, a clinical trial application must have been approved in each of the EU countries where the trial was to be conducted by two distinct

bodies: the National Competent Authority ("NCA") and one or more Ethics Committees ("ECs"). All suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial would have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation has since been reformed with the aims of 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 (the "Clinical Trials Regulation") was adopted and came into application on January 31, 2022. The Clinical Trials Regulation is directly applicable in all the EU Member States, repealing the previous Clinical Trials Directive 2001/20/EC. The extent to which ongoing clinical trials are governed by the Clinical Trials Regulation depends on when the Clinical Trials Regulation became 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 became applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial. In addition, use of the new EU-wide application procedure being implemented via the Clinical Trial Information System ("CTIS") became mandatory for new clinical trial application submissions as of February 1, 2023.

***European Union Drug Review and Approval***

In the European Economic Area ("EEA") which comprises the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization ("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 ("CHMP") of the European Medicines Agency ("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 ("RMS"). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics ("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, currently 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 biosimilar application for eight years, after which biosimilar 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.

***United Kingdom regulatory framework and operational impacts post-Brexit***

The United Kingdom left the European Union on January 31, 2020 (commonly referred to as "Brexit"), with a transitional period that expired on December 31, 2020.

In connection with Brexit, the United Kingdom and the European Union entered into a trade agreement known as the Trade and Cooperation Agreement, which was provisionally applicable as of January 1, 2021 and was ratified by the European Parliament on May 1, 2021. This agreement is intended to govern the legal relationship between the European Union and the United Kingdom post-Brexit. Any disputes or breakdowns in implementation of the Trade and Cooperation Agreement or other Brexit-related arrangements negotiated by the United Kingdom and the European Union could, among other outcomes, disrupt the free movement of goods, services and people between the United Kingdom and the European Union, and result in increased legal and regulatory complexities as well as potential higher costs of conducting business in Europe. More recently, in March 2023, the U.K. government and the European Commission reached agreement on a regulatory framework to replace the Northern Ireland Protocol, referred to as the Windsor Framework. The Windsor Framework is expected to apply as of January 1, 2025 and will change the existing system under the Northern Ireland Protocol, including the regulation of pharmaceutical products in the United Kingdom. Specifically, the United Kingdom's Medicines and Healthcare products Regulatory Agency ("MHRA") will be responsible for approving all medicines intended to be marketed in the United Kingdom (i.e., Great Britain and Northern Ireland), while the EMA will no longer be involved in approving medicines intended for sale in Northern Ireland.

In line with the Trade and Cooperation Agreement, the United Kingdom has established its own regulatory framework for product candidates, which is not identical to the European Union regulatory framework. Industry experience with navigating the two regulatory frameworks is limited at this point in time. Further regulatory divergences could arise. Any failure of the European Union and the United Kingdom to implement and maintain the Trade and Cooperation Agreement could result in the United Kingdom or the European Union significantly altering regulations affecting the clearance or approval of our product candidates that are developed in the United Kingdom or the European Union. Any delay in obtaining, or inability to obtain, any marketing approvals in the United Kingdom as a result of Brexit or failures in the implementation of the Trade and Cooperation Agreement or otherwise, could prevent us from commercializing our product candidates in the United Kingdom and reduce our ability to generate revenue and achieve and sustain profitability. Molecular is currently evaluating the potential impacts on Molecular's business of the Trade and Cooperation Agreement and guidance issued to date by the MHRA regarding the requirements for licensing and marketing drug and biologics in the United Kingdom.

Further, such outcomes could make it more difficult and expensive for Molecular to do business in Europe, complicate our clinical, manufacturing and regulatory strategies and impair our ability to obtain and maintain regulatory approval for, and, if approved, commercialize, our products and product candidates in Europe. While Molecular has undertaken a number of Brexit-related contingency planning initiatives, the full potential financial, legal, regulatory and other implications of Brexit are uncertain and Molecular cannot make any assurances regarding the extent to which Molecular's business may be adversely affected thereby.

***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 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 U.S. 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 HHS 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

and 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. Further legislative and regulatory changes under the ACA remain possible, although it is unknown what form any such changes or any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("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. More recently, the American Rescue Plan Act of 2021 included a provision that eliminated the statutory cap on rebates that drug manufacturers pay to Medicaid. Beginning in January 2024, Medicaid rebates are no longer be capped at 100 percent of the quarterly average manufacturer price ("AMP").

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. The 340B program has been under recent scrutiny by Congress and industry has challenged various aspects of the program through litigation, making it subject to current uncertainty and potential future changes.

Moreover, there has been heightened governmental scrutiny 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 drug products. HHS has solicited feedback on various measures intended to lower drug prices and reduce the out of pocket costs of drugs and has implemented others under its existing authority. For example, in August 2022 President Biden signed into law the Inflation Reduction Act ("IRA"). Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. A manufacturer of drugs or biological products covered by Medicare Parts B or D must now pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers ("PBMs") and other members of the health care and pharmaceutical supply chain, an important decision that has lead to more aggressive efforts by states in this area. The FTC in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. During the current congressional session, numerous PBM reforms are being considered in both the Senate and the House of Representatives; they include diverse legislative proposals such as eliminating rebates; divorcing service fees from the price of a drug, discount, or rebate; prohibiting spread pricing; limiting administrative fees; requiring PBMs to report formulary placement rationale; promoting transparency. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical product developers like us.

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. Molecular expects that the increasing emphasis on cost containment measures in the United States 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 medicinal product 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 a new drug candidate to currently available therapies (so called health technology assessment ("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 future commercial 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. If Molecular is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if Molecular is not able to maintain regulatory compliance, Molecular may lose any marketing approval that Molecular otherwise may have obtained and Molecular 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 U.S. 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 ACA 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 CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending. The uncertainty related to regulatory and executive actions pertaining to drug costs and drug pricing matters is described above under "Coverage, Pricing, and Reimbursement". As another example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive health care provisions and amendments to existing laws, including a requirement that all manufacturers of drugs and biological products covered under Medicare Part B report the product's average sales price to HHS beginning on January 1, 2022, subject to enforcement via civil money penalties.

Molecular 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. Molecular expects 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. Moreover, if Molecular is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if Molecular is not able to maintain regulatory compliance, our biologic candidates may lose any marketing approval that may have been obtained and Molecular may not achieve or sustain profitability, which would adversely affect our business.

***U.S. Foreign Corrupt Practices Act***

In general, the Foreign Corrupt Practices Act of 1977, as amended, (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 Molecular interacts with foreign health care professionals and researchers in testing and marketing our products abroad, Molecular 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. The Securities and Exchange Commission (the "SEC") is involved with the books and records provisions of the FCPA.

**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.

- The approved antibody-based products targeting CD38 are daratumumab (Janssen/Genmab) and isatuximab (Sanofi).
- Antibody-based products, including bi-specific antibodies, targeting CD38 in development include XmAb13551 (Amgen/Xencor), TJ202 (I-Mab), ISB1342 (Ichnos), TAK573 and TAK079 (both Takeda).
- Approved antibody-based products targeting PD-L1 include atezolizumab (Genentech/Roche), durvalumab (AstraZeneca), avelumab (Merck KGaA/Pfizer) and cemiplimab (Regeneron).
- Antibody-based products targeting PD-L1 in development include LY3300054 (Lilly).
- Approved antibody-based products targeting CTLA-4 include ipilimumab (BMS) and tremelimumab (AstraZeneca).
- Antibody-based products targeting CTLA-4 in development include quavonlimab (Merck) and zalifrelimab (Agenus).

**Environmental and Other Regulatory Requirements**

We are subject to numerous federal, state and local environmental, health and safety laws and regulations relating to, among other matters, safe working conditions, product stewardship, environmental protection, and handling or disposition of products, including those governing the generation, storage, handling, use, transportation, release, and disposal of hazardous or potentially hazardous materials, medical waste, and infectious materials. 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 biologic candidates and other hazardous compounds. If we fail to comply with such laws or obtain and comply with any applicable permits, we could face substantial fines or possible revocation of our permits or limitations on our ability to conduct our operations. See Part I, Item 1A, "Risk Factors - *If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties, revocation of our permits, or incur costs that could have a material adverse effect on our business, financial condition or results of operations*."

**Employees and Human Capital**

In March 2023 and June 2023, pursuant to the Restructuring, we reduced the Company's workforce by approximately 68%. As of December 31, 2023, we had a total of 62 employees, all of which are full-time employees. None of our employees are represented by a collective bargaining agreement, nor have we experienced any work stoppage. We believe that our relations with our employees are good.

We are committed to developing therapies that can potentially benefit patients who are resistant to conventional cancer therapies. To that end, we recognize that our industry is specialized and dynamic, and a significant aspect of our success is our continued ability to execute our human capital strategy of attracting, engaging, developing and retaining highly skilled talent. There is fierce competition for highly skilled talent, particularly in the Austin, Texas and New York, New York areas, and we offer a robust set of benefits covering employees' physical, emotional and financial health, a strong company culture and initiatives aligned with our mission, vision, and values. We offer competitive compensation for our employees and strongly embrace pay for performance. We also strive to provide a collegial atmosphere where teamwork and collaboration are emphasized and valued. Our employee led group, One MTEM, greatly contributes to the open, collaborative and team-driven culture with its dedication to community outreach, professional development and cross functional collaboration and understanding. This group sponsors a variety of community fundraisers and company events in furtherance of its mission of empowering and engaging employees. We also have dedicated full-time employees who oversee all aspects of our human capital management process.

Our Employee Handbook and Code of Business Conduct and Ethics clearly outline our unwavering commitment to diversity and inclusion, where all employees are welcomed in an environment designed to make them feel comfortable, respected, and accepted regardless of their age, race, national origin, gender, religion, disability or sexual orientation. We have a set of policies explicitly setting forth our expectations for nondiscrimination and a harassment-free work environment. We are also a proud equal opportunity employer and cultivate a highly collaborative and entrepreneurial culture.

**Corporate Information**

Molecular was incorporated under the laws of the state of Delaware in 2001, under the name Threshold Pharmaceuticals, Inc. On August 1, 2017, we completed a 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), by and among us (formerly known as Threshold Pharmaceuticals, Inc. (Nasdaq: THLD) ("Threshold")), Trojan Merger Sub, Inc., a wholly-owned subsidiary of Threshold ("Merger Sub"), and Private Molecular, pursuant to which Merger Sub merged with and into Private Molecular, with Private Molecular surviving as our wholly owned subsidiary, now "Molecular Templates OpCo, Inc." (the "Merger"). Upon the consummation of the Merger, we changed our name to "Molecular Templates, Inc."

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

**Available Information**

We file electronically with the 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 Securities Exchange Act of 1934, as amended (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.

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, proxy and information statements and amendments to those reports on the day of filing with the SEC on our website at https://www.mtem.com or by contacting the Investor Relations Department via email at Grace.Kim@mtem.com. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this Annual Report on Form 10-K.

## ITEM 1A. RISK FACTORS

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

**Summary Risk Factors**

We are subject to a number of risks that if realized could affect our business, financial condition, results of operations and cash flows. As a clinical stage biopharmaceutical company, certain elements of risk are inherent to our business. Accordingly, we encounter risks as part of the normal course of our business. Some of the more significant challenges and risks include the following:

- We expect that we will need substantial additional funding. If we are unable to raise capital when needed or to do so on terms that are favorable to us, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts or further reduce or scale back our operations. In these circumstances, investors may not receive full value, or any value, for their investment.
- We cannot assure you that our evaluation of strategic alternatives will result in any particular outcome, and the perceived uncertainties related to the Company could adversely affect our business and our shareholders.
- If we fail to achieve the cost savings and benefits expected of the Restructuring, our business prospects and our financial condition may be adversely affected. Further, the Restructuring could result in disruptions to our business.
- We have identified conditions and events that raise substantial doubt about our ability to obtain additional capital when and as needed to continue as a going concern. Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited consolidated financial statements included in this Annual Report on Form 10-K.
- We have certain obligations pursuant to the Convertible Secured Contingent Value Right Agreement (the "CVR Agreement"), and our failure to comply with these obligations could have a material adverse effect on our business, financial condition or results of operations and the price and value of our common stock.
- We may be unable to maintain compliance with the requirements of the Nasdaq Capital Market, which could cause our common stock to be delisted. A delisting of our common stock from the Nasdaq Capital Market could adversely affect our ability to raise additional capital through the public or private sale of equity securities and the ability of investors to dispose of, or obtain accurate quotations as to the market value of, our common stock.
- The ultimate effect of the Reverse Stock Split on the market price of our common stock cannot be predicted with any certainty and shares of our common stock have likely experienced decreased liquidity as a result of the Reverse Stock Split.
- Except for the first quarter of 2023, 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 have never generated any revenue from product sales and may never become profitable from the sale of commercialized product candidates.
- Manufacturing difficulties, disruptions or delays could limit supply of our biologic candidates and adversely affect our clinical trials.
- 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 biologic candidates.
- The approach we are taking to discover and develop next generation immunotoxin therapies, also commonly known as ETBs, is unproven and may never lead to marketable products.
- We are heavily dependent on the success of our biologic candidates, the most advanced of which is in the early stages of clinical development. Our ETB therapeutic biologic candidates are based on a relatively novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all. Some of our biologic candidates have produced results in preclinical settings to date and we cannot give any assurance that we will generate additional nonclinical and clinical data for any of our biologic candidates that are 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.
- Our biologic candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of an approved label, or result in significant negative consequences following marketing approval, if any.
- 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 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 biologic candidates harms study subjects or is perceived to harm study subjects even when such harm is unrelated to our biologic candidates, we could be subject to costly and damaging product liability claims. If we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition.
- Biologics carry unique risks and uncertainties, which could have a negative impact on future results of operations.
- 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.
- Healthcare legislative reform measures may have a material adverse effect on our business, financial condition or results of operations.
- 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 biologic candidates and related processes for our developmental pipeline.
- We rely on third parties to conduct our clinical trials, manufacture our biologic candidates and perform other services. If these third parties do not successfully carry out their contractual duties, meet expected timelines, or otherwise conduct the trials as required or perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our biologic candidates when expected or at all, and our business could be substantially harmed.
- We face substantial competition, and our competitors may discover, develop or commercialize drugs faster or more successfully than we do.

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

The above list is not exhaustive, and we face additional challenges and risks. Please carefully consider all of the information in this Form 10-K including matters set forth in this "Risk Factors" section.

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

***We expect that we will need substantial additional funding. If we are unable to raise capital when needed or to do so on terms that are favorable to us, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts or further reduce or scale back our operations. In these circumstances, investors may not receive full value, or any value, for their investment.***

To date, we have not generated any revenue from product sales to customers. We do not expect to receive any revenue from any ETB candidates that we or our current or future collaboration partners develop, including MT-6402, MT-8421, and MT-0169, unless and until we obtain regulatory approval and commercialize such biologics. Unless and until we can generate a substantial amount of revenue from product sales, if ever, we expect to finance our operations and future cash needs through a combination of public or private equity offerings and debt financings or other sources, which may include collaborations with third parties. 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.

Disruptions in the financial markets have made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. 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, completing acquisitions or declaring or paying dividends. Pursuant to the terms of the CVR Agreement, we are restricted from obtaining additional debt financing, subject to certain limited exceptions, unless this debt is junior and subordinated to our obligations pursuant to the CVR Agreement.

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 in the risk factor titled "*Risks Related to the Development of Our Biologic Candidates—Reliance on government funding for our programs may add uncertainty to our research and commercialization efforts with respect to those programs that are tied to such funding and may impose requirements that limit our ability to take certain actions, increase the costs of commercialization and production of biologic candidates developed under those programs and subject us to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations*." Although we might apply for government contracts and grants in the future, we cannot assure that we will be successful in obtaining additional grants for any biologic candidates or programs.

As described in the section "*Recent Developments – July 2023 Private Placement*," we anticipate closing the second tranche of the July 2023 Private Placement on April 2, 2024. However, the closing is subject to customary closing conditions such that if these conditions are not fulfilled, the closing may not occur or may not occur in the time

currently expected. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our biologic candidates or future revenue streams or grant licenses on terms that are not favorable to us. If we are unable to obtain funding on a timely basis, we may be required to further reduce or scale back our operations, delay or discontinue one or more of our development programs or the commercialization of any biologic candidates, 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, biologic candidates or programs.

If we are unable to obtain additional funding on acceptable terms when and as needed, we may be forced to delay or reduce the scope of our commercial and sales activities, extend payment terms with suppliers, liquidate assets where possible at a potentially lower amount than as recorded in our financial statements, further curtail planned operations or cease operations entirely and wind down our business. Any of these could materially and adversely affect our liquidity, financial condition and business prospects and, as a result, our stockholders may not receive full value, or may receive no value, for their investment.

***We cannot assure you that our evaluation of strategic alternatives will result in any particular outcome, and the perceived uncertainties related to the Company could adversely affect our business and our shareholders.***

On March 4, 2024, we announced our continued efforts regarding a comprehensive evaluation of strategic alternatives, including consideration of a wide range of options including, among other things, a potential financing/recapitalization, sale, merger, or other strategic transaction. We have not set a deadline or definitive timetable for the completion of the strategic review process, nor have we made any decisions relating to any strategic alternative at this time. No assurance can be given as to the outcome of the process, including whether the process will result in any particular outcome. Any potential transaction may be dependent on a number of factors that may be beyond our control, for example, market conditions, industry trends or acceptable terms. The process of reviewing potential strategic alternatives may be time consuming, distracting and disruptive to our business operations. In addition, given that the exploration of strategic alternatives may eventually result in a potential sale, merger or other strategic transaction, any perceived uncertainty regarding our future operations or employment needs may limit our ability to retain or hire qualified personnel and may contribute to unplanned loss of highly skilled employees through attrition, and result in the loss of brokers, agents or customers with whom we do business. We may ultimately determine that no transaction is in the best interest of our stockholders. We do not intend to comment further regarding the review of strategic alternatives until we determine disclosure is necessary or advisable. Accordingly, speculation regarding any developments associated with our review of strategic alternatives and any perceived uncertainties related to the Company or its business could cause the price of our shares to fluctuate significantly.

***If we fail to achieve the cost savings and benefits expected of the Restructuring, our business prospects and our financial condition may be adversely affected. Further, the Restructuring could result in disruptions to our business.***

The actual savings or benefits from the Restructuring may be less than expected or substantially less than expected. The restructuring activities may also result in a loss of continuity, accumulated knowledge and inefficiency. In addition, internal restructurings can require a significant amount of time and focus from management and other employees, which may divert attention from operations. Further, the Restructuring may result in unexpected expenses or liabilities and/or write-offs. If the Restructuring fails to achieve some or all of the expected cost-savings and benefits, our cash resources may not last as long as estimated and our business, results of operations and financial condition could be materially and adversely affected.

***We have identified conditions and events that raise substantial doubt about our ability to obtain additional capital when and as needed to continue as a going concern. Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this Annual Report on Form 10-K.***

We believe there is substantial doubt about our ability to obtain additional capital when and as needed to continue as a going concern as of the date of this Annual Report on Form 10-K. See Note 1 "*Organization and Summary of Significant Accounting Policies*" to our financial statements included in Item 8 of this Annual Report on Form 10-K for additional information on our assessment. We have not yet established an ongoing source of revenues sufficient to cover our operating and capital expenditure requirements and to cover any potential payments that may become due and payable pursuant to the CVR Agreement to provide sufficient certainty that we will continue as a going concern. Historically, the Company has financed its operations to date primarily through partnerships, funds received from public offerings of common and preferred stock, private placements of equity securities, a reverse merger, upfront and milestone payments received from its prior and current collaboration agreements, a debt financing facility, as well as funding from governmental bodies and bank and bridge loans. The Company plans to address this condition through the sale of common stock in public offerings and/or private placements, debt financings, or through other capital sources, including collaborations with other companies or other strategic transactions, but there is no assurance these plans will be completed successfully or at all. Based on our unrestricted cash and cash equivalents as of December 31, 2023 (approximately $11.5 million), we anticipate that we will be able to fund our planned operating expenses and capital expenditure requirements to the end of the second quarter of 2024. If we are able to complete the Second Closing, we anticipate that we will be able to fund our planned operating expenses and capital expenditure requirements to the end of the fourth quarter of 2024.

If we are unable to obtain additional funding on acceptable terms when and as needed, we may be forced to delay or reduce the scope of our commercial and sales activities, extend payment terms with suppliers, liquidate assets where possible at a potentially lower amount than as recorded in our financial statements, further curtail planned operations or cease operations entirely and wind down our business. Any of these could materially and adversely affect our liquidity, financial condition and business prospects and, as a result, our stockholders may not receive full value, or may receive no value, for their investment.

Our lack of capital resources and our conclusion that we may be unable to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.

***We have certain obligations pursuant to the CVR Agreement, and our failure to comply with these obligations could have a material adverse effect on our business, financial condition or results of operations and the price and value of our common stock.***

In June 2023, we entered into the CVR Agreement with K2 HealthVentures LLC ("K2HV") to fully satisfy and discharge our outstanding secured debt obligations and terminate all other obligations under the existing debt financing facility between us and K2HV in exchange for an aggregate repayment in cash of $27.5 million and the granting of a contingent value right to K2HV and a warrant to purchase common stock to K2HV's affiliated holder. These contingent value rights require payments to K2HV upon the occurrence of certain events or Acceleration Events described in the CVR Agreement, and payments due for these events is initially capped at $10.3 million which, if not repaid, is subject to various escalating multipliers. Alternatively, K2HV may, subject to the terms of the CVR Agreement, convert $3.0 million of these contingent value rights into up to 408,267 shares of our common stock (together with the K2HV warrants, subject to a 19.99% blocker). In the event of a Change in Control as described in the CVR Agreement, we are required to pay an additional $2.5 million. Additionally, in connection with the CVR Agreement, the Company issued to K2HV warrants to purchase 340,222 shares of the Company's common stock for an exercise price of $5.8785 per share, which have a term of ten years. Pursuant to the terms of the CVR Agreement and subject to certain limited exceptions, we may not incur additional indebtedness unless it is junior to our obligations pursuant to the CVR Agreement. The Company's obligations pursuant to the CVR Agreement are secured by substantially all of the Company's assets (including intellectual property), subject to limited exceptions. Our failure to make payments as due under the CVR Agreement could result in an Acceleration Event, as defined in the CVR Agreement, under which certain of our obligations pursuant to the CVR Agreement, at the election of K2HV, may be deemed accelerated and due and payable in full. Acceleration Events include, but are not limited to, material breaches of certain covenants, initiation of insolvency proceedings, impairments in liens held by K2HV under the CVR Agreement, and failure to maintain the listing of shares of our common stock on a trading market, including certain over-the-counter ("OTC") markets, for more than two business days. Our obligations to make payments in the event of certain changes of control and otherwise pursuant to the CVR Agreement are senior to our obligations to make payments and distributions to holders of our common stock. Any accelerated amounts under the CVR Agreement could materially and adversely impact our business, results of operations and financial condition, as well as increase our need to raise additional capital, cause us to cease our operations entirely and may result in the holders of our common stock not receiving value for or reducing the value of their investment.

***We may be unable to maintain compliance with the requirements of the Nasdaq Capital Market, which could cause our common stock to be delisted. A delisting of our common stock from the Nasdaq Capital Market could adversely affect our ability to raise additional capital through the public or private sale of equity securities and the ability of investors to dispose of, or obtain accurate quotations as to the market value of, our common stock.***

For continued listing on the Nasdaq Capital Market, we must, among other requirements, have a market value of listed securities of at least $35 million or a stockholders' equity of at least $2.5 million, and maintain a price per share of at least $1.00. As of December 31, 2023, we were in compliance with these listing requirements. Should we become unable to remain in compliance with these requirements, our stock could become subject to delisting. If our common stock is ultimately delisted by the Nasdaq Stock Market LLC ("Nasdaq"), our common stock may be eligible to trade on the OTC Bulletin Board or another OTC market. Any such alternative would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of, or obtain accurate quotations as to the market value of, our common stock. In addition, there can be no assurance that our common stock would be eligible for trading on any such alternative exchange or markets.

As previously disclosed and in connection with the deficiency and delisting notices the Company received from Nasdaq on April 13, 2023 the Company presented a plan to the Nasdaq Hearing Panel (the "Panel") to regain compliance with both the bid price and stockholders' equity requirements as needed for continued listing on the Nasdaq Capital Market. The Panel granted the Company an extension on May 8, 2023 to regain compliance with both requirements by August 28, 2023, subject to certain conditions. On August 28, 2023, we received a notification letter from Nasdaq notifying us that we had regained compliance with the bid price requirement set forth in Listing Rule 5550(a)(2). However, per the terms of a notification that we received from Nasdaq on August 2, 2023, we are subject to a one-year mandatory monitoring period commencing on August 2, 2023 regarding our ability to satisfy the market

value of listed securities standard (or an alternative listing standard). We currently qualify under the equity standard as we presently have a stockholders' equity in excess of $2.5 million. If, within this one-year monitoring period, the Nasdaq staff again finds that we are not in compliance with the market value of listed securities standard (or an alternative continued listing standard), the Nasdaq staff will issue a delisting determination letter without any grace period. We would then have the opportunity to respond and present to the Panel pursuant to applicable Nasdaq rules, following which, if our efforts are unsuccessful, our securities would be delisted from Nasdaq. A delisting for these reasons or any other reason could materially affect our ability to raise capital, adversely affect our business and the price of our common stock.

***The ultimate effect of the Reverse Stock Split on the market price of our common stock cannot be predicted with any certainty and shares of our common stock have likely experienced decreased liquidity as a result of the Reverse Stock Split.***

On August 11, 2023, the Company effected a 1-for-15 reverse stock split (the "Reverse Stock Split"). The liquidity of our common stock has likely been adversely affected and may continue to be adversely affected by the Reverse Stock Split given the reduced number of shares of our common stock that are now outstanding following the Reverse Stock Split, particularly if the market price of our common stock does not increase from its recent decline after the Reverse Stock Split. As a result of the lower number of shares outstanding following the Reverse Stock Split, the market for our common stock may also become more volatile, which may lead to reduced trading and a smaller number of market makers for our common stock. The Reverse Stock Split also increased the number of stockholders who own "odd lots" of less than 100 shares of common stock. A purchase or sale of less than 100 shares of common stock (an "odd lot" transaction) may result in incrementally higher trading costs through certain brokers, particularly "full service" brokers. Therefore, those stockholders who own fewer than 100 shares of common stock following the Reverse Stock Split may be required to pay higher transaction costs if they sell their common stock.

There can be no assurance that our share prices will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. The trading liquidity of our common stock may not improve.

***Except for the first quarter of 2023, 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 currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a biologic candidate. We have incurred net losses in each year since 2009, excluding the first quarter of 2023. The net loss attributable to common stockholders was $8.1 million for the year ended December 31, 2023. As of December 31, 2023, we had an accumulated deficit of $452.9 million.

We have devoted substantially all of our financial resources to identify, acquire, and develop our biologic candidates, including conducting clinical trials and providing general and administrative support for our operations. To date, we have financed our operations primarily through the sale of equity securities, debt financing and collaborations. 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 to continue to incur significant expenses and increasing operating losses for the foreseeable future.

***Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002, as amended (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 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 from the sale of commercialized product candidates.***

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 biologic candidates. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

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

Even if one or more of the biologic candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with launching and commercializing any approved biologic candidate. We also will have to further develop or acquire manufacturing capabilities or continue to contract with CMOs, in order to continue development and potential commercialization of our biologic candidates. For instance, if our costs of manufacturing our biologic 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.

***We hold a portion of our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts that could be adversely affected if the financial institutions holding such funds fail.***

We hold a portion of cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts. The balance held in these accounts exceeds the Federal Deposit Insurance Corporation standard deposit insurance limit of $250,000. If a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any loss or lack of

access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations.

***Changes in interpretation or application of U.S. generally accepted accounting principles ("U.S. GAAP") may adversely affect our operating results.***

We prepare our consolidated financial statements to conform to U.S. GAAP. These principles are subject to interpretation by the Financial Accounting Standards Board, 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.

***Inflation may adversely affect us by materially increasing our costs.***

Recently, inflation has increased throughout the U.S. economy. Inflation can adversely affect us by materially increasing the costs of clinical trials and research, the development of our product candidates, administration, and other costs of doing business. We may experience material increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may materially outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected.

***Political uncertainty may have an adverse impact on our operating performance and results of operations.***

General political uncertainty may have an adverse impact on our operating performance and results of operations. In particular, the United States continues to experience significant political events that cast uncertainty on global financial and economic markets, especially in light of the upcoming presidential election. It is presently unclear exactly what actions the new administration in the United States will implement, and if implemented, how these actions may impact the biopharmaceutical industry in the United States. Any actions taken by a new U.S. administration may have a negative impact on the United States economies and on our business, financial condition, and results of operations.

**Risks Related to the Development of Our Biologic Candidates**

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

We currently have a cGMP manufacturing facility and we have developed the capability to manufacture biologic candidates for use in the conduct of our clinical trials. We may not be able to manufacture biologic candidates or there may be substantial technical or logistical challenges to supporting manufacturing demand for biologic candidates. We may also fail to comply with cGMP requirements and standards which would require us to not utilize the manufacturing facility to make clinical trial supply.

We plan to rely in part on third-party contract manufacturers, and their responsibilities will include purchasing from third-party suppliers the materials necessary to produce our biologic candidates for our clinical trials and to support 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 biologic candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our biologic candidates for our clinical trials, and, if approved, ultimately for commercial sale.

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

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

- limited capacity of manufacturing facilities;
- contamination of biologic candidates in the manufacturing process;
- events that affect, or have the potential to affect, general economic conditions, including but not limited to political unrest, global trade wars, inflation, natural disasters, acts of war, terrorism, such as the conflicts and recent events in Ukraine and the Middle East, or disease outbreaks;
- labor strikes or shortages, work stoppages or boycotts, including the effects of health emergencies, epidemics, pandemics, or natural disasters;
- failure to ensure 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;
- disruptions or restrictions on the ability of our, our collaborators', or our suppliers' personnel to travel that could result in temporary closures of our facilities or the facilities of our collaborators or suppliers;
- breakdown, failure, substandard performance or improper installation or operation of equipment;
- following BLA approval, a change in the manufacturing site would require additional approval from the FDA, which could require new testing and compliance inspections, and we carry the risk of non-compliance with such 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 biologic candidate manufacturer, we are subject to ongoing periodic unannounced inspection by the FDA and some state agencies to ensure strict compliance with cGMPs and other U.S. and corresponding foreign requirements, and we carry the risk of non-compliance with these regulations and standards.

Each of these risks could delay our clinical trials, the marketing approval, if any, of our biologic candidates or the commercialization of our biologic candidates or result in higher costs or deprive us of potential product revenue. In addition, we rely on third parties to perform release testing on our biologic candidates prior to delivery to clinical sites participating in our clinical trials. If these tests are not appropriately conducted and test data are not reliable, subjects participating 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 biologic candidates.***

Clinical development is expensive, time consuming and involves significant risk. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can

occur at any stage of development. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- potential delays in patient enrollment for our clinical trials due to competing trials (similar to the delays in enrollment we experienced in our discontinued trial for MT-0169 in multiple myeloma), public health emergencies or pandemics, natural disasters, labor strikes or shortages, work stoppages or boycotts, or other events, which may affect our ability to initiate and/or complete preclinical studies, conduct ongoing clinical trials, and delay or cancel initiation of planned and future clinical trials;
- 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 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 an institutional review board 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 subjects 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 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, such as the recent clinical hold regarding MT-0169;
- occurrence of adverse events associated with our biologic candidates;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of our biologic candidates;
- negative or inconclusive results from our clinical trials which may result in us deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in other ongoing or planned indications for a biologic candidate; and
- delays in reaching agreement on acceptable terms with third-party manufacturers or an inability to manufacture sufficient quantities of our biologic candidates for use in clinical trials.

Congress also recently amended the FDCA to require sponsors of a Phase III clinical trial, or other “pivotal study” of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Although none of our product candidates has reached Phase III of clinical development, we must submit a diversity action plan to the FDA by the time we submit a Phase III trial, or pivotal study, protocol to the agency for review, unless we are able to obtain a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect the planning and timing of any future Phase III trial for our product candidates or what specific information FDA will expect in such plans. However, initiation of such trials may be delayed if the FDA objects to our proposed diversity action plans for any future Phase III trial for our product candidates, and we may experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan.

Any inability to successfully complete clinical development and obtain regulatory approval for one or more of our biologic candidates could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our biologic candidates, we may need to conduct additional nonclinical

studies and/or clinical trials to show that the results obtained from such new formulation are consistent with previous results. Clinical trial delays could also shorten any periods during which our biologic candidates have patent protection and may allow competitors to develop and bring products to market before we do, which could impair our ability to successfully commercialize our biologic candidates and may harm our business and results of operations.

Additionally, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for our biologic candidates which would materially harm our business. The FDA may disagree with our clinical trial design and our interpretation of data from clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. For example, the FDA published guidance in January 2023 on "Project Optimus," an initiative to reform dose selection in oncology drug development with the goal of optimizing the design of early dose-finding trials. If the FDA does not believe we have sufficiently demonstrated that the selected doses for our biologic candidates maximize not only the efficacy of such candidate, but the safety and tolerability as well, our ability to initiate new studies may be delayed and our costs may be increased. Even if we conducted the additional studies or generated the additional information requested, the FDA could disagree that we have satisfied the agency's requirements, all of which would cause significant delays and expense to our programs.

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

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

***We are heavily dependent on the success of our biologic candidates, the most advanced of which is in the early stages of clinical development. Our ETB therapeutic biologic candidates are based on a relatively novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all. Some of our biologic candidates have produced results in preclinical settings to date and we cannot give any assurance that we will generate additional nonclinical and clinical data for any of our biologic candidates that are 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 biologic candidates based on our ETB therapeutic platform and identifying our initial targeted disease indications. We have invested substantially all of our efforts and financial resources to identify, acquire and develop our portfolio of biologic candidates. Our future success is dependent on our ability to successfully further develop, obtain regulatory approval for,

and commercialize one or more biologic candidates. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a biologic candidate. Our ETB candidate MT-6402, is currently being tested in a Phase I study in relapsed/refractory patients with PD-L1 expressing tumors, which began dosing patients in the third quarter of 2021. Despite the early signals of activity, we were not able to meet our enrollment goals after re-initiating MT-0169 Phase 1 study after the FDA's partial clinical hold was lifted on May 31, 2023. We decided to discontinue the clinical study for relapse and/or refractory multiple myeloma and pursue alternative CD38+ hematological malignancies as a result of us not being able to meet our enrollment goals. Our enrollment for this study was impeded by the clinical hold previously imposed on MT-0169 and due to the effects of competing clinical trials. We are currently negotiating an IST and anticipates initiating a Phase I study for MT-0169 at the 5 and 10 mcg/kg dose levels for CD38+ leukemia in mid-2024. There can be no assurances that we will successfully negotiate an IST and initiate a Phase 1 study in CD38+ leukemia for MT-0169. Our ETB candidate MT-8421 dosed its first patient in a Phase I study in the fourth quarter of 2023. There can be no assurance that we will not experience problems or delays in developing our biologic candidates and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved. Additionally, not all of our clinical and preclinical data to date have been 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 biologic candidates in our planned indications will be sufficient to obtain regulatory approval.

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

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

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

Government agencies' adaptations in response to the COVID-19 pandemic could continue to have an impact on the timeline for review and approval of new marketing applications. For example, the FDA announced in July 2022 that remote regulatory assessments of facilities and other alternative approaches developed during the first two years of the COVID-19 pandemic would continue to be used by the agency in order to supplement its in-person inspection program. Subsequently, Congress endorsed the FDA's approach to remote facility assessments via amendments made to the FDCA as part of the Consolidated Appropriations Act for 2023.

***We have previously experienced difficulty enrolling patients and were unable to complete enrollment of patients in certain of our clinical trials, which led to the termination of clinical trials for one of our biologic candidates in one of its indications. In the future, we may continue to experience these difficulties given the limited number of patients who have the diseases for which our biologic candidates are being studied, which could delay or prevent clinical trials of our biologic candidates.***

Identifying and enrolling patients to participate in clinical trials of our ETB biologic candidates is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients to participate in clinical trials of our biologic candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment, particularly due to public health emergencies or pandemics, natural disasters, acts of terror or war, staffing shortages, or otherwise. For instance, despite early signals of activity, we were not able to meet our enrollment goals after re-initiating MT-0169 Phase 1 study for relapsed and/or refractory multiple myeloma after the FDA lifted its partial clinical hold on May 31, 2023. The approval of two new therapies for relapsed and/or refractory multiple myeloma in August 2023 added to the enrollment challenges of the MT-0169 Phase I study for relapsed and/or refractory multiple myeloma. As a result, we decided to discontinue the Phase 1 study for relapse and/or refractory multiple myeloma and pursue alternative CD38+ hematological malignancies.

The eligibility criteria of our other ongoing and 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. 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 biologic candidate under study, the availability and efficacy of competing therapies and clinical trials, and the willingness of physicians to participate in our planned clinical trials. If patients are unwilling to participate in our clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of our biologic candidates may be delayed.

Any delays in the completion of, or termination of, any clinical trials of our biologic candidates, have harmed and could continue to harm the commercial prospects of our biologic candidates, and delay or prevent or continue to delay or prevent our ability to generate product revenue from any of these biologic candidates. In addition, any delays in completing our clinical trials have and could continue to increase our overall costs, impair biologic candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences have harmed and could continue to harm our business, financial condition, and prospects significantly.

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

As previously disclosed, the clinical hold for MT-0169 was recently lifted. Undesirable side effects caused by our biologic candidates could cause us or regulatory authorities to interrupt, delay, or terminate clinical trials or result in a restrictive label or delay regulatory approval. In addition, our ETB product candidates have been studied in only a limited number of subjects. Based on observations with a similar class of immunotoxins or ETBs, the AEs considered to be important or potential risks of MT-6402 include, but are not limited to, CRS, infusion-related reactions ("IRR"), immune-related adverse reactions, hepatotoxicity, acute kidney injury, hematologic toxicity, coagulation and clinical chemistry toxicity, CLS, reproductive risks, and cardiovascular toxicity. The important or potential risks and AEs of MT-0169 include, but are not limited to, CRS, skeletal muscle and cardiac injury, CLS, IRR, thrombotic microangiopathy ("TMA") with glomerular endothelial cell swelling/injury and increased risk of infections.

In addition to the side effects that are known to be associated with MT-6402, continued clinical trials could reveal higher incidence of side effects, or AEs, previously unknown side effects, or side effects having greater severity, which could each or all lead to delays in our clinical programs, including MT-8421, or discontinuation of our trials. Though the clinical hold for MT-0169 was recently lifted on May 31, 2023, regulatory authorities may again suspend or terminate a clinical trial due to a number of factors, including, among other things, failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in cited deficiencies, or the imposition of a clinical hold, study subject safety

concerns, adverse effects or events, severe adverse events including death, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions. The occurrence of adverse side effects could jeopardize or preclude our ability to develop, obtain or maintain marketing approval for, or successfully commercialize, market and sell any or all of our product candidates for one or more indications. There is no guarantee that additional or more severe side effects will not be identified through ongoing clinical trials of our biologic candidates for current and other indications. There can be no assurance that other patients treated with MT-6402, MT-8421, MT-0169, or any other of our biologic candidates, will not experience CLS or other serious side effects and there can be no assurance that the FDA, EMA or comparable regulatory authorities in other jurisdictions will not place additional clinical holds on our current or future clinical trials, the result of which could delay or prevent us from obtaining regulatory approval for any or all ETB product candidates.

Even if approved in the future, MT-6402, MT-8421, MT-0169 or any other of our biologic candidates, may carry boxed warnings or other warnings and precautions. Undesirable side effects and negative results for any of our biologic candidates may negatively impact the development and potential for approval of our biologic candidates for their proposed indications.

Additionally, even if one or more of our biologic candidates receives marketing approval, if 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 or new contraindications on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategies plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, or other elements to assure safe use;
- we may be required to change the way such biologic candidates are distributed or administered, or change the labeling of the biologic candidates;
- we may be subject to regulatory investigations and government enforcement actions;
- the FDA or a comparable foreign regulatory authority may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the product;
- we may decide to recall such biologic candidates from the marketplace; and
- our reputation may suffer.

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

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

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

could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our biologic candidates, stricter labeling requirements for those biologic candidates that are approved and a decrease in demand for any such biologic candidates.

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

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. For example, we depend on the availability of non-human primates ("NHP") to conduct certain preclinical studies that we are required to complete prior to submitting an IND and initiating clinical development. There is currently a global shortage of NHPs available for drug development. This has caused the cost of obtaining NHPs for our preclinical studies to increase dramatically and, if the shortage continues, could also result in delays to our development timelines. Failure can occur at any time during the clinical development process. Clinical trials may produce negative or inconclusive results, and we or any current or 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 biologic candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. The results of preclinical studies and early clinical trials of our biologic candidates may not be predictive of the results of larger, later-stage controlled clinical trials. Biologic candidates that have shown promising results in early-stage clinical trials may still suffer significant setbacks or failure in subsequent clinical trials. Our clinical trials to date have been conducted on a small number of subjects 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 product 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 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 biologic candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We therefore do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our biologic candidates.

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

Because we have limited financial and human resources, we may forego or delay pursuit of opportunities with certain programs or biologic candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or more profitable market opportunities. Our spending on current and future research and development programs and future biologic candidates for specific indications may not yield any commercially viable products. We may also enter into additional strategic collaboration agreements to develop and commercialize some of our programs and potential biologic candidates in indications with potentially large commercial markets. If we do not accurately evaluate the commercial potential or

target market for a particular biologic candidate, we may relinquish valuable rights to that biologic candidate through strategic collaborations, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such biologic candidate. We may allocate internal resources to a biologic candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement, or we may enter into supply agreements with third parties that may be costly for us to maintain.

***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 biologic candidates harms study subjects or is perceived to harm study subjects even when such harm is unrelated to our biologic candidates, we could be subject to costly and damaging product liability claims. If we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition.***

The use or misuse of our biologic candidates in clinical trials and the sale of any products for which we may obtain marketing approval exposes us to the risk of potential product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our biologic candidates and approved products, if any. There is a risk that our biologic candidates may induce AEs. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs.

Some of our ETB product candidates have shown in clinical trials to induce adverse events. The adverse events considered to be important or potential risks of MT-6402 include, but are not limited to, CRS, IRR, immune-related adverse reactions, hepatotoxicity, acute kidney injury, hematologic toxicity, coagulation and clinical chemistry toxicity, CLS, reproductive risks, and cardiovascular toxicity. The important or potential risks of MT-0169 include, but are not limited to, CRS, skeletal muscle and cardiac injury, CLS, IRR, TMA with glomerular endothelial cell swelling/injury and increased risk of infections.

There is a risk that our future biologic candidates may induce similar or more severe adverse events. Patients with the diseases targeted by our biologic candidates may already be in severe or advanced stages of disease and have both known and unknown significant preexisting and potentially life-threatening health risks. During the course of treatment, subjects may suffer adverse events, including death, for reasons that may be related to our biologic candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured subjects, 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 biologic candidates, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may again delay our regulatory approval process or impact and limit the type of regulatory approvals our biologic candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Although we have a claims-made 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, and coverage for our clinical trials outside of the United States, 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 biologic candidates, we will need to expand our insurance coverage to include the sale of commercial products. There is no way to know if we will be able to continue to obtain product liability coverage and obtain expanded coverage if we require it, in sufficient amounts to protect us against losses due to liability, on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. Where we have provided indemnities in favor of third parties under our agreements with them, there is also a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that one of our biologic candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and breach of warranties. Claims

also could be asserted under state consumer protection acts. Any product liability claim brought against us, with or without merit, could result in:

- withdrawal of clinical trial volunteers, investigators, subjects or trial sites;
- the inability to commercialize, or if commercialized, decreased demand for, our biologic candidates;
- if commercialized, product recalls, limitations on approved indications, marketing or promotional restrictions or the need for product modification;
- initiation of investigations by regulators or government enforcement bodies;
- loss of revenues;
- substantial costs of litigation, including monetary awards to subjects 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 biologic candidates would adversely impact our business and future results of operations.

***Our international activities, including clinical trials previously opened 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, some of which were previously open abroad and may be opened abroad in the future, any one of which could adversely impact our business. In addition to currency fluctuations, these risks include, among other things: economic downturns, acts of war and terror, pandemics, changes in or interpretations of local law, varying data protection requirements, 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 incurred, and may incur again in the future, significant expenses denominated in foreign currencies, specifically in connection with our clinical trial sites, several of which were located in various countries outside of the

United States. These clinical trial sites invoiced us in the local currency of the site. If 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 U.S. 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 FCPA and similar anti-bribery and anti-corruption laws of other countries in which we operate.***

We have conducted studies in international locations and may in the future initiate studies in countries other than the United States. Our business activities may be subject to the 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 Biologic Candidates and Other Legal Compliance Matters**

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

We may seek a breakthrough therapy designation from the FDA for one or more of our biologic candidates. A breakthrough therapy is defined as a 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 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 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. 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 biologic candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a biologic candidate may not result in a faster development process, review or approval, compared to biologics considered for approval under conventional or other accelerated FDA procedures and does not ensure ultimate approval by the FDA. In addition, even if one or more of our biologic candidates qualify and are designated as a breakthrough therapy, the FDA may later decide that the biological products no longer meet the conditions for designation and the designation may be rescinded.

***MT-6402 has been granted Fast Track designation by the FDA and we may seek Fast Track designation for one or more of our other biologic candidates in the future. Even if we apply for Fast Track designation in the future, 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, and further, such designation could be withdrawn by the FDA.***

If a biologic candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, a product sponsor may request an FDA Fast Track designation from the FDA. If we seek Fast Track designation for a biologic candidate, we may not receive it from the FDA. However, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures. In November 2021, MT-6402 was granted Fast Track designation for the treatment of patients with advanced NSCLC expressing PD-L1.

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

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

Any regulatory approvals that we receive for our biologic candidates may be subject to limitations on the approved indicated uses for which the biologic candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the biologic candidate. In addition, if the FDA, EMA or a comparable foreign regulatory authority approves any of our biologic candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and record keeping for the products will be subject to extensive and ongoing regulatory requirements. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a biologic candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit for our products. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval.

We must also comply with requirements concerning advertising and promotion for any of our biologic candidates for which we hope to obtain marketing approval. Promotional communications with respect to prescription 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 or our CMOs' manufacturing or analytical testing 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 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 biologic candidates. For example, in April 2023 the European Commission issued a proposal to revise and replace the existing general pharmaceutical legislation. If adopted and implemented as currently proposed, these revisions will significantly change several aspects of drug development and approval in the EU.

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 biologic candidates, if approved, among physicians, patients, third-party payors and other members of the medical community.***

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

- the efficacy and potential advantages compared to alternative treatments or competitive products;

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

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

Our ability to negotiate, secure and maintain third-party coverage and reimbursement for our biologic candidates may be affected by political, economic and regulatory developments in the United States, the European Union and other jurisdictions. Governments continue to impose cost containment measures, and third-party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of market acceptance of any biologic candidate of ours that receives marketing approval in the future. See also the risk disclosures below under "*Healthcare legislative reform measures may have a material adverse effect on our business, financial condition or results of operations.*"

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed. The ACA was 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. The ACA also included the Biologics Price Competition and Innovation Act, that created the abbreviated application and licensure pathway for biosimilar and interchangeable biological products. As another example, the 2021 Consolidated Appropriations Act, which was signed into law on December 27, 2020, incorporated extensive health care provisions and amendments to existing laws, including a requirement that all manufacturers of drugs and biological products covered under Medicare Part B report the product's average sales price to the HHS beginning on January 1, 2022, as well as several changes to the statutes governing FDA's drug and biologic programs.

Further legislative and regulatory changes under the ACA remain possible, although it is unknown what form any such future changes or any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States.

In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our biologic candidates, restrict or regulate post-approval activities, or affect our ability to profitably sell any biologic candidates for which we obtain marketing approval, if any. For example, as part of the Consolidated Appropriations Act for 2023, Congress provided the FDA additional authorities related to the accelerated approval pathway for human drugs and biologics. Under these recent amendments to the FDCA, the agency may require a sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The amendments also give the FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product. Legislators continue to debate various reforms that have the potential to significantly alter FDA authorities or existing agency policies pertaining to biopharmaceutical 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 biologic candidates, may be or whether such changes will have any other impacts on our business. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

Further, over the past several years there has been heightened governmental scrutiny over the manner in which biopharmaceutical manufacturers set prices for their marketed products, which has resulted in several U.S. 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 drug products. The probability of success of these newly announced policies, many of which have been or are expected to be subjected to legal challenge in the federal court system, and their potential impact on the U.S. prescription drug marketplace is unknown. There are likely to be continued political and legal challenges associated with implementing these reforms as they are currently envisioned. For example, on August 16, 2022, President Biden signed into the law the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. A manufacturer of drugs or biological products covered by Medicare Parts B or D must now pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA's impact on the biopharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

Additionally, in July 2021, President Biden issued a sweeping executive order promoting competition in the American economy that includes several mandates pertaining to the pharmaceutical and healthcare insurance industries. Among other things, the executive order directs the FDA to work towards implementing a system for importing drugs from Canada (following finalization of the Canadian drug importation rulemaking in October 2020), and to clarify and improve the standards for interchangeable biosimilars. The Biden order also called on HHS to release a comprehensive plan to combat high prescription drug prices, and it includes several directives regarding the FTC oversight of potentially anticompetitive practices within the pharmaceutical industry. The drug pricing plan released by HHS in September 2021 in response to the executive order makes clear that the Biden Administration supports aggressive action to address rising

drug prices, and such actions have started within the implementation of the IRA. In addition to the IRA's drug price negotiation provisions summarized above, President Biden's Executive Order 14087, issued in October 2022, called for the CMS innovation center to prepare and submit a report to the White House on potential payment and delivery modes that would complement to IRA, lower drug costs, and promote access to innovative drugs. This CMS report was released in February 2023 and describes three models to be tested by the agency, the results of which are expected to further inform the current Administration's priorities and activities in this area. Accordingly, there remains a large amount of uncertainty regarding the federal government's approach to making pharmaceutical treatment costs more affordable for patients.

There also are a number of state and local legislative and regulatory efforts related to biologic pricing, including biologic price transparency laws that apply to pharmaceutical manufacturers, that may have an impact on our business. Individual states in the U.S. have become increasingly active in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, and restrictions on certain product access. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate PBMs and other members of the health care and pharmaceutical supply chain, an important decision that has led to further and more aggressive efforts by states in this area. The FTC in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements, and Congress has been actively convening hearings and considering legislation related to PBM practices. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical product developers like us. Further, in September 2023, the FTC issued a policy statement articulating its view that certain "improper" patent listings by drug developers in FDA's Orange Book represent an unfair trade practice and indicated that industry should be prepared for potential enforcement actions based on its analysis. The FTC followed that action in November 2023 by publicly calling out over 100 "improper" patent listings made by ten large pharmaceutical companies and initiating an FDA administrative process with respect to those patents. It remains to be seen whether the FTC, other governmental agencies, pharmaceutical manufacturers, or other stakeholders continue to prioritize the policy issue of "improper" patent listings and whether significant litigation will develop in this area. Accordingly, regulatory and government interest in biopharmaceutical industry business practices continues to expand and pose a risk of uncertainty.

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 cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action. We expect that additional federal and state 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, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

***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 biologic candidates and begin commercializing those products in the United States, our operations will be subject to additional health care statutory and regulatory requirements and oversight by federal and state governments in the United States as well as foreign governments in the jurisdictions in which we conduct our business. Physicians, other healthcare providers and third-party payors will play a primary role in the recommendation, prescription and use of any biologic candidates for which we obtain marketing approval. In the United States, 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. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation

in federal and state health care programs, including Medicare and Medicaid. 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;
- HIPAA, which 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 Physician Payments Sunshine Act, enacted as part of the ACA, which requires among other things, manufacturers of drugs, devices, biologics and medical supplies that are reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain advanced non-physician health care practitioners (such as physician assistants and nurse practitioners) and teaching hospitals, as well as physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members;
- 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 or conflict with each other 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 biologic candidates, we will be subject to an expanded number of these laws and regulations and will need to expend resources to develop and implement policies and processes to promote ongoing compliance. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations, resulting in government enforcement actions. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***We are 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 potential future customer base, and thereby decrease our revenue.***

In many activities, including the conduct of clinical trials, we are 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, affected individuals or others, which could be extraordinarily expensive to defend and 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 ("GDPR") took effect on May 25, 2018. The GDPR imposes numerous requirements on entities that process personal data, including clinical trial data, in the context of an establishment in the EEA or that process the personal data, including clinical trial data, of data subjects who are located in the EEA. These requirements include, for example, providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be "forgotten" and rights to data portability, as well as enhanced current rights (e.g., access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; and a new mandatory data breach regime. In particular, medical or health data, genetic data and biometric data where the latter is used to uniquely identify an individual are all classified as "special category" data under the GDPR and afford greater protection and require additional compliance obligations. Further, EU member states have a broad right to impose additional conditions—including restrictions—on these data categories. This is because the GDPR allows EU member states to derogate from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). As the EU states continue to reframe their national legislation to harmonize with the GDPR, we will need to monitor compliance with all relevant EU member states' laws and regulations, including where permitted derogation from the GDPR are introduced. The United Kingdom has

incorporated the GDPR into its Data Protection Act 2018, and substantially equivalent requirements and penalties apply in the United Kingdom.

EU laws on data export are also evolving. The GDPR only permits exports of data outside the EU where there is a suitable data transfer solution in place to safeguard personal data (e.g. the EU Commission approved Standard Contractual Clauses or certification under the recently-adopted Data Privacy Framework). On July 16, 2020, the Court of Justice of the European Union issued a landmark opinion in the case *Maximilian Schrems vs. Facebook* (Case C-311/18), called *Schrems II.* This decision invalidated certain data transfer mechanisms as between the European Union member states and the United States. On July 10, 2023, the European Commission adopted an adequacy decision for a new EU to U.S data transfer mechanism, the EU-U.S Data Privacy Framework, intended to facilitate the transfer of personal data from the European Union to the United States. The EU-U.S Data Privacy Framework takes into account the *Schrems II* decision and heightened the burden on data importers to assess U.S. national security laws on their business, and future actions of European Union data protection authorities are difficult to predict. While the newly-adopted ER-U.S. Data Privacy Framework was meant to address the concerns raised by the CJEU in Schrems II, it will likely be subject to future legal challenges. Consequently, there is some risk of any such data transfers from the European Union being halted by one or more European Union member states. If we have to rely on third parties to carry out services for us, including processing personal data on our behalf, we are required under GDPR to enter into contractual arrangements to help ensure that these third parties only process such data according to our instructions and have sufficient security measures in place. Any security breach or non-compliance with our contractual terms or breach of applicable law by such third parties could result in enforcement actions, litigation, fines and penalties or adverse publicity and could cause customers to lose trust in us, which would have an adverse impact on our reputation and business. Any contractual arrangements requiring the transfer of personal data from the European Union to us in the United States will require greater scrutiny and assessments as required following *Schrems II* and may have an adverse impact on cross-border transfers of personal data or increase costs of compliance.

HIPAA establishes a set of national privacy and security standards for the protection of protected health information ("PHI") by health plans, 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 are indirectly impacted by HIPAA because HIPAA regulates the ability of clinical investigators and other health care providers to share PHI with us. Failure to receive this information properly could subject us or our health care provider collaborators 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, to the federal privacy regulations, there are a number of state laws regarding the privacy and security of health information and personal data that are applicable to clinical laboratories. The compliance requirements of these laws, including additional breach reporting requirements, and the penalties for violation vary widely and new privacy and security laws in this area are evolving. For example, several states, such as California, have implemented comprehensive privacy laws and regulations. The California Confidentiality of Medical Information Act ("CCMIA") imposes 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 CCMIA, California also enacted the California Consumer Privacy Act of 2018 ("CCPA") which became effective January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered businesses, and provides new privacy rights for California residents, including the right to opt out of certain disclosures of their information. It increases the privacy and security obligations of entities handling personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches, fueling an increase of data breach litigation. Although the law includes limited exceptions, including for PHI maintained by a covered entity or business associate under HIPAA and medical information maintained by healthcare providers under the CCMIA, it may regulate or impact our processing of personal information depending on the context. Further, the California Privacy

Rights Act ("CPRA") went into effect on January 1, 2023, amending the CCPA. The CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California Privacy Protection Agency authorized to issue substantive regulations, although enforcement of the first set of CPRA's implementing regulations finalized by CPPA has been delayed until March 29, 2024 by a California Superior Court judge. The CPRA also extends the provisions of both the CCPA and the CPRA to the personal information of California-based employees. In addition to California, more U.S. states are enacting similar legislation, increasing compliance complexity and increasing risks of failures to comply. In 2023, comprehensive privacy laws in Virginia, Colorado, Connecticut, and Utah all took effect, and laws in Montana, Oregon, and Texas will take effect in 2024. While certain clinical trial activities are exempt from some state privacy law requirements, other personal data that we handle may be subject to these various laws, which may increase our compliance costs, exposure to regulatory enforcement action and other liabilities.

As various states implement their own privacy laws and regulations, 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 biologic candidates developed under those programs and subject us to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations.***

During the course of our development of our biologic candidates, we have been funded in significant part through state grants, including but not limited to the substantial funding we have received from the CPRIT. On September 18, 2018, we entered into the CD38 CPRIT Agreement, which was extended in September 2023. 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 CD38 CPRIT 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 biologic candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials

and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations; environmental damage resulting in costly clean-up; and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of specified materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future 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 biologic candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business rely, which could negatively impact our business.***

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

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

**Risks Related to Our Intellectual Property**

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

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

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

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

- we or our past, current or future licensors or collaboration partners may not have been the first to make the inventions disclosed in or covered by pending patent applications or issued patents;
- we or our past, current or future licensors or collaboration partners may not have been the first to file patent applications, including covering our ETB technology, biologic candidates, compositions or their uses;
- others may independently develop identical, similar or alternative methods, products, biologic candidates or compositions and uses thereof;
- our disclosures in patent applications or our past, 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 pending patent applications or our current or future licensors or collaboration partners' pending patent applications, may not result in issued patents;
- we or our current or future licensors or collaboration partners may not seek or obtain patent protection in jurisdictions or countries that may provide us with a significant business opportunity;
- we or our current or future licensors or collaboration partners might seek or obtain patent protection in jurisdictions or countries that might not provide us with a significant business opportunity;
- any patents issued to us or to our past, current or future licensors or collaboration partners may not provide a basis for commercially viable products, may not provide any competitive advantages or may be successfully challenged by one or more third parties;
- our products, biologic candidates, compositions, methods or uses thereof, or our past, current or future licensors' or collaboration partners' products, biologic candidates, compositions, methods or uses thereof may not be patentable;
- we or our past, current or future licensors or collaboration partners might fail to maintain our or their patents, resulting in their abandonment;
- we or our current or future licensors or collaboration partners might fail to obtain PTEs available in the United States or in foreign jurisdictions or countries;
- others may design around our patent claims or our past, current or future licensors' or collaboration partners' patent claims to produce competitive technologies, products or uses which fall outside of the scope of our patents or other intellectual property rights;
- others may identify prior art or other bases which could render unpatentable our patent applications or our past, current or future licensors' or collaboration partners' patent applications, or invalidate our patents or our past, 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 past, 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' biologic candidates or their uses in the United States or in other countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our technologies, biologic candidates, compositions or their uses, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our biologic candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

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

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

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

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

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

***We may not have sufficient patent term or regulatory exclusivity protections for our biologic candidates to effectively protect our competitive position.***

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

PTEs 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 biologic candidates depending on the timing and duration of the regulatory review process relative to patent term. In addition, upon issuance of a United States patent, any patent term may be adjusted based on specified delays during patent prosecution caused by the applicant(s) or the USPTO. Although we will likely seek PTEs in the U.S. and in one or more foreign jurisdictions where available, we cannot provide any assurances that any such PTEs will be granted and, if so, for how long. As a result, we may not be able to maintain exclusivity for our biologic candidates for an extended period after regulatory approval, if any, which would negatively impact our business, financial condition, results of operations and prospects. If we do not have sufficient patent term or regulatory exclusivity to protect our biologic candidates, our business and results of operations will be adversely affected.

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

As is the case with other biotechnology companies, our success is heavily dependent on patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has enacted and enforces 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.

Under the Leahy-Smith America Invents Act ("AIA"), the United States adopted 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 with the USPTO after March 16, 2013 but before we file an application could therefore have been granted a patent covering an invention of ours even if we had made the invention before it was made by the third party. Since certain patent applications in the United States and most other countries are confidential at least 18 months after filing, we cannot be certain that we were the first to file any patent application related to our biologic candidates.

The AIA also provides a process known as inter partes review ("IPR"), which has been used by many third parties to challenge and invalidate patents. The IPR process is not limited to patents filed after the AIA was enacted and would therefore be available to a third party seeking to invalidate any of our U.S. patents, even those issued or filed before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures, e.g., an IPR, to invalidate our patent claims that would not have been invalidated if first challenged by the third party in a district court action.

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

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

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

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

In administrative and court actions, grounds for a patent validity challenge may include alleged failures to meet any of several statutory requirements, including novelty, nonobviousness (or inventive step), clarity, adequate written description and enablement of the claimed invention. Grounds for unenforceability assertions include allegations that someone associated with the filing or prosecution of the patent withheld material information from the Examiner during prosecution in the USPTO or made a misleading statement during prosecution in the USPTO, the EPO or elsewhere. Third parties also may raise similar claims before administrative bodies in the USPTO or the EPO, even outside the context of litigation. The outcome following legal assertions of invalidity or unenforceability are unpredictable. With

respect to patent claim validity, for example, we cannot be certain that there is no invalidating prior art, of which we or the patent examiner was unaware during prosecution. Further, we cannot be certain that all of the potentially relevant art relating to our patents and patent applications has been brought to the attention of every patent office. If a defendant or other patent challenger were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on our ETB technology, biologic candidates, compositions and associated uses.

In addition, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new unitary patent system was launched on June 1, 2023, which significantly impacted European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications now have the option, upon grant of a patent, of becoming a Unitary Patent which are subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

***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 past, current or future licensors. If we or one of our past, current or future collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our biologic candidates, the defendant could counterclaim that the patent covering our biologic candidate is invalid and/or unenforceable. In addition, a third party might initiate legal proceedings against us alleging that our patent covering one or more of our biologic candidates is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, nonobviousness, adequate written description, clarity or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly, for example, such that they do not cover our biologic candidates or decide that we do not have the right to stop the other party from using the claimed invention at issue on the grounds that our or our past, 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.

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 biologic candidates to market.

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

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

Although our current employment contracts require assignment of inventor's rights of intellectual property to us, 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 biologic candidates and use our proprietary technology without infringing the patent rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. We are currently not aware of U.S. or foreign patents or pending patent applications that are owned by one or more third parties and that cover our ETB biologic candidates or therapeutic uses of those ETB biologic candidates. In the future, we may identify such third-party U.S. and non-U.S. issued patents and pending applications. If we identify any such patents or pending applications, we may in the future pursue available proceedings in the U.S. and foreign patent offices to challenge the validity of these patents and patent applications. In addition, or alternatively, we may consider whether to seek to negotiate a license of rights to technology covered by one or more of such patents and patent applications. If any patents or patent applications cover our biologic candidates or technologies or a requisite manufacturing process, we may not be free to manufacture or market our biologic candidates, including MT-6402, MT-8421 or MT-0169, 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 biologic candidates and technologies with certainty. 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 biologic candidate, or we may incorrectly conclude that a patent office or court would determine that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to specified limitations, be later amended in a manner that could cover our technologies, our biologic candidates or the use of our biologic candidates.

There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding foreign patent offices. Third parties own numerous U.S. and foreign issued patents and pending patent applications in the fields in which we are developing biologic candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our biologic candidates may be subject to claims of infringement of the patent rights of third parties. Parties making patent infringement claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our biologic candidates. Defense of these claims, regardless of their merit, may involve substantial litigation expense and may require a substantial diversion of 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 biologic candidates and our business could materially suffer.

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

Presently, we have intellectual property rights to our ETB technologies under patent applications that we own and to certain targeting antibody domains through our license agreements that we have entered into. 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 biologic candidates may require specific formulations or manufacturing technologies to be safe, work effectively or be manufactured efficiently, and these rights may be held by others. We may be unable to acquire or in-license on reasonable terms any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we have previously collaborated, and may collaborate in the future, with federal, state or international academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions grant the rights to the collaborator and retain a non-commercial license to all rights as well as retain march-in rights in the situation that the collaborator fails to exercise or commercialize certain covered technologies. Regardless of such initial rights, we may be unable to exercise or commercialize certain funded

technologies thereby triggering march-in rights of the funding institution. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

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

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

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

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

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

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

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

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

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

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

***Our actual or perceived failures to comply with applicable data protection laws and regulations, and the increasing use of social media, 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. See the risk disclosures above under "*We are 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 potential future customer base, and thereby decrease our revenue.*"

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. Complying with the enhanced obligations imposed by 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.

Additionally, despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our biologic candidates or business may cause us to be found in violation of applicable requirements, including but not limited to FDA prohibitions on the promotion of unapproved medical products. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our internal policies or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, future customers and others. Our potential patient population may also be active on social media and use these platforms to comment on the perceived effectiveness of, or adverse experiences with, our biologic candidates. Negative posts or comments about us or our biologic candidates on social media could seriously damage our reputation, brand image and goodwill.

**Risks Related to Our Reliance on Third Parties**

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

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

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

We currently have a cGMP manufacturing facility and we have developed the capability to manufacture biologic candidates for use in the conduct of our clinical trials. We may not be able to manufacture biologic candidates or there may be substantial technical or logistical challenges to supporting manufacturing demand for biologic candidates. We may also fail to comply with cGMP requirements and standards which would require us to not utilize the manufacturing facility to make clinical trial supply. We plan to rely at least in part on third-party contract manufacturers, and their responsibilities often include purchasing from third-party suppliers the materials necessary to produce our biologic candidates for our clinical trials and to support 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 biologic candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our biologic candidates for our clinical trials, and, if approved, ultimately for commercial sale.

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

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

- we may be unable to identify manufacturers to manufacture our biologic 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 biologic candidates;
- biologic manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMPs and other government regulations and corresponding foreign standards, and we do not have direct control over third-party manufacturers' compliance with these regulations and standards;
- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own or be able to license, or we may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our biologic candidates;
- while we currently carry insurance in an amount and on terms and conditions that are customary for similarly situated companies and that are satisfactory to our board of directors, we and/or our third-party manufacturers may not have sufficient insurance coverage in the event of any inadvertent destruction of or loss of any drug substance by them, which could result in delays in production and/or our clinical trials and/or result in additional costs to us; 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 biologic candidates, or the commercialization of our biologic candidates or result in higher costs or deprive us of potential product revenue. In addition, we rely on third parties to perform release testing on our biologic candidates prior to delivery to subjects in our clinical trials. If these tests are not appropriately conducted and test data are not reliable, subjects in our clinical trials, or patients treated with our biologic candidates, if any are approved in the future, could be put at risk of serious harm, which could result in product liability suits.

***Our employees, independent contractors, principal investigators, CROs, consultants or vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants or vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; manufacturing standards; federal and state health care fraud and abuse laws and regulations; or laws that require the true, complete and accurate reporting of financial information or data. In addition, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks

or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished potential profits and future earnings, and curtailment of our operations, any of which could adversely affect our business, financial condition, results of operations or prospects.

***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 our existing strategic collaboration and to license or partner with new strategic partners. Even if we are successful at entering into one or more additional collaborations with respect to the development and/or commercialization of one or more biologic candidates, there is no guarantee that any of these collaborations will be successful. We believe collaborations allow us to leverage our resources and technologies and we anticipate deriving some revenues from research and development fees, license fees, milestone payments, and royalties from our collaborative partner. Collaborations may pose a number of risks, including the following:

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

There can be no assurance that we will be successful at establishing collaborative arrangements on acceptable terms or at all, that collaborative partners will not terminate funding before the completion of projects, that our collaborative arrangements will result in successful product commercialization, or that we will derive any revenues from

such arrangements. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position and our internal capabilities. Additionally, the negotiation, documentation and implementation of collaborative arrangements are complex and time-consuming. Our discussions with potential collaborators may not lead to new collaborations on favorable terms and may have the potential to provide collaborators with access to our key intellectual property rights.

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

In the normal course of business, we have and expect to continue periodically to enter into academic, commercial, service, collaboration, licensing, supply, 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 biologic candidates, processes or services made, used, or performed pursuant to the agreements, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to our collaboration agreement, we indemnify our collaboration partner from third-party liability claims that could result from the exploitation of our ETB technology by us or any of our affiliates, licensees, agents, contractors, or consultants, a material breach of the collaboration agreement by us or any of our affiliates, licensees, agents, contractors, or consultants or any gross negligence or willful misconduct by us or any of our affiliates, licensees, agents, contractors, or consultants. With respect to consultants and service providers, 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 Biologic 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 biologic candidates, we may be unable to generate any revenue.***

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

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

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

We may attempt to form strategic collaborations, create joint ventures or enter into licensing arrangements with third parties with respect to our programs in addition to those that we currently have that we believe will complement or

augment our existing business. We may face significant competition in seeking appropriate strategic collaboration partners, and the negotiation process to secure appropriate terms is time consuming and complex. We may not be successful in our efforts to establish such a strategic collaboration for any biologic candidates and programs on terms that are acceptable, or at all. This may be because our biologic candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, the competitive or intellectual property landscape may be viewed as too intense or risky, and/or third parties may not view our biologic candidates and programs as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile.

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

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

Our estimates for the addressable patient population and our estimates for the prices we can charge for our biologic candidates may differ significantly from the actual market addressable by our biologic candidates and 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, the potentially addressable patient population for each of our biologic candidates may be limited or may not be amenable to treatment with our biologic candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our business, financial condition, results of operations and prospects.

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

The development and commercialization of new drug products is highly competitive. We face competition from large pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions worldwide with respect to MT-6402, MT-8421, MT-0169, and the other biologic candidates that we may seek to develop or commercialize in the future. We are aware that companies including the following have products marketed or in development that could compete directly or indirectly with ETBs: Merck, Bayer, Takeda, AbbVie, Immunogen, Morphosys, Genmab, Bristol-Myers Squibb, Novartis, Regeneron, Janssen, Xencor, Amgen, AstraZeneca, Lilly, Merck KGaA, Pfizer, Sanofi, Spectrum Pharmaceuticals, Cogent Biosciences, Karyopharm, ADC Therapeutics, 2seventy bio, Gilead, GlaxoSmithKline, Incyte, TG Therapeutics, Mersana Therapeutics, Seagen, and Verastem. Our competitors may succeed in developing, acquiring or licensing technologies or biological products that are more effective or less costly than MT-6402, MT-8421, MT-0169, or any other biologic candidates that we are currently developing or that we may develop, which could render our biologic candidates obsolete and noncompetitive.

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

products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors.

If our competitors obtain marketing approval from the FDA or comparable foreign regulatory authorities for their biologic candidates more rapidly than we do, it could result in our competitors establishing a strong market position before we are able to enter the market. In addition, third-party payors, including governmental and private insurers, also may encourage the use of generic products. For example, if MT-6402, MT-8421, or MT-0169 is ultimately approved, it may be priced at a significant premium over other competitive products. This may make it difficult for, MT-6402, MT-8421, MT-0169, or any other of our future drugs or biologics to compete with these products. Failure of MT-6402, MT-8421, MT-0169, or any other of our biologic candidates to effectively compete against established treatment options or in the future with new products currently in development would harm our business, financial condition, results of operations and prospects.

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

Even with the approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our drugs will depend in part on the health care providers, patients and third-party payors accepting our biologic candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients or third-party payors. The degree of market acceptance of any of our drug candidates 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 perceptions by the medical community, physicians, and patients, regarding the safety and effectiveness of our products and 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, supply and distribution support for the product;
- the publicity concerning our drugs or biologics or competing products and treatments; and
- the pricing and availability of third-party insurance coverage and reimbursement.

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

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

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

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

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

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

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

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

In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved drugs. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by CMS, an agency within the HHS, 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

biologic candidates such as ours and what reimbursement codes our biologic candidates may receive if approved. Moreover, as noted above under "*Healthcare legislative reform measures may have a material adverse effect on our business, financial condition or results of operations,*" in 2022 Congress enacted and President Biden signed into law new authorities for CMS to negotiate drug prices annually for certain prescription drugs and biological products, subject to statutory criteria and a future selection process that is in the process of being developed by CMS. It is unclear how these forthcoming changes in the way that CMS does business with certain members of the biopharmaceutical industry may impact coverage or reimbursement decisions across the industry as a whole.

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

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

**Risks Related to Ownership of Our Common Stock**

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

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

- our ability to obtain regulatory approvals for MT-6402, MT-8421, MT-0169, or other biologic candidates, and delays or failures to obtain such approvals;
- adverse results, clinical holds, or delays in the clinical trials of our biologic candidates or any future clinical trials we may conduct, or changes in the development status of our biologic candidates;
- failure of any of our biologic candidates, if approved, to achieve commercial success;
- failure to maintain our existing third-party collaboration, 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 biologic candidates;
- any inability to obtain adequate supply of our biologic candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;

- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, strategic alternatives, 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, such as inflation;
- sales of our common stock by us or our stockholders in the future;
- the trading volume of our common stock;
- our ability to maintain the listing of our common stock on the Nasdaq Capital Market;
- the issuance of additional shares of our preferred stock or common stock, or the perception that such issuances may occur, including through the amended and restated second tranche of the July 2023 Private Placement, pursuant to the CVR Agreement, 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 healthcare payment systems;
- disruptions in the financial markets;
- the impact of political instability and military conflicts, such as the conflicts and recent events in Ukraine and the Middle East, which has resulted in instability in the global financial markets and export controls; 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.

***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, 2023, a total of 5,374,268 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. Further, our stockholders will experience additional dilution when and if shares of common stock (or securities exercisable or convertible into shares of common stock) are issued by us, including when we issue securities in the amended and restated second tranche of the July 2023 Private Placement, the CVR Agreement or pursuant to any of our recently issued warrants to purchase shares of our

common stock, and these issuances (or the belief that these issuances may occur) may adversely affect the price of our common stock.

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.

***We may become involved in securities litigation that could materially divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.***

We may be exposed to securities litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources. We may become involved in such litigation, and 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 current or future collaboration partners or competitors, the addition or departure of our key personnel, the announcement of a strategic restructuring, 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 (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 if we cease to be a "smaller reporting company," we are incurring and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company or as a public company without 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, 2023, 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 66% 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 specified 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, to the fullest extent permitted by law, that the Court of Chancery of the State of Delaware will be the exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a breach of fiduciary duty; (3) any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; or (4) any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act, in as much as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rule and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. This 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 any of our directors, officers, or other employees, which may discourage lawsuits

with respect to such claims. Alternatively, if a court were to find the choice of forum provisions 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, which could harm our business, results of operations and financial condition.

***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. As calculated as of June 30, 2023, 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 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. Our strategic prioritization and restructuring may result in the loss of personnel with deep institutional or technical knowledge. Further, the transition could potentially disrupt our operations and relationships with employees, suppliers and partners and due to added costs, operational inefficiencies, decreased employee morale and productivity and increased turnover. Furthermore, these personnel changes may increase our dependency on the other members of our leadership team and other employees that remain with us, who are not contractually obligated to remain employed with us and may leave at any time. Any such departure could be particularly disruptive and, to the extent we experience additional turnover, competition for top talent is high such that it may take some time to find a candidate that meets our requirements. Our competitors may seek to use these transitions and the related potential disruptions to gain a competitive advantage over us. 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 biologic candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel, or the loss of the services of Dr. Poma may impede the progress of our research, development and commercialization objectives and would negatively impact our ability to succeed in our product development strategy.

***We 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 ("IT") systems, some of which are in our control and some of which are in the control of third parties. 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 ("Confidential 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, including the implementation of a Company cybersecurity program, which includes network penetration testing, detecting and addressing threats and cybersecurity training for employees, our IT systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, cyber-attacks, computer viruses, ransomware attacks, phishing schemes, cybersecurity incidents, unauthorized access, interruptions due to employee error or malfeasance or other disruptions, or damage from natural disasters, terrorism, war and telecommunication and electrical failures, or other attempts to harm or access our systems. Moreover, despite network security and back-up measures, some of our servers and those of our business partners 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 Confidential Information. Cybersecurity incidents resulting in the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized disclosure or use of Confidential Information, or the unauthorized access to, disruption of, or interference with any future products and services, can occur in a variety of ways, including but not limited to, negligent or wrongful conduct by employees or others with permitted access to our IT systems and information, or wrongful conduct by hackers, competitors, or certain governments. Our third-party vendors and business partners face similar risks.

Cyber-attacks come in many forms, including the deployment of harmful malware or ransomware, exploitation of vulnerabilities, phishing and other use of social engineering, and other means to compromise the confidentiality, integrity, and availability of our IT systems and Confidential 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, even with appropriate monitoring controls, 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 or intercept any such disruption or cybersecurity incident, 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, to the extent we have such information, 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 biologic candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce data and cybersecurity incidents 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 1C. CYBERSECURITY

We recognize the critical importance of maintaining the trust and confidence of customers, clients, patients, business partners and employees toward our business and are committed to protecting the confidentiality, integrity and availability of our business operations and systems. Our board of directors is actively involved in oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. Our cybersecurity policies, standards, processes and practices are based on recognized frameworks established by the National Institute of Standards and Technology, ("NIST"), and other applicable industry standards. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

***Cybersecurity Risk Management and Strategy; Effect of Risk***

We face risks related to cybersecurity such as unauthorized access, cybersecurity attacks and other security incidents, including as perpetrated by hackers and unintentional damage or disruption to hardware and software systems, loss of data, and misappropriation of confidential information. To identify and assess material risks from cybersecurity threats, we maintain a comprehensive cybersecurity program to ensure our systems are effective and prepared for information security risks, including regular oversight of our programs for security monitoring for internal and external threats to ensure the confidentiality and integrity of our information assets. We consider risks from cybersecurity threats alongside other company risks as part of our overall risk assessment process. We employ a range of tools and services, including deployment of threat monitoring and mitigation solutions, regular network and endpoint monitoring, audits, vulnerability assessments, penetration testing, threat modeling and tabletop exercises to inform our risk identification and assessment. As discussed in more detail under "Cybersecurity Governance" below, our audit committee provides oversight of our cybersecurity risk management and strategy processes, which are led by our Chief Financial Officer.

We also identify our cybersecurity threat risks by comparing our processes to standards set by the NIST as well as by engaging experts to attempt to infiltrate our information systems. To provide for the availability of critical data and systems, maintain regulatory compliance, manage our material risks from cybersecurity threats, and protect against and respond to cybersecurity incidents, we undertake the following activities:

- monitor emerging data protection laws and implement changes to our processes that are designed to comply with such laws;
- through our policies, practices and contracts (as applicable), require employees, as well as third parties that provide services on our behalf, to treat confidential information and data with care;
- employ technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence;

- provide regular, mandatory training for our employees and contractors regarding cybersecurity threats as a means to equip them with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices;
- conduct regular phishing email simulations for all employees and contractors with access to our email systems to enhance awareness and responsiveness to possible threats;
- run tabletop exercises to simulate a response to a cybersecurity incident and use the findings to improve our processes and technologies;
- leverage internal incident response plans and procedures to help us identify, protect, detect, respond and recover when there is an actual or potential cybersecurity incident; and
- carry information security risk insurance that provides protection against the potential losses arising from a cybersecurity incident.

Our incident response plan coordinates the activities we take to prepare for, detect, respond to and recover from cybersecurity incidents, which include processes to triage, assess severity for, escalate, contain, investigate and remediate the incident, as well as to comply with potentially applicable legal obligations and mitigate damage to our business and reputation, including coordination with public relations and internal and external communications teams.

As part of the above processes, we regularly engage with third parties to review our cybersecurity program and help identify areas for continued focus, improvement and compliance.

Our processes also address cybersecurity threat risks associated with our use of third-party service providers, including our suppliers and manufacturers or who have access to patient and employee data or our systems. We generally require those third parties that could introduce significant cybersecurity risk to us to agree by contract to manage their cybersecurity risks in specified ways, and to agree to be subject to cybersecurity audits, which we conduct as appropriate.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading “Risks Related to Our Business Operations,” which disclosures are incorporated by reference herein.

In the last two fiscal years, we have not experienced any material cybersecurity incidents and the expenses we have incurred from cybersecurity incidents were immaterial. This includes penalties and settlements, of which there were none.

***Cybersecurity Governance; Management***

Cybersecurity is an important part of our risk management processes and an area of focus for our board of directors and management. The audit committee of our board of directors is responsible for the oversight of risks from cybersecurity threats.

At least quarterly, our audit committee receives an update from management of our cybersecurity threat risk management and strategy processes covering topics such as data security posture, results from third-party assessments, progress towards pre-determined risk-mitigation-related goals, our incident response plan, and material cybersecurity threat risks or incidents and developments, as well as the steps management has taken to respond to such risks. In such sessions, our audit committee generally receives materials that include a cybersecurity scorecard / dashboard and other materials discussing current and emerging material cybersecurity threat risks, and describing our ability to mitigate those risks, as well as recent developments, evolving standards, technological developments and information security considerations arising with respect to our peers and third parties, and discusses such matters with our head of Information Technology. Our audit committee also receive prompt and timely information regarding any cybersecurity incident that meets establishing reporting thresholds, as well as ongoing updates regarding any such incident until it has been addressed.

Members of our audit committee are also encouraged to regularly engage in conversations with management on cybersecurity-related news events and discuss any updates to our cybersecurity risk management and strategy programs. Material cybersecurity threat risks are also considered during separate board meeting discussions of important matters like enterprise risk management, operational budgeting, business continuity planning, mergers and acquisitions, brand management, and other relevant matters.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by our head of Information Technology. Such individuals have collectively over 6 years of prior work experience in various roles involving managing information security, developing cybersecurity strategy, implementing effective information and cybersecurity programs. These management team members are informed about and monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan. As discussed above, these management team members report to the audit committee of our board of directors about cybersecurity threat risks, among other cybersecurity related matters, on a quarterly basis.

## 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 and extend the term of the lease through May 2023. In June 2017, Molecular entered into a third amendment to the lease to set the Lease Commencement Date (as such term is defined therein) with respect to the additional space leased pursuant to the second amendment and provided that the term of Molecular's lease for the Austin, Texas space was set to expire August 2023. In July 2022, Molecular exercised the option to extend the lease for an additional five-year period, through August 2028. In October 2022, Molecular entered into a fourth amendment to further extend the lease term to August 2029 and included an option to extend the term for an additional seven years.

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

We leased one property for use as office space of approximately 10,000 square feet in Jersey City, New Jersey under a lease, as amended, which was set to expire in January 2023. The lease had an option to renew for one additional five-year period at our discretion. The space was vacated in 2022 because employees had transitioned to long-term remote working arrangements or the Company's office space in New York, New York. The lease for this office space expired pursuant to its terms in January 2023 following our decision not to renew.

In June 2020, the Company entered into a sublease agreement for office space in New York, New York. The space consists of an initial 9,289 square feet and an additional 3,000 square feet upon expansion. The sublease for the initial space commenced on August 1, 2020 and the possession of the expansion space commenced on December 4, 2020. In August 2022, the Company entered into a first amendment to the sublease to add an additional approximately 3,000 square feet. The term for both spaces will expire on October 30, 2025 and the sublease does not contain an option to renew.

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.

## PART II

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

**Market Information**

Our common stock is traded on the Nasdaq Capital Market under the symbol "MTEM."

**Stockholders**

As of March 25, 2024, we had 5,374,268 outstanding shares of common stock, no outstanding shares of preferred stock, and approximately 5,374,268 holders of record of our outstanding shares of common stock.

**Dividend Policy**

We currently anticipate that we will retain any future earnings to finance the continued development, operation and expansion of our business. As a result, we do not anticipate declaring or paying any cash dividends or other distributions in the foreseeable future. Any determination to pay dividends would be at the discretion of our board of directors and subject to the terms of the CVR Agreement, would depend on our results of operation, financial condition and other factors that our board of directors, in its discretion, considers relevant.

**Securities Authorized for Issuance under Equity Compensation Plans**

See Part III, Item 12 of this Annual Report on Form 10-K under the section titled "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" for information about our equity compensation plans which is incorporated by reference herein.

**Unregistered Sales of Equity Securities**

None.

### ITEM 6. RESERVED

## 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 biopharmaceutical company focused on the discovery and development of targeted biologic therapeutics. Our proprietary biologic drug platform technology, known as ETBs, leverages the resident biology of a genetically engineered form of SLTA to create novel therapies with potent and differentiated mechanisms of action for cancer.

### Recent Developments

#### *Strategic Alternatives*

On March 4, 2024, we announced that we are continuing comprehensive evaluation of strategic alternatives, including consideration of a wide range of options including, among other things, a potential financing/recapitalization, sale, merger, or other strategic transaction. We have not set a deadline or definitive timetable for the completion of the strategic review process, nor have we made any decisions relating to any strategic alternative at this time.

#### *July 2023 Private Placement*

On July 12, 2023 and as described in Note 11 "Stockholders' Equity (Deficit)" of the financial statements included in Item 8 of this Annual Report on Form 10-K, we entered into a securities purchase agreement (the "July 2023 Purchase Agreement") with certain institutional and accredited investors (the "July 2023 Purchasers") which provides for the private placement (the "July 2023 Private Placement") of shares of our common stock and warrants to purchase shares of our common stock in two tranches. The initial tranche of the July 2023 Private Placement closed on July 17, 2023, and consisted of the issuance of (i) 1,617,365 shares of our common stock at a price of $7.05 per share (the closing price per share of our common stock as reported by the Nasdaq Capital Market on July 12, 2023), and (ii) pre-funded warrants (the "July 2023 Pre-Funded Warrants") exercisable for up to 1,222,100 shares of our common stock. The price of the July 2023 Pre-Funded Warrants was $7.035 per underlying share of our common stock, and these warrants contain an exercise price of $0.015 per share. We received approximately $20 million in gross proceeds in connection with the closing of the initial tranche and net proceeds, following the payment of related offering expenses, of approximately $18.4 million.

On March 28, 2024, we and certain institutional and accredited investors (the "March 2024 Purchasers") entered into an Amended and Restated July 2023 Purchase Agreement pursuant to which we will issue common stock, pre-funded warrants, and common warrants with an aggregate purchase price of $9.5 million on amended and restated second tranche terms. The second tranche, as amended and restated, will consist of the sale and issuance of (i) 1,209,612 shares of our common stock (and, in lieu thereof, prefunded warrants to purchase 2,460,559 shares of our common stock (the "March 2024 Prefunded Warrants")) for a purchase price of $2.35 per share of our common stock (the closing price of our common stock on March 27, 2024 as reported by the Nasdaq Capital Market) and $2.349 per March 2024 Prefunded Warrant, and (ii) common stock warrants (the "March 2024 Common Warrants") to purchase up to 7,340,342 shares of our common stock (or March 2024 Prefunded Warrants in lieu thereof) at an exercise price of $2.35 per share of our common stock underlying the March 2024 Common Warrants. The March 2024 Common Warrants will be sold at a price equal to $0.125 per underlying share of common stock and will have a term of five years. The March 2024 Prefunded Warrants will expire when fully exercised in accordance with their terms. The March 2024 Prefunded

Warrants and March 2024 Common Warrants may not be exercised if the aggregate number of shares of our common stock beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation (4.99%/9.99%/19.99%); provided, however, that a holder may increase or decrease the beneficial ownership limitation by giving 61 days' notice to us, but not to any percentage in excess of 19.99%. The Amended and Restated July 2023 Purchase Agreement contains customary representations and warranties and agreements of us and the Purchasers and customary indemnification rights and obligations of the parties. The second tranche will include gross proceeds of approximately $9.5 million and net proceeds, following the payment of related offering expenses, of approximately $8.9 million.

The second tranche of the July 2023 Private Placement is anticipated to close on April 2, 2024, subject to the satisfaction customary closing conditions. The Company intends to use the net proceeds from the second tranche of the July 2023 Private Placement to fund its ongoing clinical studies, working capital and for general corporate purposes.

***Nasdaq Compliance and Reverse Stock Split***

In connection with the deficiency and delisting notices received from Nasdaq, as previously disclosed on April 13, 2023, we presented our plan to the Panel to regain compliance with both the bid price and stockholders' equity requirements as needed for continued listing on the Nasdaq Capital Market. We were granted an extension on May 8, 2023, to regain compliance with both requirements by August 28, 2023, subject to certain conditions as set forth by the Panel. On July 28, 2023 and regarding the stockholders' equity requirement, we submitted an update to the Panel informing the Panel that we did meet an alternative continued listing standard, the market value of listed securities standard, which requires a company to have at least $35 million in market value of listed securities. On August 2, 2023, Nasdaq notified us that we had demonstrated compliance with this market value of listed securities standard but will be subject to a one-year monitoring period commencing on August 2, 2023. In connection with the bid price requirement, we effected the Reverse Stock Split on August 11, 2023. All share and per share data in this Annual Report on Form 10-K have been retroactively adjusted for the Reverse Stock Split. On August 28, 2023, Nasdaq notified us that the Company has regained compliance with the bid price requirement. If Nasdaq again finds that we are not in compliance with the market value of listed securities standard (or an alternative continued listing standard) within the one-year monitoring period, a delisting determination letter will be triggered without any grace period. We would then have the opportunity to respond to the Panel pursuant to applicable Nasdaq rules, following which, if our efforts are unsuccessful, our securities may be delisted from Nasdaq. In addition, the Panel may reconsider the matters described in the Panel decisions and notices, and any matters related to our efforts to regain compliance, which may be based upon future events, conditions or circumstances that may arise with the Company, which in the opinion of the Panel, may make continued listing on the Nasdaq Capital Market inadvisable.

**Collaboration Agreements**

***Bristol-Myers Squibb Company***

On February 10, 2021, we entered into the BMS Collaboration Agreement with Bristol-Myers Squibb, in which we and Bristol-Myers Squibb agreed to enter into a strategic research collaboration to leverage our ETB technology platform to discover and develop novel products containing ETBs directed to multiple targets. On March 15, 2024, we announced that following a corporate portfolio prioritization process, Bristol-Myers Squibb notified us on March 13, 2024 that it does not intend to continue the research collaboration it entered into with us pursuant to the BMS Collaboration Agreement and would be terminating the BMS Collaboration Agreement in its entirety. The termination will be effective on June 13, 2024, or 90 days following our receipt of Bristol-Myers Squibb's written notice of termination.

Pursuant to the BMS Collaboration Agreement, Bristol-Myers Squibb paid us an upfront payment of $70.0 million. We would have been eligible to receive near term and development and regulatory milestone payments of up to an additional $874.5 million and would be eligible to receive up to an additional $450.0 million in milestone payments upon the achievement of certain sales milestone events. We would have also been entitled to receive, subject to certain reductions, tiered royalties ranging from mid-single digits up to mid-teens as percentages of calendar year net sales, if any, on any licensed product.

We would have been responsible for conducting the research activities through the designation, if any, of one or more development candidates. Upon the exercise of its option for a development candidate, Bristol-Myers Squibb would have been responsible for all development, manufacturing, regulatory and commercialization activities with respect to that development candidate, subject to the terms and conditions of the BMS Collaboration Agreement.

For more information concerning this collaboration agreement, refer to Note 3, "Research and Development Agreements" to our audited consolidated financial statements for the year ended December 31, 2023, included in this Annual Report on Form 10-K.

***Previous Agreements***

In September 2018, we entered into the Takeda Development and License Agreement with Takeda for the development and commercialization of products incorporating or comprised of one or more CD38 SLT-A fusion proteins for the treatment of patients with diseases such as multiple myeloma.

In April 2021, we received a notice of termination from Takeda for the Takeda Development and License Agreement. Following receipt of the termination notice from Takeda, we notified Takeda of our intent to assume full rights to MT-0169, a second-generation ETB targeting CD38, by entering into an agreement for such rights pursuant to the termination provisions of the Takeda Development and License Agreement. The termination of the Takeda Development and License Agreement was effective in August 2021. As of the same date, we assumed full rights to MT-0169, including full control of MT-0169 clinical development, per the terms of the terminated Takeda Development and License Agreement. Following the transfer of the full MT-0169 rights to us, we may owe low-single digit royalties on future net sales of MT-0169 to Takeda as well as to certain third-party licensors. We may also owe certain third-party licensors potential aggregate clinical and regulatory milestone payments of up to $22.25 million.

In June 2017, we entered into the Takeda Multi-Target Agreement with Takeda, pursuant to which we agreed to collaborate with Takeda to identify, generate and evaluate ETBs, against certain targets designated by Takeda. In March 2022, following our request to bring the agreement to an end, we and Takeda mutually agreed to terminate the Takeda Multi-Target Agreement. As a result of the termination, we regained full rights to pursue the targets worked on under the Takeda Multi-Target Agreement. There are no ongoing activities or economic obligations in connection with the Takeda Multi-Target Agreement.

**Grant Agreements**

**CPRIT Grant Contract**

In September 2018, we entered into the CD38 CPRIT Agreement with CPRIT, which was extended in September 2022 and further extended in September 2023 to May 31, 2024, in connection with a grant of the Award. Pursuant to the CD38 CPRIT Agreement, we might also use such funds to develop a replacement CD38 targeting ETB, with or without a partner. The Award is contingent upon funds being available during the term of the CD38 CPRIT Agreement and subject to CPRIT's ability to perform its obligations under the CD38 CPRIT Agreement as well as our progress towards achievement of specified milestones, among other contractual requirements.

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, which are known as the Project Results. With respect to any Project Results, we agreed to grant to CPRIT a nonexclusive, irrevocable, royalty-free, perpetual, worldwide license, solely for academic, research and other non-commercial purposes, under the Project Results and to exploit any necessary additional intellectual property rights, subject to certain exclusions.

We will pay to CPRIT, during the term of the CD38 CPRIT Agreement, certain payments equal to a percentage of revenue ranging from the low- to mid-single digits. These payments will continue up to and until CPRIT receives an aggregate amount of 400% of the sum of all monies paid to us by CPRIT under the CD38 CPRIT Agreement. If we

are required to obtain a license from a third party to sell any such product, the revenue sharing percentages might be reduced. In addition, once we pay CPRIT 400% of the monies 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) May 31, 2024 or (b) the occurrence of any of the following events: (i) by mutual written consent of the parties, (ii) by CPRIT for an Event of Default (as defined in the CD38 CPRIT Agreement) by us, (iii) by CPRIT if allocated funds should become legally unavailable during the term of the CD38 CPRIT Agreement and CPRIT is unable to obtain additional funds or (iv) by us for convenience. CPRIT might approve a no cost extension for the CD38 CPRIT Agreement for a period of six months or twelve 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 year ended December 31, 2023, 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 or our current or future collaboration partners develop, including MT-6402, MT-8421, MT-0169, until we obtain regulatory approval and commercialize such biologics. Our revenue consists principally of collaboration revenue and grant revenue.

Research and Development revenue primarily relates to our collaboration agreement with Bristol-Myers Squibb which is accounted for using the percentage-of-completion cost-to-cost method.

Grant revenue relates to our CPRIT grant for a CD38 ETB (MT-0169). CPRIT grant funds for MT-0169 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 grant receivable. Funds received in excess of expenditures incurred are recorded as deferred revenue.

For more information about our revenue recognition policy, please see Note 1, "Organization and Summary of Significant Accounting Policies" to our audited consolidated financial statements for the year ended December 31, 2023, included in this Annual Report on Form 10-K.

***Research and Development Expenses***

Research and development expenses consist principally of:

- salaries for R&D staff and related expenses, including stock-based compensation expenses;
- costs for cGMP manufacturing of drug substances and drug products by contract manufacturers;
- fees and other costs paid to clinical trials sites and 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 R&D expenses may vary substantially from period to period based on the timing of our R&D activities, including the initiation and enrollment of subjects in clinical trials and manufacture of biologic materials for clinical

trials. We expect R&D expenses to increase as we advance the clinical development of MT-6402, MT-8421, and/or MT-0169. The successful development of our ETB candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and 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 R&D 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-6402, MT-8421, MT-0169, or any other ETB candidate that we or our current or future collaboration partners may develop in the future.

Any of these variables with respect to the development of MT-6402, MT-8421, MT-0169, 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 such candidates. For example, if the FDA, the EMA or other regulatory authority were to require us to conduct pre-clinical and clinical studies beyond those which we currently anticipate will be required for the completion of clinical development or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of our clinical development programs.

***General and Administrative Expenses***

Our general and administrative expenses consist principally of:

- salaries for employees other than R&D 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.

***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.

**Results of Operations**

**Revenues**

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

| | Years ended December 31, | | | |
|---|---|---|---|---|
| | 2023 | 2022 | Change ($) | Change (%) |
| Research and development revenue | $ 52,625 | $ 19,754 | $ 32,871 | 166 % |
| Grant revenue | 4,681 | — | 4,681 | 100 % |
| Total revenue | $ 57,306 | $ 19,754 | $ 37,552 | 190 % |

***Research and Development Revenue***

The increase in research and development revenue for the year ended December 31, 2023 compared to the year ended December 31, 2022 was primarily due to the completion of the research program for one of the collaboration's targets and the completion of the related performance obligations under the BMS Collaboration Agreement with Bristol-Myers Squibb, resulting in recognition of $25.8 million of research and development revenue in the first quarter of 2023.

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, 2023, included in this Annual Report on Form 10-K.

***Grant Revenue***

The increase in grant revenue for the year ended December 31, 2023 compared to the year ended December 31, 2022 is primarily due to recognizing revenue for the grant received under the CD38 CPRIT Agreement with the CPRIT during the period.

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, 2023, included in this Annual Report on Form 10-K.

**Operating Expenses**

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

| | Years ended December 31, | | | |
|---|---|---|---|---|
| | 2023 | 2022 | Change ($) | Change (%) |
| Research and development expenses | $ 48,875 | $ 82,425 | $ (33,550) | (41)% |
| General and administrative expenses | 18,897 | 26,200 | (7,303) | (28)% |
| Total operating expenses | $ 67,772 | $ 108,625 | $ (40,853) | (38)% |

***Research and Development Expenses***

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

| | Years ended December 31, | | | |
|---|---|---|---|---|
| | 2023 | 2022 | Change ($) | Change (%) |
| Program costs | $ 15,771 | $ 24,408 | $ (8,637) | (35)% |
| Employee compensation | 18,293 | 37,398 | (19,105) | (51)% |
| Laboratory costs | 7,011 | 9,962 | (2,951) | (30)% |
| Other research and development costs | 7,800 | 10,657 | (2,857) | (27)% |
| Total research and development expenses | $ 48,875 | $ 82,425 | $ (33,550) | (41)% |

R&D expenses decreased $33.6 million during the year ended December 31, 2023 compared to the year ended December 31, 2022. This decrease is primarily due to decreased headcount and program costs related to our collaboration agreements.

Program costs decreased $8.6 million during the year ended December 31, 2023 compared to the year ended December 31, 2022. The programs primarily driving the decrease were $3.2 million for MT-8421, $2.8 million for MT-5111, $1.6 million for other programs, $1.1 million for BMS and $0.7 for MT-6402 which is partially offset by an increase of $1.0 million for MT-0169.

Headcount decreased in R&D by 73% from December 31, 2022 to December 31, 2023. This staffing decrease resulted in a decrease in employee compensation costs of $19.1 million for the year ended December 31, 2023 compared to the year ended December 31, 2022.

Laboratory costs decreased by $3.0 million during the year ended December 31, 2023 compared to the year ended December 31, 2022, which is due to decreases in laboratory supplies and equipment. The decrease in expense reflects the costs of outfitting, supplying and maintaining laboratory facilities.

Other R&D costs decreased by $2.9 million during the year ended December 31, 2023 compared to the year ended December 31, 2022 due to lower depreciation expense related to the lab buildouts and related equipment.

***General and Administrative Expenses***

General and administrative expenses decreased by $7.3 million during the year ended December 31, 2023 compared to the year ended December 31, 2022. The main driver of this decrease is related to a decrease of headcount resulting in a decrease of employee compensation expenses.

**Nonoperating activities**

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

| | Years ended December 31, | | | |
|---|---|---|---|---|
| | 2023 | 2022 | Change ($) | Change (%) |
| Interest and other income, net | $ 1,208 | $ 988 | $ 220 | 22 % |
| Interest and other expense, net | (2,654) | (4,716) | 2,062 | (44)% |
| Gain on extinguishment of debt | 1,795 | — | 1,795 | 100 % |
| Change in valuation of contingent value right | 2,457 | — | 2,457 | 100 % |
| Loss on disposal of property and equipment | (475) | (66) | (409) | 620 % |
| Total nonoperating activities | $ 2,331 | $ (3,794) | $ 6,125 | (161)% |

***Interest and Other Income and Interest and Other Expense***

The increase in interest and other income, net for the year ended December 31, 2023 compared to the year ended December 31, 2022 was primarily due to higher interest related to our marketable securities.

The decrease in interest and other expense, net for the year ended December 31, 2023 compared to the year ended December 31, 2022 was primarily due to the extinguishment on our debt holdings.

**Liquidity and Capital Resources**

***Sources of Funds***

Historically, we have funded our operations by raising capital from external sources, especially through the sale of common stock, preferred stock, instruments convertible or exercisable for shares of our common stock and our borrowings under the K2 Loan and Security Agreement. As mentioned in Note 8, “Borrowing Arrangements and Extinguishment” of the financial statements in Item 8 of this Annual Report on Form 10-K, we recently restructured and extinguished our obligations pursuant to the K2 Loan and Security Agreement. Also as mentioned above and in Note 11, “Stockholders’ Equity (Deficit)” of the financial statements included in Item 8 of this Annual Report on Form 10-K, we raised approximately $20.0 million in gross proceeds (and $18.4 million in net proceeds) through the sale and issuance of shares of our common stock and July 2023 Pre-Funded Warrants in the first tranche of the July 2023 Private Placement. In addition, we expect approximately $9.5 million in gross proceeds through the sale and issuance of shares of our common stock, March 2024 Prefunded Warrants and March 2024 Common Warrants pursuant to the amended and restated second tranche terms of our July 2023 Purchase Agreement. Additionally, there can be no assurance as to

whether the proceeds received from the initial tranche, any potential proceeds received in connection with the second tranche, and/or the proceeds from the exercise, if any, of the July 2023 Pre-Funded Warrants or March 2024 Prefunded Warrants and March 2024 Common Warrants will be sufficient for us to maintain compliance with the applicable listing criteria of the Nasdaq Capital Market or will be sufficient for us to continue as a going concern.

***Future Funding Requirements and Liquidity***

Adequate additional funds needed to support our ongoing operations may not be available to us on acceptable terms, or at all. Following the Reverse Stock Split, the market price of our common stock may not attract new investors and may not satisfy the investing requirements of those investors. 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.

Our financial statements are prepared using U.S. GAAP applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We have not yet established an ongoing source of revenues sufficient to cover our operating costs and to provide sufficient certainty that we will continue as a going concern.

***Cash Flows***

***Comparison of Years Ended December 31, 2023 and 2022***

The table below summarizes our cash flows for the years ended December 31, 2023 and 2022:

| | Years ended December 31, | | | |
|---|---|---|---|---|
| | 2023 | 2022 | Change ($) | Change (%) |
| Net cash used in operating activities | $ (41,820) | $ (89,024) | $ 47,204 | (53)% |
| Net cash provided by investing activities | 29,095 | 95,317 | (66,222) | (69)% |
| Net cash used in financing activities | (9,116) | (265) | (8,851) | 3,340 % |
| Net (decrease)/increase in cash, cash equivalents, and restricted cash | $ (21,841) | $ 6,028 | $ (27,869) | (462)% |

The decrease in net cash used in operating activities for the year ended December 31, 2023 compared to the year ended December 31, 2022 was primarily due to the decrease in deferred revenue related to BMS Collaboration Agreement in Q1 2023.

The decrease in net cash provided by investing activities for the year ended December 31, 2023 compared to the year ended December 31, 2022 was primarily due to investment activity in marketable securities.

The increase in net cash used in financing activities for the year ended December 31, 2023 compared to the year ended December 31, 2022 was primarily due to the repayment of long-term debt partially offset by proceeds from the issuance of common stock and prefunded warrants.

***Operating and Capital Expenditure Requirements***

We have not achieved profitability since our inception and had an accumulated deficit of $452.9 million as of December 31, 2023. We expect to continue to incur significant operating losses for the foreseeable future as we continue our R&D 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-6402, MT-8421, and MT-0169. In addition, we expect to incur additional costs associated with continuing to operate as a public company. We anticipate that our expenses will increase substantially if and as we:

- support the PD-L1 program and the ongoing Phase I study for MT-6402;
- support the ongoing Phase I study of MT-8421;
- initiate a Phase I study of MT-0169 in CD38+ hematological malignancies;
- 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; and
- service long-term liability.

Because of the numerous risks and uncertainties associated with the development of MT-6402, MT-8421, and MT-0169 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 amount of increased capital outlays and operating expenses associated with completing the research and development of our ETB candidates. Our future capital requirements for MT-6402, MT-8421, or MT-0169 will depend on many factors, including:

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

- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our ETB candidates, if approved.

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

***Going Concern and Liquidity***

Management has identified certain conditions or events, which, when considered in the aggregate, raise substantial doubt as to our ability to continue as a going concern. We have not yet established an ongoing source of revenues sufficient to cover our operating and capital expenditure requirements and to cover any potential payments that may become due and payable pursuant to the CVR Agreement to provide sufficient certainty that we will continue as a going concern. Based on our unrestricted cash and cash equivalents as of December 31, 2023 (approximately $11.5 million), we anticipate that we will be able to fund our planned operating expenses and capital expenditure requirements to the end of the second quarter of 2024. If we are able to complete the Second Closing, we anticipate that we will be able to fund our planned operating expenses and capital expenditure requirements to the end of the fourth quarter of 2024.

Our financial statements are prepared using U.S. GAAP applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. As noted above, we have not yet established an ongoing source of revenues sufficient to cover our operating costs or potential obligations pursuant to the CVR Agreement to provide sufficient certainty that we will continue as a going concern. If we are unable to obtain additional funding on acceptable terms when and as needed, we may be forced to delay or reduce the scope of our commercial and sales activities, extend payment terms with suppliers, liquidate assets where possible at a potentially lower amount than as recorded in our financial statements, further curtail planned operations or cease operations entirely and wind down our business. Any of these could materially and adversely affect our liquidity, financial condition and business prospects and, as a result, our stockholders may not receive full value, or may receive no value, for their investment.

***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 R&D 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.

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 our 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 R&D 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, 2023, included in this Annual Report on Form 10-K.

***Research and Development Expenses***

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

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

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

***Income Taxes***

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***

We account 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, the 2014 Equity Incentive Plan, as amended, and the 2004 Amended and Restated Equity Incentive Plan, by estimating the fair value of each stock option or award on the date of grant using the Black-Scholes model. We recognize stock-based compensation expense on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period.

***Contingent Value Right Liability Valuation***

We account for the contingent value right as a derivative liability based on the terms of the contract, which is dependent upon an exercise and/or occurrence of future events. As the contingent value right derivative liability is not designated nor qualifies as a hedging instrument, remeasurement of the derivative liability subsequent to initial recognition is recorded to earnings.

We initially measured the contingent value right liability at fair value. The fair value of such contingent value right, included as contingent value right liability on the consolidated balance sheet, is derived using a probability weighted expected return method approach. Estimates and assumptions used in the probability weighted expected return method approach include probabilities related to the timing and outcome of future financing and/or liquidity events. These unobservable inputs represent a Level 3 measurement because they are supported by little or no market activity and reflect our own assumptions in measuring fair value.

We reassess the fair value of contingent value right liability on a quarterly basis. Changes in the fair value of contingent value right liability subsequent to the initial measurement date are recognized as a change in valuation of contingent value right liability in our consolidated statements of operations.

***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, 2023, included in this Annual Report on Form 10-K.

***Off-Balance Sheet Arrangements***

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

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS**

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

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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

**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, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

**The Company's Ability to Continue as a Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has a lack of revenue from product sales and has suffered recurring losses from operations since inception and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

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

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

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

**Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion

on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

***Progress Toward Completion of Collaboration Agreements***

*Description of the Matter*

As discussed in Note 1 and 3 to the consolidated financial statements, the Company recognizes revenue arising from collaboration agreements. Revenue generated from the Company's collaboration agreements relates to research and development services whereby revenue is recognized under an input method using the ratio of costs incurred to date compared to the total estimated costs required to complete the performance obligation. For the year ended December 31, 2023, the Company has recognized $52.6 million in research and development revenue.

Auditing the progress toward completion of collaboration agreements was especially challenging because it involves subjective management assumptions about estimating the remaining research and development costs necessary to satisfy a performance obligation. The calculation of the total remaining estimated research and development cost includes forecasted costs associated with internal employee efforts, materials costs, and third-party contract costs, as well as the assumed timing and duration of these activities. The recognition of revenue pursuant to collaboration arrangements is subject to these estimates and judgments developed by management and is sensitive to changes in these assumptions.

*How We Addressed the Matter in Our Audit*

To test the progress toward completion of collaboration agreements, we performed audit procedures that included, among others, reading the collaboration agreements and testing the accuracy and completeness of the underlying data used in evaluating the estimates and significant judgments described above. To assess the reasonableness of the Company's significant estimates and judgments, we corroborated management estimates and judgments by performing sensitivity analyses of key inputs, comparing cost estimates to costs previously incurred for similar activities, inspecting communications between the Company and its collaborators regarding updates to estimated budgeted costs, evaluating the remaining level of effort required to complete the agreement, and inspecting evidence of actual costs incurred. We also discussed the basis for key assumptions with the Company's research and development personnel, who oversee the completion of the collaboration arrangements.

/s/ Ernst & Young LLP

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

Austin, Texas
March 29, 2024

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

| | December 31, 2023 | December 31, 2022 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $ 11,523 | $ 32,190 |
| Marketable securities, current | — | 28,859 |
| Prepaid expenses | 2,195 | 3,459 |
| Grants revenue receivable | 250 | — |
| Other current assets | 2,804 | 3,790 |
| Total current assets | 16,772 | 68,298 |
| Operating lease right-of-use assets | 9,161 | 11,132 |
| Property and equipment, net | 7,393 | 14,632 |
| Other assets | 2,057 | 3,486 |
| Total assets | $ 35,383 | $ 97,548 |
| LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT) | | |
| Current liabilities: | | |
| Accounts payable | $ 1,523 | $ 504 |
| Accrued liabilities | 4,279 | 8,823 |
| Deferred revenue, current | 9,031 | 45,573 |
| Other current liabilities | 2,488 | 2,182 |
| Total current liabilities | 17,321 | 57,082 |
| Deferred revenue, long-term | — | 5,904 |
| Long-term debt, net of current portion | — | 36,168 |
| Operating lease liabilities, long term portion | 9,742 | 12,231 |
| Contingent value right liability | 2,702 | — |
| Other liabilities | 1,406 | 1,295 |
| Total liabilities | 31,171 | 112,680 |
| Commitments and contingencies (Note 10) | | |
| Stockholders' equity/(deficit) | | |
| Preferred stock, $0.001 par value per share: | | |
| Authorized: 2,000,000 shares as of December 31, 2023 and 2022; Issued and outstanding: 250 shares as of December 31, 2023 and 2022 | — | — |
| Common stock, $0.001 par value per share: | | |
| Authorized: 150,000,000 shares as of December 31, 2023 and 2022; Issued and outstanding: 5,374,268 shares as of December 31, 2023 and 3,756,711 shares as of December 31, 2022[1] | 5 | 4 |
| Additional paid-in capital[1] | 457,099 | 429,698 |
| Accumulated other comprehensive loss | — | (66) |
| Accumulated deficit | (452,892) | (444,768) |
| Total stockholders' equity/(deficit) | 4,212 | (15,132) |
| Total liabilities and stockholders' equity/(deficit) | $ 35,383 | $ 97,548 |

1. Prior period amounts have been retrospectively adjusted for the 1-for-15 reverse stock split that was effective August 11, 2023 (see Note 1).

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

**MOLECULAR TEMPLATES, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**
**(in thousands, except share and per share data)**

| | Year Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Research and development revenue | $ 52,625 | $ 19,754 |
| Grant revenue | 4,681 | — |
| Total revenue | 57,306 | 19,754 |
| Operating expenses: | | |
| Research and development | 48,875 | 82,425 |
| General and administrative | 18,897 | 26,200 |
| Total operating expenses | 67,772 | 108,625 |
| Loss from operations | 10,466 | 88,871 |
| Interest and other income, net | 1,208 | 988 |
| Interest and other expense, net | (2,654) | (4,716) |
| Gain on extinguishment of debt | 1,795 | — |
| Change in valuation of contingent value right (Note 4) | 2,457 | — |
| Loss on disposal of property and equipment | (475) | (66) |
| Loss before provision (benefit) for income taxes | 8,135 | 92,665 |
| Provision (benefit) for income taxes | (11) | 53 |
| Net loss attributable to common shareholders | $ 8,124 | $ 92,718 |
| Net loss per share attributable to common shareholders: | | |
| Basic and diluted | $ 1.80 | $ 24.69 |
| Weighted average number of shares used in net loss per share calculations: | | |
| Basic and diluted | 4,501,206 | 3,755,564 |

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

**MOLECULAR TEMPLATES, INC.**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**
**(in thousands, except share and per share data)**

| | Year Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| **Net loss** | $ 8,124 | $ 92,718 |
| **Other comprehensive loss:** | | |
| Unrealized gain/(loss) on available-for-sale securities | 66 | (18) |
| **Comprehensive loss** | $ 8,058 | $ 92,736 |

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

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

| | Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital[1] | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares[1] | Amount[1] | | | | |
| Balances, December 31, 2021 | 250 | $ — | 3,753,606 | $ 4 | $ 417,756 | $ (48) | $ (352,050) | $ 65,662 |
| Issuance of common stock pursuant to stock plans | — | — | 3,105 | — | 33 | — | — | 33 |
| Stock-based compensation | — | — | — | — | 11,909 | — | — | 11,909 |
| Other comprehensive loss | — | — | — | — | — | (18) | — | (18) |
| Net loss | — | — | — | — | — | — | (92,718) | (92,718) |
| Balances, December 31, 2022 | 250 | — | 3,756,711 | 4 | 429,698 | (66) | (444,768) | (15,132) |
| Issuance of common stock and prefunded warrants pursuant to private placement, net of issuance costs | — | — | 1,617,365 | 1 | 18,382 | — | — | 18,383 |
| Issuance of common stock pursuant to stock plans | — | — | 192 | — | 1 | — | — | 1 |
| Stock-based compensation | — | — | — | — | 6,702 | — | — | 6,702 |
| Issuance of warrants | | | | | 2,316 | | | 2,316 |
| Other comprehensive income | — | — | — | — | — | 66 | — | 66 |
| Net loss | — | — | — | — | — | — | (8,124) | (8,124) |
| Balances, December 31, 2023 | 250 | $ — | 5,374,268 | $ 5 | $ 457,099 | $ — | $ (452,892) | $ 4,212 |

1. Prior period amounts have been retrospectively adjusted for the 1-for-15 reverse stock split that was effective August 11, 2023 (see Note 1).

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

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

| | Year Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| **Cash flows from operating activities:** | | |
| Net loss | $ 8,124 | $ 92,718 |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation, amortization and other | 6,645 | 7,383 |
| Loss on disposal of property and equipment | 475 | 66 |
| Change in valuation of contingent value right | (2,457) | — |
| Stock-based compensation expense | 6,702 | 11,909 |
| Amortization of debt discount and accretion related to debt | 393 | 975 |
| Impairment of fixed assets and intangibles | — | 430 |
| Gain on extinguishment of debt | (1,795) | — |
| Accretion of asset retirement obligations | 111 | 124 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses | 1,264 | 458 |
| Grants revenue receivable | (250) | — |
| Other assets | 1,190 | (438) |
| Operating lease right-of-use assets and liabilities | (212) | (550) |
| Accounts payable | 1,019 | (1,108) |
| Accrued liabilities | (4,335) | (745) |
| Deferred revenue | (42,446) | (14,810) |
| Net cash used in operating activities | (41,820) | (89,024) |
| **Cash flows from investing activities:** | | |
| Purchases of property and equipment | (200) | (3,198) |
| Proceeds from sale of equipment | 260 | — |
| Purchase of marketable securities | (2,365) | (55,525) |
| Sales of marketable securities | 31,400 | 154,040 |
| Net cash provided by investing activities | 29,095 | 95,317 |
| **Cash flows from financing activities:** | | |
| Proceeds from issuance of common stock and prefunded warrants, net offering expenses | 18,383 | — |
| Repayment of long-term debt | (27,500) | — |
| Proceeds from stock option exercises | 1 | 33 |
| Fees paid on loan modification | — | (298) |
| Net cash used in financing activities | (9,116) | (265) |
| Net (decrease)/increase in cash, cash equivalents, and restricted cash | (21,841) | 6,028 |
| Cash, cash equivalents and restricted cash, beginning of period | 34,679 | 28,651 |
| Cash, cash equivalents and restricted cash, end of period | $ 12,838 | $ 34,679 |
| **Reconciliation of cash, cash equivalents and restricted cash** | | |
| Cash and cash equivalents | $ 11,523 | $ 32,190 |
| Restricted cash included in Other assets | 1,315 | 2,489 |
| Total cash, cash equivalents and restricted cash | $ 12,838 | $ 34,679 |
| **Supplemental Cash Flow Information** | | |
| Cash paid for interest | $ 2,293 | $ 3,495 |
| Non-cash right-of-use asset obtained in exchange for operating lease obligation | $ — | $ 4,517 |
| **Non-Cash Investing and Financing Activities** | | |
| Fixed asset additions in accounts payable and accrued expenses | $ — | $ 53 |

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

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

## NOTE 1—ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

***Organization and Nature of the Business***

Molecular Templates, Inc. (the "Company") is a clinical stage biopharmaceutical company formed in 2001, with a biologic therapeutic platform for the development of novel targeted therapeutics for cancer, 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").

***Basis of Presentation***

The accompanying audited consolidated financial statements have been prepared in accordance with U.S. GAAP and include the accounts of the Company and its wholly owned subsidiary and reflect the elimination of intercompany accounts and transactions.

***Reverse Stock Split***

On August 11, 2023, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Amended and Restated Certificate of Incorporation to effect a one-time reverse stock split of the Company's common stock, at a ratio of 1-for-15 (the "Reverse Stock Split"). The Reverse Stock Split was effective at 5 p.m. Eastern Time, after the close of trading on the Nasdaq Capital Market, on August 11, 2023 (the "Effective Time"). At the Effective Time, every 15 shares of the Company's issued and outstanding common stock were automatically converted into one share of common stock, without any change in the par value per share. Any stockholder who was entitled to a fractional share of common stock created as a result of the Reverse Stock Split received a cash payment in lieu thereof equal to the fractional share to which the stockholder was entitled multiplied by the closing sales price of a share of common stock on August 11, 2023, as adjusted for the Reverse Stock Split. All common stock, per share and related information presented in the condensed consolidated financial statements and notes prior to the Reverse Stock Split have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented, to the extent applicable.

***Going Concern***

The Company has adopted as required the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40, Presentation of Financial Statements - Going Concern, which requires that management contemplate the realization of assets and liquidation of liabilities in the normal course of business, and evaluate whether there are relevant conditions and events that in the aggregate raise substantial doubt about the entity's ability to continue as a going concern and to meet its obligations as they become due within one year after the date that the financial statements are issued. Under this standard, management's assessment shall not take into consideration the potential mitigating effects of management's plans that have not been fully implemented as of the date the financial statements are issued.

As of December 31, 2023, the Company had an accumulated deficit of $452.9 million and had unrestricted cash and cash equivalents of $11.5 million. Based on the Company's unrestricted cash and cash equivalents as of December 31, 2023, management anticipates that the Company will be able to fund its planned operating expenses and capital expenditure requirements to the end of the second quarter of 2024. The Company has not yet established an ongoing source of revenues sufficient to cover its operating and cash expenditure requirements or to cover any potential payments that may become due and payable pursuant to the CVR Agreement as described in Note 8, "Borrowing Arrangements and Debt Extinguishment" to provide sufficient certainty that it will continue as a going concern. For these reasons, there is substantial doubt about the Company's ability to continue as a going concern as of the issuance of these financial statements.

Historically, the Company financed its operations to date primarily through partnerships, funds received from public offerings of common and preferred stock, private placements of equity securities, a reverse merger, upfront and milestone payments received from its prior and current collaboration agreements, a debt financing facility, as well as funding from governmental bodies and bank and bridge loans. The Company plans to address this condition through the sale of common stock in public offerings and/or private placements, debt financings, or through other capital sources, including collaborations with other companies or other strategic transactions, but there is no assurance these plans will be completed successfully or at all.

If the Company is unable to obtain additional capital when and as needed to continue as a going concern, it might have to further reduce or scale back its operations, cease operations entirely, and/or liquidate its assets, and the values it receives for its assets in liquidation or dissolution could be significantly lower than the values reflected in its financial statements.

These financial statements do not give effect to any adjustments which will be necessary should the Company be unable to continue as a going concern and therefore be required to realize its assets and discharge its liabilities in other than the normal course of business and at amounts different from those reflected in the accompanying financial statements.

***Reclassifications***

The preparation of consolidated financial statements requires management to make estimates and assumptions that affect the recorded amounts reported therein. A change in facts or circumstances surrounding the estimates could result in a change to estimates and impact future operating results. Certain accounts in the prior financial statements have been reclassified for comparative purposes to conform to the presentation in the current financial statements. These reclassifications have no material effect on previously reported financials. In the opinion of management of the Company, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation have been included. In the Consolidated Statement of Cash Flows, the presentation of Interest due on long-term debt was reclassified from non-cash adjustments in the prior year presentation to Accrued liabilities in the current year presentation. In addition, in the Consolidated Statements of Operations, the loss on disposal of property and equipment was included in interest and other expense, net in prior year presentation.

***Accounting Estimates***

The preparation of financial statements in conformity with U.S. GAAP as defined by the FASB 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 $1.3 million and $2.5 million of restricted cash as of December 31, 2023 and 2022, respectively, related to letters of credit in lieu of a cash deposit for the Company’s leases.

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

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

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

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

The Company utilizes the market approach or probability 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. Level 3 securities utilize a probability weighted expected return method or Black-Scholes option-pricing model. Significant estimates and assumptions required for these valuations include, but are not limited to, probabilities related to the timing and outcome of future financing and/or liquidity events. These unobservable inputs represent a Level 3 measurement because they are supported by little or no market activity and reflect our own assumptions in measuring fair value.

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

The Company performs an ongoing credit evaluation of its strategic partners' financial conditions and generally does not require collateral to secure accounts receivable from its strategic partners. As of December 31, 2023, the Company's exposure to credit risk associated with non-payment will be affected principally by conditions or occurrences within Bristol-Myers Squibb Company ("Bristol-Myers Squibb"). In past years, the Company's exposure to credit risk associated with non-payment were also affected principally by conditions or occurrences within Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Ltd ("Takeda"). Takeda accounted for approximately 0% and 13% of total revenues for the years ended December 31, 2023 and 2022, respectively. Bristol-Myers Squibb accounted for approximately 92% and 87% of total revenues for the years ended December 31, 2023 and 2022, respectively.

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

***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 three to five 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 $0.6 million and $0.7 million as of December 31, 2023 and 2022, respectively, and are recorded in Other assets. The Company recorded $0.1 million of amortization expense for both the years ended December 31, 2023 and 2022, with estimated expense to remain $0.1 million for each of the five successive years subsequent to December 31, 2023. For the years ended December 31, 2023 and 2022, the Company recorded impairments of zero and $0.4 million, respectively, related to patents, which is recorded in general and administrative expenses.

***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 had no material impairments recorded for the years ended December 31, 2023 and 2022.

***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 collaboration 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.

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***

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 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 its incremental borrowing rate in determining the present value of lease payments. Right-of-use assets ("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.

***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. 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 the Securities and Exchange Commission (the "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*" and ASC 815, "*Derivatives and Hedging*," that clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock. For warrants classified as equity, the Company records the value of the warrants in additional paid-in capital on the balance sheet.

***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 ("CROs"), clinical trial sites, laboratories, other clinical service providers and contract manufacturing organizations ("CMOs"). 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 CROs and/or clinical investigators, and clinical supplies are manufactured by 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 as well as management's best estimate 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.

***Recently Issued Accounting Pronouncements***

In August 2020, the FASB issued ASU No. 2020-06, "Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" (Subtopic 470-20: Debt with Conversion and Other Options and Subtopic 815-40: Derivatives and Hedging - Contracts in Entity's Own Equity). The new guidance simplifies accounting for convertible instruments by removing major separation models, removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. The amendment is effective for the Company for fiscal years beginning after December 15, 2023. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, "Improvements to Income Tax Disclosures" (Topic 740: Income Taxes). The new guidance requires that public entities disclose more consistent categories and greater disaggregation of information in the income tax rate reconciliations and further disaggregate income taxes paid by jurisdiction. The amendment is effective for the Company for fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

**NOTE 2—NET LOSS PER COMMON SHARE**

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period utilizing the two-class method. Preferred stockholders participate equally with common stock stockholders 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, as of December 31, 2023 and 2022, stock options, warrants, convertible common shares related to the Conversion Right, as defined in the CVR Agreement, and described in Note 4, "Fair Value Measurements," and, if converted, preferred stock totaling approximately 2,500,000 and 789,000 common stock, respectively, were excluded from the computation of diluted net loss per share as their effect would have been anti-dilutive.

## NOTE 3 — RESEARCH AND DEVELOPMENT AGREEMENTS

***Disaggregated Research and Development Revenue***

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

| | Year Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| United States | $ 52,625 | $ 17,168 |
| Japan | — | 2,586 |
| Total research and development revenue | $ 52,625 | $ 19,754 |

***Collaboration Agreements***

***Bristol-Myers Squibb Collaboration Agreement***

In February 2021, the Company entered into a Collaboration Agreement, as amended (the "BMS Collaboration Agreement"), with Bristol-Myers Squibb Company ("Bristol-Myers Squibb") to perform strategic research collaboration leveraging the Company's engineered toxin body ("ETB") technology platform to discover and develop novel products containing ETBs directed to multiple targets. On March 15, 2024, Bristol-Myers Squibb notified the Company on March 13, 2024 that it does not intend to continue the research collaboration it entered into with the Company pursuant to the BMS Collaboration Agreement and would be terminating the BMS Collaboration Agreement in its entirety. The termination will be effective on June 13, 2024, or 90 days following the Company's receipt of Bristol-Myers Squibb's written notice of termination.

Pursuant to the terms of the BMS Collaboration Agreement, the Company granted Bristol-Myers Squibb a series of exclusive options to obtain one or more exclusive licenses under the Company's intellectual property to exploit products containing ETBs directed against certain targets designated by Bristol-Myers Squibb.

Bristol-Myers Squibb paid the Company an upfront payment of $70.0 million. In addition to the upfront payment, the Company would have been eligible to receive near term and development and regulatory milestone payments of up to $874.5 million. The Company would also have been eligible to receive up to an additional $450.0 million in payments upon the achievement of certain sales milestones, and subject to certain reductions, tiered royalties ranging from mid-single digits up to mid-teens as percentages of calendar year net sales, if any, on any licensed product.

The Company would have been responsible for conducting the research activities through the designation, if any, of one or more development candidates. Upon the exercise of its option for a development candidate, Bristol-Myers Squibb would have been responsible for all development, manufacturing, regulatory and commercialization activities with respect to that development candidate, subject to the terms of the BMS Collaboration Agreement.

Unless earlier terminated, the BMS Collaboration Agreement would expire (i) on a country-by-country basis and licensed product-by-licensed product basis, on the date of expiration of the royalty payment obligations under the BMS Collaboration Agreement with respect to such licensed product in such country and (ii) in its entirety upon the earlier of (a) the expiration of the royalty payment obligations under the BMS Collaboration Agreement with respect to all licensed products in all countries or (b) upon Bristol-Myers Squibb's decision not to exercise any option on or prior to the applicable option deadlines. Bristol-Myers Squibb had the right to terminate the BMS Collaboration Agreement for convenience upon prior written notice to the Company. Either party had the right to terminate the BMS 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 had the right upon prior written notice to terminate the BMS Collaboration Agreement in the event that Bristol-Myers Squibb or any of its affiliates asserts a challenge against the Company's patents.

The Company identified multiple performance obligations at the inception of the BMS Collaboration Agreement consisting of research and development services and material rights related to additional developmental targets. The transaction price of $70.0 million was allocated to the performance obligations based upon their relative stand-alone selling price and was recognized over time as the underlying research and development services are performed.

The Company recognized revenue for research and development services under the BMS Collaboration Agreement using a cost-based input measure. In applying the cost-based input method of revenue recognition, the Company would use actual costs incurred relative to budgeted costs expected to be incurred. These costs consisted primarily of internal employee efforts and third-party contract costs. Revenue was recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completed its performance obligation over the estimated service period.

For the years ended December 31, 2023 and 2022, the Company recognized $52.6 million and $17.2 million, respectively, of research and development revenue related to the BMS Collaboration Agreement, which was primarily related to the completion of the research program for one of the collaboration's targets and the completion of the related performance obligation by the Company under the BMS Collaboration Agreement, resulting in recognition of $25.8 million of research and development revenue in the quarter ended March 31, 2023.

The Company had $9.0 million and $45.3 million of deferred revenue, current as of December 31, 2023 and 2022, respectively, related to the BMS Collaboration Agreement. The Company had zero and $5.9 million of deferred revenue, non-current, as of December 31, 2023 and 2022, respectively, related to the BMS Collaboration Agreement.

***Takeda Multi-Target Agreement***

In June 2017, the Company entered into a Multi-Target Collaboration and License Agreement (the "Takeda Multi-Target Agreement") with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda ("Takeda"), in which the Company agreed to collaborate with Takeda to identify and generate ETBs, against two targets designated by Takeda. In March 2022, following the Company's request to bring the agreement to an end, the Company and Takeda mutually agreed to terminate the Takeda Multi-Target Agreement. As a result of the termination, the Company regained full rights to pursue the targets worked on under the Takeda Multi-Target Agreement. There are no ongoing activities or economic obligations in connection with the Takeda Multi-Target Agreement.

For the years ended December 31, 2023 and 2022, the Company recognized zero and $2.6 million, respectively, as research and development revenue, related to the Takeda Multi-Target Agreement. As of December 31, 2023 and 2022, there was no deferred revenue related to the performance obligation.

***Grant Agreements***

In September 2018, the Company entered into a Cancer Research Agreement (the "CD38 CPRIT Agreement") with the Cancer Prevention and Research Institute of Texas ("CPRIT") which was extended in September 2023, under which CPRIT awarded a $15.2 million product development grant to fund research of a cancer therapy involving a CD38 targeting ETB. As of December 31, 2023, the Company has cumulatively recognized $14.1 million of grant revenue related to the CD38 CPRIT Agreement. 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.

For the years ended December 31, 2023 and 2022, the Company recognized grant revenue under this award of $4.7 million and zero, respectively. Qualified expenditures submitted for reimbursement in excess of amounts received are recorded as receivables in grant revenue receivable. As of December 31, 2023 and 2022, the Company recorded grant revenue receivable of $0.3 million and zero, respectively. As of December 31, 2023 and 2022, the Company recorded deferred revenue of zero and $0.2 million, respectively.

**NOTE 4—FAIR VALUE MEASUREMENTS**

The following table sets forth the Company's financial assets (cash equivalents and marketable securities) at fair value on a recurring basis (in thousands) as of December 31, 2023 and 2022:

| | | Basis of Fair Value Measurements | | |
|---|---|---|---|---|
| | December 31, 2023 | Level 1 | Level 2 | Level 3 |
| Money market funds | $ 11,395 | $ 11,395 | $ — | $ — |
| Total | $ 11,395 | $ 11,395 | $ — | $ — |
| Amounts included in: | | | | |
| Cash and cash equivalents | $ 11,395 | | | |
| Total cash equivalents | $ 11,395 | | | |

| | | Basis of Fair Value Measurements | | |
|---|---|---|---|---|
| | December 31, 2022 | Level 1 | Level 2 | Level 3 |
| Money market funds | $ 24,546 | $ 24,546 | $ — | $ — |
| Commercial paper | 21,134 | — | 21,134 | — |
| United States Treasury Bills | 10,702 | — | 10,702 | — |
| Cash | 2,500 | 2,500 | — | — |
| Total | $ 58,882 | $ 27,046 | $ 31,836 | $ — |
| Amounts included in: | | | | |
| Cash and cash equivalents | $ 30,023 | | | |
| Marketable securities, current | 28,859 | | | |
| Total cash equivalents and marketable securities | $ 58,882 | | | |

The Company invests in highly-liquid, investment-grade securities. The following is a summary of the Company's available-for-sale securities (in thousands) as of December 31, 2023 and 2022:

| | December 31, 2023 | | | |
|---|---|---|---|---|
| | Cost Basis | Unrealized Gain | Unrealized Loss | Fair Value |
| Cash equivalents - money market funds | $ 11,395 | $ — | $ — | $ 11,395 |

| | December 31, 2022 | | | |
|---|---|---|---|---|
| | Cost Basis | Unrealized Gain | Unrealized Loss | Fair Value |
| Cash equivalents - money market funds, commercial paper | $ 30,022 | $ 1 | $ — | $ 30,023 |
| Marketable securities, current - commercial paper, Treasury bills | 28,926 | — | (67) | 28,859 |

As of both December 31, 2023 and 2022, all of the Company's available-for-sale investments were due in one year or less.

The Company received no proceeds from the sale of available-for-sale securities for both of the years ended December 31, 2023 and 2022, with no realized gain for both of the years ended December 31, 2023 and 2022. The basis on which the cost of the security sold was determined is by specific share identification.

***Contingent Value Right and Common Stock Warrant Valuation***

On June 16, 2023, the Company entered into a Convertible Secured Contingent Value Right Agreement (the "CVR Agreement") with K2 HealthVentures LLC ("K2HV"), as further described in Note 8, "Borrowing Arrangements

and Debt Extinguishment." ASC 815 "Derivatives and Hedging" requires the Conversion Right, as defined in the CVR Agreement, and Contingent Value Right, as defined in the CVR Agreement, to be accounted for as liabilities and changes to their fair value recognized in the condensed consolidated statement of operations. The Conversion Right and Contingent Value Right liability will be remeasured each reporting period. The Company utilized a probability weighted expected return method to value the Conversion Right and Contingent Value Right liability (collectively, the "CVR"). The CVR was split into two components: (a) the Conversion Right of the holder to convert $3.0 million of the Remaining Value into shares and (b) the Contingent Value Right liability. Various payoff scenarios were projected and weighted to determine the payoff of the CVR. Within each scenario, the stock price at each event was forecasted to determine if K2VH would convert $3.0 million of the Remaining Value, as defined below, into shares of the Company's common stock. If K2HV elected to convert any amount up to $3.0 million into shares of the Company's common stock, then the value of the Conversion Right was the expected stock price times the number of conversion shares; otherwise, the value was determined to be zero. The Contingent Value Right liability component was calculated as the Remaining Value less $3.0 million conversion amount if converted at the time of the event, discounted back to present value. As of June 16, 2023, the value of the Conversion Right and Contingent Value Right liability were calculated within each scenario and probability weighted to derive the total fair value of the Conversion Right and the Contingent Value Right liability was $3.3 million and $1.9 million, respectively. As of December 31, 2023, the fair value of the Conversion Right and the Contingent Value Right liability was $1.5 million and $1.2 million, respectively. For the year ended December 31, 2023, the change in fair value related to the Conversion Right and Contingent Value Right liability was $1.8 million and $0.7 million, respectively.

The following table sets forth the Company's financial liabilities (convertible secured contingent value right) at fair value on a recurring basis (in thousands):

| | | Basis of Fair Value Measurements | | |
|---|---|---|---|---|
| | December 31, 2023 | Level 1 | Level 2 | Level 3 |
| Conversion right and contingent value right | $ 2,702 | $ — | $ — | $ 2,702 |
| Total | $ 2,702 | $ — | $ — | $ 2,702 |

In satisfaction of its obligations to issue the warrant to K2HV's affiliated holder pursuant to the CVR Agreement, the Company issued a warrant to purchase up to 340,222 shares of the Company's common stock at an exercise price of $5.8785 per share. The warrant has a term of 10 years. The Company accounted for its common stock warrants under the guidance in ASC 480, "Distinguishing Liabilities from Equity" and ASC 815, "Derivatives and Hedging," that clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock. The warrants were classified as equity and were fair valued as the date of the transaction. The fair value of these warrants was determined using a Black-Scholes option-pricing model with the following key inputs:

| | June 16, 2023 |
|---|---|
| Risk-free interest rate | 3.77 % |
| Expected term (in years) | 10.0 |
| Dividend yield | — |
| Volatility | 80.00 % |
| Stock price | $ 0.53 |

On June 16, 2023, the Company determined the fair value of the warrants to be $2.3 million and classified that amount to additional paid in capital.

**NOTE 5—PROPERTY AND EQUIPMENT**

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

| | December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Laboratory equipment | $ 20,695 | $ 21,831 |
| Leasehold improvements | 12,974 | 12,971 |
| Furniture and fixtures | 518 | 518 |
| Computer and equipment | 254 | 658 |
| | 34,441 | 35,978 |
| Less: Accumulated depreciation | (27,048) | (21,346) |
| Total property and equipment, net | $ 7,393 | $ 14,632 |

Depreciation expense was $6.7 million and $7.7 million for the years ended December 31, 2023 and 2022, respectively.

In connection with the continued expansion of the Company's facilities, as of December 31, 2023 and 2022, the Company had net Asset Retirement Obligation ("ARO") assets totaling $0.2 million and $0.3 million, respectively. The ARO assets are included in Leasehold improvements. For the years ended December 31, 2023 and 2022, the Company recorded a non-cash adjustment related to the ARO assets of zero and $0.2 million, respectively. See Note 9, "Leases" for further discussion.

**NOTE 6—BALANCE SHEET COMPONENTS**

Accrued liabilities comprise the following (in thousands):

| | December 31, 2023 | December 31, 2022 |
|---|---|---|
| Accrued liabilities: | | |
| General and administrative | $ 225 | $ 855 |
| Clinical trial related costs | 3,574 | 1,327 |
| Non-clinical research and manufacturing operations | 404 | 1,779 |
| Payroll related | 60 | 4,828 |
| Other accrued expenses | 16 | 34 |
| Total Accrued liabilities | $ 4,279 | $ 8,823 |

**NOTE 7 — RELATED PARTY TRANSACTIONS**

***Takeda***

In connection with the Takeda Multi-Target Agreement described in Note 3, "Research and Development Agreements," Takeda became a related party following the Takeda Stock Purchase Agreement, as described in Note 11, "Stockholders' Equity (Deficit)." In August 2021, Takeda ceased to be a related party after a sale of the above-mentioned shares.

**NOTE 8 — BORROWING ARRANGEMENTS AND DEBT EXTINGUISHMENT**

***K2 HealthVentures Loan and Security Agreement***

In May 2020, the Company entered into a Loan and Security Agreement with K2HV (the "K2 Loan and Security Agreement") in the amount of $45.0 million. The K2 Loan and Security Agreement was drawable in three tranches and the Company had drawn down $35.0 million with the remaining tranche of $10.0 million having lapsed as of December 31, 2021. Pursuant to the terms of the K2 Loan and Security Agreement, the principal accrued interest at an

annual rate equal to the greater of 8.45 % or the sum of the Prime Rate plus 5.2%. In April 2022, the K2 Loan and Security Agreement was amended in exchange for a $0.3 million amendment fee so that (i) payments would be interest only until the loan's maturity date of June 1, 2024, and (ii) the Financial Covenant would apply for the entire term of the K2 Loan and Security Agreement. This amendment resulted in a debt modification with the $0.3 million amendment fee recorded as a debt discount.

On June 16, 2023, the Company entered into the CVR Agreement with K2HV to fully discharge and satisfy the Company's outstanding loan obligations under the K2 Loan and Security Agreement, and to terminate the K2 Loan and Security Agreement, in exchange for an aggregate repayment in cash of $27.5 million, the granting of a contingent value right to K2HV, and the issuance of a warrant to purchase shares of common stock to K2HV's affiliated holder. These contingent value rights require payments to K2HV if certain Contingent Payment Events, as defined in the CVR Agreement, occur, or if there is an Acceleration Event, as defined in the CVR Agreement. The payment due upon any Contingent Payment Event or an Acceleration Event is capped at an amount (the "Remaining Value") which is initially $10,303,646, which amount, to the extent not repaid is subject to escalating multipliers which increases from the closing date by multiplying the Remaining Value by a multiplier ranging between 1.0 at closing to 2.5x for any Remaining Value not yet paid as of September 16, 2024, resulting in a potential maximum payment obligation of $25,759,115. In addition, upon a Change in Control, as defined in the CVR Agreement, the Company is required to pay an additional payment of $2,500,000.

For Contingent Payment Events, the Company must pay K2HV either a specified percentage of the proceeds received, up to an amount equaling the applicable Remaining Value, 50% of such Remaining Value, or 100% of the Remaining Value, depending on the Contingent Payment Event which occurred. Upon the occurrence and continuation of any Acceleration Event, the applicable Remaining Value shall, at the election of K2HV, be due and payable in full. The Company may at any time elect to repay some or all of the Remaining Value without penalty. In lieu of a portion of these contingent value rights, K2HV may convert up to $3,000,000 of the Remaining Value into an aggregate of 408,267 shares of common stock, subject to adjustment for any stock splits and similar events so long as the number of shares of common stock underlying such conversion right, together with the shares of common stock underlying the warrants described below, do not exceed 19.99% of the number of shares of common stock outstanding immediate prior to the execution of the CVR Agreement.

In satisfaction of its obligations to issue the warrant to K2HV's affiliated holder pursuant to the CVR Agreement, the Company issued a warrant to purchase up to 340,222 shares of the Company's common stock at an exercise price of $5.8785 per share. The warrant has a term of 10 years. To protect its interest in any potential payment of the Remaining Value, K2HV has a security interest in, subject to certain limited exceptions, all assets (including intellectual property) of the Company. Further, the Company may not (i) incur any indebtedness for borrowed money that is structured as senior or pari passu to K2HV's outstanding contingent payments without K2HV's consent or (ii) permit any other liens (other than customary permitted liens) on this collateral without K2HV's consent.

In accordance with ASC Topic 740-50, "Debt – Modifications and Extinguishments," the transaction noted above was determined to be an extinguishment of the existing long-term debt. As a result, the Company recorded a gain on the extinguishment of long-term debt in the amount of $1.8 million in the line item "Gain on the extinguishment of debt" in the condensed consolidated statement of operations.

**NOTE 9 – LEASES**

The Company has operating leases for administrative offices and research and development facilities, and certain finance leases for equipment. The operating leases have remaining terms of less than three years to less than six 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. Certain leases include options to renew, with renewal terms that can extend the lease term for seven years. The exercise of lease renewal options for the Company's existing leases is at the Company's sole discretion and not included in the measurement of lease liability and right-of-use asset as they are not reasonably certain to be exercised. Certain finance leases also include options to purchase the leased equipment. The depreciable life of assets and leasehold

improvements are limited by the expected lease term, unless there is a transfer of title or purchase option reasonably certain of exercise. The leases do not contain any residual value guarantees or material restrictive covenants.

In July 2022, the Company exercised its option to extend the term for its lease of its principal executive office at 9301 Amberglen Blvd, Building J, Austin TX 78729 (the "Property") for an additional five-year term beginning August 31, 2023 and ending August 31, 2028 pursuant to the terms and conditions of that certain Lease, dated October 1, 2016, by and between the Company and NW Austin Office Partners LLC as previously amended (the "Lease Agreement").

In October 2022, the Company entered into that certain Fourth Amendment to the Lease Agreement, by and between the Company and NW Austin Office Partners LLC (the "Lease Amendment") which amended the Lease Agreement to document the exercise of the Company's option to extend the term of its lease of the Property for an additional six-year term beginning September 1, 2023 and ending August 31, 2029 (the "Extension Term"). Pursuant to the terms of the Lease Amendment, the aggregate commitments will be $6.7 million over the six-year Extension Term and the parties agreed that so long as the Company is not in default an aggregate amount of $0.2 million shall be abated in installments from the monthly lease commitments until exhausted. The Lease Amendment also provides that prior to the expiration of the Extension Term, the Company has the option to extend the Extension Term for an additional period of seven years.

Changes in the carrying amounts of the Company's AROs for the years ended December 31, 2023 and 2022 are shown below (in thousands):

| | 2023 | 2022 |
|---|---|---|
| Balance at beginning of year | $ 1,295 | $ 1,625 |
| Revisions in estimated cash flows | — | (454) |
| Accretion expense | 111 | 124 |
| Balance at end of year | $ 1,406 | $ 1,295 |

For the year ended December 31, 2023, there were no revisions to the original estimated cash flows for the Company's AROs. For the year ended December 31, 2022, in connection with the extension of the lease term for the Property, the original estimated cash flows for the related ARO was reduced by $0.5 million. In addition, resulting from the 2022 change in estimated cash flows, the Company recorded a non-cash adjustment to the remaining ARO asset balance of $0.2 million, which is recorded within Leasehold Improvements, see Note 5, "Property and Equipment." As the reduction of the ARO was greater than the ARO asset balance, the remainder of the non-cash adjustment was recorded to the ROU asset. For the years ended December 31, 2023 and 2022, the Company recorded non-cash adjustment to the ROU assets of zero and $0.3 million, respectively.

As of December 31, 2023 and 2022, the Company did not have any operating and finance leases that have not yet commenced.

The components of lease expense for the years ended December 31, 2023 and 2022 were as follows (in thousands):

| | 2023 | 2022 |
|---|---|---|
| **Operating leases** | | |
| Operating lease expense | $ 2,909 | $ 2,611 |
| Variable lease expense | 553 | 524 |
| Total operating lease expense | $ 3,462 | $ 3,135 |

The following table summarizes the balance sheet classification of leases as of December 31, 2023 (in thousands):

| | | |
|---|---|---|
| **Operating leases** | | |
| Operating lease right-of-use assets | $ | 9,161 |
| | | |
| Operating lease liabilities, current[1] | $ | 2,488 |
| Operating lease liabilities, non-current | | 9,742 |
| Total operating lease liabilities | $ | 12,230 |

1. Included in other current liabilities.

The following table presents other information on leases as of December 31, 2023 and 2022 (in thousands):

| | 2023 | 2022 |
|---|---|---|
| Weighted average remaining lease term, operating leases | 4.65 years | 5.54 years |
| Weighted average discount rate, operating leases | 8.21 % | 8.21 % |

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, 2023 (in thousands):

| | Operating Leases |
|---|---|
| 2024 | $ 3,369 |
| 2025 | 3,299 |
| 2026 | 2,564 |
| 2027 | 2,636 |
| 2028 | 2,148 |
| Thereafter | 724 |
| Total lease payments | 14,740 |
| Less: | |
| Imputed interest | (2,510) |
| Total lease liabilities | $ 12,230 |

Supplemental cash flow information related to the Company's leases were as follows for the years ended December 31, 2023 and 2022 (in thousands):

| | 2023 | 2022 |
|---|---|---|
| Cash paid for amounts included in the measurement of lease liabilities: | | |
| Operating cash flows operating leases | $ 3,288 | $ 3,252 |

**NOTE 10—COMMITMENTS AND CONTINGENCIES**

***Commitments***

The Company has entered into project work orders for each of its clinical trials with CROs 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 zero as of December 31, 2023. 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 biologic candidates. The Company was contractually obligated for up to approximately $32.5 million of future services under these agreements as of December 31, 2023, 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.

The Company has entered into estimated purchase obligations. These estimated purchase obligations total in range from $3.7 million to $4.0 million.

***Contingencies***

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to vendors, suppliers, 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 and may enter in the future 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 (DEFICIT)**

***K2HV CVR Agreement and Related Warrants***

On June 16, 2023, in satisfaction of its obligations to issue the warrant to K2HV's affiliated holder pursuant to the CVR Agreement, as further described in Note 8, "Borrowing Arrangements and Debt Extinguishment," the Company issued a warrant to purchase up to 340,222 shares of the Company's common stock at an exercise price of $5.8785 per share. The warrant is exercisable upon issuance and have a term of ten years. The Company determines whether the warrant should be classified as a liability or equity according to ASC 480, "Distinguishing Liabilities from Equity" and ASC 815, "Derivatives and Hedging." Upon issuance of the outstanding warrants, the Company determined that equity classification was appropriate. For warrants classified as equity, the Company records the value of the warrants in additional paid-in capital on the condensed consolidated balance sheet. As of December 31, 2023, there were 340,222 warrants issued related to the CVR Agreement. On June 16, 2023, the warrant was valued at $2.3 million using a Black-Scholes option-pricing model. The Black-Scholes option-pricing model inputs used were: (i) expected dividend yield of 0%, (ii) expected volatility of 80%, (iii) risk free interest rate of 3.77%, and (iv) expected term of 10.0 years.

***Private Placement and Related Warrants***

On August 1, 2017, the Company entered into a securities purchase agreement with Longitude Venture Partners III, L.P. and certain other accredited investors (the "Longitude Securities Purchase Agreement"), pursuant to which the Company sold an aggregate of 386,204 units (the "Units") having an aggregate purchase price of $40.0 million (the "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 the Company's 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 2017 and June 2017. The purchase price per Unit was $103.5720. The Warrants are exercisable for a period of seven years from the date of their issuance at a per-share exercise price of $102.6345 (which exercise

price shall be payable in cash or through a cashless exercise mechanic), subject to certain adjustments as specified in the Warrants. As of December 31, 2023, there were warrants outstanding under this agreement to purchase 193,093 shares of the Company's 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: (i) expected dividend rate of 0%, (ii) expected volatility of 147%, (iii) risk free interest rate of 2.07%, and (iv) 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 (the "Wedbush Agreement") with Wedbush Securities Inc. ("Wedbush"), which was subsequently amended in December 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 3,862 shares of its common stock (the "Wedbush Warrants"). The Wedbush Warrants are exercisable for a period of seven years from the date of their reissuance at a per-share exercise price of $102.6345 (which exercise price shall be payable in cash or through a cashless exercise mechanic), subject to certain adjustments as specified in the Warrants. As of December 31, 2023, there were Wedbush Warrants outstanding to purchase 3,862 shares of common stock. The Wedbush Warrants were valued at $0.4 million using the Black-Scholes model. The Black-Scholes inputs used were: (i) expected dividend rate of 0%, (ii) expected volatility of 108%, (iii) risk free interest rate of 2.3%, and (iv) expected term of 7.0 years. The warrants were exercisable upon issuance and expire December 1, 2024.

In connection with the execution of the Takeda Multi-Target Agreement, the Company entered into a stock purchase agreement with Takeda (the "Takeda Stock Purchase Agreement"). Pursuant to the Takeda Stock Purchase Agreement, following the consummation of the Private Placement, Takeda purchased 194,866 shares of the Company's common stock, at a price per share of $102.6345, for an aggregate purchase price of $20.0 million.

In November 2019, the Company entered into a Master Collaboration Agreement ("Vertex Collaboration Agreement") with Vertex Pharmaceuticals Incorporated ("Vertex"), In connection with the execution of the Vertex Collaboration Agreement, the Company entered into a stock purchase agreement with Vertex (the "Vertex Stock Purchase Agreement"). Pursuant to the Vertex Stock Purchase Agreement, Vertex purchased 111,111 shares of the Company's common stock, at a price per share of $135.00, for an aggregate purchase price of $15.0 million.

***July 2023 Private Placement and Related Warrants***

On July 12, 2023, the Company entered into a securities purchase agreement (the "July 2023 Purchase Agreement") with certain institutional and accredited investors (the "July 2023 Purchasers") which provides for the private placement (the "July 2023 Private Placement") of shares of the Company's common stock and warrants to purchase shares of the Company's common stock in two tranches, as described below.

The closing of the initial tranche occurred on July 17, 2023 and consisted of the issuance of (i) 1,617,365 shares of the Company's common stock and at a price of $7.05 per share and (ii) pre-funded warrants exercisable for up to 1,222,100 shares of the Company's common stock (the "July 2023 Pre-Funded Warrants"). The price of the July 2023 Pre-Funded Warrants was $7.035 per underlying share of the Company's common stock, and the exercise price for the Pre-Funded Warrants was $0.015 per underlying share. The Company received approximately $20.0 million in gross proceeds in connection with the closing of the initial tranche and net proceeds, following the payment of related offering expenses, of approximately $18.4 million.

The Company has assessed the July 2023 Pre-Funded Warrants for appropriate equity or liability classification. The July 2023 Pre-Funded Warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria.

In addition, the July 2023 Pre-Funded Warrants do not provide any guarantee of value or return and do not provide the warrant holders with the option to settle any unexercised warrants for cash outside of the Company's control. The

July 2023 Pre-Funded Warrants also include a separate provision whereby the exercisability of the warrants may be limited if, upon exercise, the warrant holder or any of its affiliates would beneficially own more than 19.99% of the Company's common stock. The Company valued the pre-funded common stock warrants at issuance, concluding that their sale price approximated their fair value. Accordingly, the July 2023 Pre-Funded Warrants are accounted for as a component of additional paid-in capital at the time of issuance.

For further information regarding the Second Closing of the 2023 Private Placement, please see Note 16, "Subsequent Events" below.

Pursuant to the July 2023 Purchase Agreement, the Company granted to the July 2023 Purchasers certain registration rights, pursuant to which, among other things, the Company agreed to (i) file with the SEC a registration statement on Form S-3 after each of the initial tranche and the second tranche to register for resale the shares of common stock issued (and the shares issuable upon exercise of any pre-funded warrants or Second Closing Warrants issued) in the applicable closing, within 30 calendar days following each closing, and (ii) use its commercially reasonable efforts to have each registration statement declared effective as soon as practicable, and in any event no later than 90 days following the applicable closing date (or 120 days following the applicable closing date if the applicable registration statement is reviewed by the SEC). The registration rights covenants are subject to customary terms and conditions for a transaction of this type, including certain customary cash penalties on the Company for its failure to satisfy specified filing and effectiveness time periods. On August 10, 2023, the Company filed with the SEC a registration statement on Form S-3 (File No. 333-273864) registering for resale up to 2,839,465 shares of the Company's common stock, which consist of 1,617,365 shares of the Company's common stock and 1,222,100 shares of the Company's common stock issuable upon the exercise of the July 2023 Pre-Funded Warrants. Additionally, the July 2023 Purchase Agreement contains customary representations and warranties and agreements of the Company and the July 2023 Purchasers and customary indemnification rights and obligations of the parties. There can be no assurance as to the timing of the closing of the second tranche, or whether the second tranche will close at all. Additionally, there can be no assurance as to whether the proceeds received from the initial tranche, any potential proceeds received in connection with the second tranche, and/or the proceeds from the exercise, if any, of the warrants issued in connection with the July 2023 Private Placement will be sufficient for the Company to maintain compliance with the applicable listing criteria of the Nasdaq Capital Market or will be sufficient for the Company to continue as a going concern.

***Public Offerings***

On September 25, 2018, the Company closed its underwritten public offering (the "2018 Public Offering") of 628,666 shares of its common stock, which included the exercise in full by the underwriters of their option to purchase 82,000 additional shares of common stock, at a price to the public of $82.50 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 460,000 shares of its common stock at a price to the public of $120.00 per share, and 250 shares of newly designated Series A Convertible Preferred Stock ("Series A Preferred Stock") at a price to the public of $8.00 per share. The offering included the exercise in full by the underwriters of their option to purchase up to 60,000 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 approximately 66 shares of the Company's common stock, provided that the holder of Series A Preferred Stock will be prohibited from converting the Series A Preferred Stock into shares of the Company's 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 $0.02 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. Holders of 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 beneficial conversion feature ("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.

In July 2020, the Company raised gross proceeds of approximately $50.0 million and net proceeds of $48.5 million through at-the-market sales ("ATM") of its common stock pursuant to its ATM facility. The Company sold approximately 0.24 million shares of the Company's common stock at a purchase price of $180.00 per share and 0.03 million shares at a purchase price of $190.50, in each case the market price at the time of sale. These sales constituted the full available dollar amount under the Company's current ATM facility, and with such completion, this ATM facility terminated.

On August 7, 2020, the Company filed with the SEC a registration statement on Form S-3 for $300.0 million of securities (the "Shelf Registration Statement"), inclusive of a $100.0 million ATM program. This Shelf Registration Statement is in replacement of the Company's existing registration statement on Form S-3 and incorporates the unsold balance remaining thereto. The SEC declared the Shelf Registration Statement effective on August 17, 2020 and the Company may make sales of securities from time to time, depending on market conditions, pursuant to the Shelf Registration Statement.

In February 2021, the Company completed a public offering of 0.4 million shares of common stock at an offering price of $189.75 per share. The net proceeds to the Company were $71.1 million, after deducting underwriting discounts, commissions and other estimated offering expenses paid by the Company.

***Subsequent Common Stock Warrants***

On February 28, 2018, in connection with the Perceptive Credit Facility, the Company issued warrants to purchase 12,666 shares of the Company's common stock with an exercise price of $143.69 per underlying share (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 option-pricing model. The Black-Scholes option-pricing model inputs used were: (i) expected dividend rate of 0%, (ii) expected volatility of 105%, (iii) risk free interest rate of 2.8%, and (iv) expected term of 7.0 years.

**NOTE 12—EQUITY INCENTIVE PLANS AND STOCK-BASED COMPENSATION**

***2018 Equity Incentive Plan***

In May 2018, the Company adopted the 2018 Equity Incentive Plan (the "2018 Plan"). The 2018 Plan serves as a successor to the 2004 Amended and Restated Equity Incentive Plan (the "2004 Plan"), the 2009 Stock Plan, as amended (the "2009 Plan") and the 2014 Equity Incentive Plan, as amended (the "2014 Plan") with any forfeited, expired or cancelled 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) 133,333 newly reserved shares, which included, as of April 30, 2018, 6,945 shares reserved and unallocated under the 2009 Stock Plan, and 22,336 shares reserved and unallocated under the 2014 Equity Incentive Plan, plus (ii) up to 192,341 additional shares that may be added to the 2018 Plan in connection with the forfeiture, expiration or cancellation 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 shall increase on each January 1, beginning with January 1, 2019, and continuing through and including 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, 2023, options to purchase 386,600 shares of common stock were available for future grants under the 2018 Plan.

***2004 Employee Stock Purchase Plan***

On January 1, 2017, an additional 606 shares were authorized for issuance under the 2004 Employee Stock Purchase Plan (the "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 both the years ended December 31, 2023 and 2022, no shares were purchased by employees under the 2004 Purchase Plan. As of December 31, 2023 and 2022, 576 shares were authorized and available for issuance under the 2004 Purchase Plan.

***Equity Incentive Plan***

The following table summarizes information about stock option activity for years ended December 31, 2023 and 2022:

| | Outstanding Options Number of Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value (in millions): |
|---|---|---|---|---|
| Balances, December 31, 2021 | 523,411 | $ 153.11 | 6.72 | $ 0.95 |
| Granted | 194,679 | $ 33.09 | | |
| Exercised | (3,106) | $ 10.65 | | |
| Cancelled | (152,106) | $ 141.63 | | |
| Balances, December 31, 2022 | 562,878 | $ 115.50 | 7.09 | $ — |
| Granted | 236,651 | $ 7.25 | | |
| Exercised | (192) | $ 7.20 | | |
| Cancelled | (285,273) | $ 88.62 | | |
| Balances, December 31, 2023 | 514,064 | $ 80.62 | 7.03 | $ — |
| | | | | |
| Vested and expected to vest, December 31, 2023 | 514,064 | $ 80.62 | 7.03 | $ — |
| Exercisable at December 31, 2023 | 302,935 | $ 115.92 | 5.67 | $ — |

As of December 31, 2023, stock options outstanding and exercisable by exercise price were as follows:

| | Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|---|
| Range of Exercise Prices | Number Outstanding | Weighted Average Remaining Contractual Life (Years) | Weighted Average Exercise Price | Number Exercisable | Weighted Average Exercise Price |
| $ 3.73-6.32 | 35,149 | 9.79 | $ 5.61 | 83 | $ 4.95 |
| $ 7.20-7.20 | 79,708 | 9.11 | $ 7.20 | 8,705 | $ 7.20 |
| $ 7.95-10.95 | 62,747 | 9.39 | $ 9.04 | 12,402 | $ 9.82 |
| $ 12.60-35.25 | 34,026 | 3.96 | $ 18.91 | 29,418 | $ 18.62 |
| $ 41.55-41.55 | 57,562 | 8.12 | $ 41.55 | 26,305 | $ 41.55 |
| $ 58.80-80.85 | 32,766 | 5.11 | $ 70.30 | 32,555 | $ 70.28 |
| $ 94.65-94.65 | 57,099 | 4.41 | $ 94.65 | 57,099 | $ 94.65 |
| $ 98.55-174.15 | 52,390 | 4.85 | $ 140.17 | 50,061 | $ 140.19 |
| $ 189.30-210.75 | 55,727 | 7.00 | $ 209.03 | 41,151 | $ 208.64 |
| $ 217.50-638.55 | 46,890 | 6.11 | $ 221.20 | 45,156 | $ 221.33 |
| $ 3.73-638.55 | 514,064 | 7.03 | $ 80.62 | 302,935 | $ 115.92 |

The total intrinsic value of stock options exercised during both the years ended December 31, 2023 and 2022 was zero, as determined at the date of the option exercise.

Cash received from stock option exercises was zero, for both the years ended December 31, 2023 and 2022. The Company issues new shares of common stock upon exercise of options. In connection with the exercises, there is no tax benefit realized by the Company due to the Company's current loss position.

***Equity-Based Compensation Expense***

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):

| | Year Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Research and development | $ 2,833 | $ 6,096 |
| General and administrative | 3,869 | 5,813 |
| Total stock-based compensation | $ 6,702 | $ 11,909 |

As of December 31, 2023, the total unrecognized compensation cost related to unvested stock-based awards granted to employees under the Company's 2018 equity incentive plan was approximately $4.7 million. This cost will be recorded as compensation expense on a ratable basis over the remaining weighted average requisite service period of approximately 2.41 years.

***Valuation Assumptions***

The Company estimated the fair value of stock options granted using the Black-Scholes option-pricing formula and a single option award approach. This fair value is being amortized ratably over the requisite service periods of the awards, which is generally the vesting period.

The fair value of employee stock options was estimated using the following weighted-average assumptions:

| | Year Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Employee Stock Options: | | |
| Risk-free interest rate | 4.10 % | 2.35 % |
| Expected term (in years) | 6.08 | 6.08 |
| Dividend yield | — | — |
| Volatility | 77.72 % | 88.59 % |
| Weighted-average fair value of stock options granted | $ 5.09 | $ 24.75 |

**NOTE 13—INCOME TAXES**

For the years ended December 31, 2023 and 2022, the Company recorded an income tax provision (benefit) expense of ($11) thousand and $53 thousand, respectively.

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):

| | 2023 | 2022 |
|---|---|---|
| U.S. federal taxes (benefit) at statutory rate | $ (1,709) | $ (19,459) |
| State federal income tax benefit | 447 | (8,653) |
| Permanent differences and other | 2 | 3 |
| Stock compensation | 1,792 | 1,964 |
| Research and development credits | (1,426) | (2,494) |
| Change in valuation allowance | (2,328) | 30,619 |
| Change in state rate and carryovers | 3,211 | (1,927) |
| Total | $ (11) | $ 53 |

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, | |
|---|---|---|
| | 2023 | 2022 |
| **Deferred tax assets** | | |
| Net operating loss carryforward | $ 58,843 | $ 53,957 |
| Interest | 304 | — |
| Research and development credits | 16,630 | 15,235 |
| Deferred stock compensation | 6,982 | 8,086 |
| Deferred revenue | 2,641 | 16,127 |
| Lease liability | 3,561 | 4,516 |
| Accrued expenses and other | 415 | 1,846 |
| Depreciable and amortizable assets | 126 | — |
| Capitalized Research & Experimental Expenditures | 26,268 | 19,764 |
| **Total deferred tax assets** | 115,770 | 119,531 |
| | | |
| **Total deferred tax liabilities** | | |
| Depreciable and amortizable assets | — | (1,329) |
| Right-of-use asset | (2,668) | (3,488) |
| Note payable - CVR | (716) | — |
| **Total deferred tax liabilities** | (3,384) | (4,817) |
| Less: Valuation allowance | (112,386) | (114,714) |
| **Net deferred tax assets** | $ — | $ — |

As of December 31, 2023, the Company had federal net operating loss carryforwards of approximately $524.8 million and state net operating loss carryforwards of approximately $35.3 million available to offset future taxable income. $286.9 million of the Company's federal net operating loss carryforwards will begin to expire in 2025 through 2037, if not used before such time to offset future taxable income or tax liabilities. $237.9 million of the Company's federal net operating loss has an indefinite life and will 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. The Company currently anticipates $253.2 million of net operating losses unutilized due to a previous Section 382 limitation.

As of December 31, 2023, the Company had federal research and development tax credits available to offset future taxes of approximately $23.9 million, which expire in the year beginning 2024, and state research and development tax credits of approximately $2.9 million, which expire beginning 2033. The Company currently anticipates $9.5 million of unutilized federal research and development tax credits to expire unutilized due to a previous Section 382 limitation.

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 decreased by $2.3 million from continuing operations.

The Company has no uncertain tax positions as of December 31, 2023 and 2022. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2023 and 2022, the Company had no accrued interest or penalties due to the Company's net operating losses available to offset any tax adjustment. The Company currently has no federal or state tax examinations in progress nor has it had any federal or state tax examinations since its inception. As a result of the Company's net operating loss carryforwards, all of its tax years are subject to federal and state tax examination.

**NOTE 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 $0.7 million for the years ended December 31, 2023 and 2022, respectively.

**NOTE 15 – RESTRUCTURING RELATED EXPENSES**

On March 29, 2023 and June 16, 2023, the Company implemented a strategic reprioritization and corresponding reduction in workforce by approximately 68%, designed to focus on the clinical development programs for MT-6402, MT-8421 and MT-0169, and preclinical activities related to the Company's collaboration with Bristol-Myers Squibb (the "Restructuring"). The Restructuring reduced the Company's workforce, ceased further development of the Company's MT-5111 clinical development program, and refocused the majority of the Company's pre-clinical efforts around activities related to the Bristol-Myers Squibb collaboration. For the year ended December 31, 2023, the Company incurred $0.3 million in expenses related to the Restructuring, which is included in research and development and general and administrative expenses in the consolidated statement of operations. The expenses related to the Restructuring related to severance pay and other related termination benefits. The Company estimates that it will not incur any additional Restructuring related costs as of the time of issuance of these financial statements.

The following table summarizes the activity for the year ended December 31, 2023 for expenses related to the Restructuring accruals, which are included in Accrued liabilities in the Company's condensed consolidated balance sheets as of December 31, 2023 (in thousands):

| | |
|---|---|
| Balance, December 31, 2022 | $ — |
| Expenses related to the Restructuring | 276 |
| Cash payments | (276) |
| Balance, December 31, 2023 | $ — |

**NOTE 16—SUBSEQUENT EVENTS**

***Strategic Alternatives***

On March 4, 2024, the Company announced that management is continuing a comprehensive evaluation of strategic alternatives, including consideration of a wide range of options including, among other things, a potential financing/recapitalization, sale, merger, or other strategic transaction. The Company has not set a deadline or definitive timetable for the completion of the strategic review process, nor has management made any decisions relating to any strategic alternative at this time.

***Collaboration Agreements***

On March 15, 2024, Bristol-Myers Squibb notified the Company on March 13, 2024 that it does not intend to continue the research collaboration it entered into with the Company pursuant to the BMS Collaboration Agreement and would be terminating the BMS Collaboration Agreement in its entirety. The termination will be effective on June 13, 2024, or 90 days following the Company's receipt of Bristol-Myers Squibb's written notice of termination.

***Second Closing of the 2023 Private Placement***

On March 28, 2024, the Company and certain institutional and accredited investors (the "March 2024 Purchasers") entered into an Amended and Restated July 2023 Purchase Agreement pursuant to which the Company will issue common stock, prefunded warrants, and common warrants with an aggregate purchase price of $9.5 million on amended and restated second tranche terms. The second tranche, as amended and restated, will consist of the sale and issuance of (i) 1,209,612 shares of the Company's common stock (and, in lieu thereof, prefunded warrants to purchase 2,460,559 shares of the Company's common stock (the "March 2024 Prefunded Warrants")) for a purchase price of $2.35 per share of the Company's common stock (the closing price of our common stock on March 27, 2024 as reported by the Nasdaq Capital Market) and $2.349 per March 2024 Prefunded Warrant, and (ii) common stock warrants (the "March 2024 Common Warrants") to purchase up to 7,340,342 shares of the Company's common stock (or March 2024 Prefunded Warrants in lieu thereof) at an exercise price of $2.35 per share of the Company's common stock underlying the March 2024 Common Warrants. The March 2024 Common Warrants will be sold at a price of $0.125 per underlying share of common stock and will have a term of five years. The March 2024 Prefunded Warrants will expire when fully exercised in accordance with their terms. The March 2024 Prefunded Warrants and March 2024 Common Warrants may not be exercised if the aggregate number of shares of our common stock beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation (4.99%/9.99%/19.99%); provided, however, that a holder may increase or decrease the beneficial ownership limitation by giving 61 days' notice to the Company, but not to any percentage in excess of 19.99%. The Amended and Restated July 2023 Purchase Agreement contains customary representations and warranties and agreements of the Company and the Purchasers and customary indemnification rights and obligations of the parties. The second tranche will include gross proceeds of approximately $9.5 million and net proceeds, following the payment of related offering expenses, of approximately $8.9 million.

Pursuant to the Amended and Restated July 2023 Purchase Agreement, the Company granted to the March 2024 Purchasers certain registration rights, pursuant to which, among other things, the Company will (i) file with the SEC a registration statement on Form S-3 after the second tranche of the July 2023 Private Placement to register for resale the shares of common stock (and the shares of common stock issuable upon exercise of the prefunded warrants and common warrants ) issued in the second tranche of the July 2023 Private Placement, within 30 calendar days following the second

tranche closing (the "Second Closing"), and (ii) use its commercially reasonable efforts to have the registration statement declared effective as soon as practicable, and in any event no later than 90 days following the Second Closing date (or 120 days following the Second Closing date if the registration statement is reviewed by the SEC). The registration rights covenants are subject to customary terms and conditions for a transaction of this type, including certain customary cash penalties on the Company for its failure to satisfy specified filing and effectiveness time periods.

## 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, 2023. 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 Securities Exchange Act of 1934, as amended (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, 2023, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective.

***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 Exchange Act 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, 2023. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework (2013). Based on this evaluation, management has concluded our internal control over financial reporting as of December 31, 2023 was effective.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the year ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## ITEM 9B. OTHER INFORMATION

**Rule 10b5-1 trading arrangements**

As of December 31, 2023, none of our directors or officers adopted or terminated "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

## ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 is incorporated by reference to the definitive proxy statement for our 2024 annual meeting of stockholders or an amendment to this Annual Report on Form 10-K, to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

### ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated by reference to the definitive proxy statement for our 2024 annual meeting of stockholders or an amendment to this Annual Report on Form 10-K, to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

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

The information required by this Item 12 is incorporated by reference to the definitive proxy statement for our 2024 annual meeting of stockholders or an amendment to this Annual Report on Form 10-K, to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

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

The information required by this Item 13 is incorporated by reference to the definitive proxy statement for our 2024 annual meeting of stockholders or an amendment to this Annual Report on Form 10-K, to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 is incorporated by reference to the definitive proxy statement for our 2024 annual meeting of stockholders or an amendment to this Annual Report on Form 10-K, to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

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

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

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

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

| EXHIBIT NUMBER | DESCRIPTION |
|---|---|
| 2.1^ | Agreement and Plan of Merger and Reorganization, dated March 16, 2017, by and among the Company, Molecular Templates OpCo, Inc. and Trojan Merger Sub, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, as amended (File No. 001-32979) filed on March 17, 2017). |
| 3.1 | Amended and Restated Certificate of Incorporation of the Company, as subsequently amended (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 6, 2014). |
| 3.2 | Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Company, dated August 1, 2017 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on August 1, 2017). |
| 3.3 | Certificate of Amendment (Name Change) of Amended and Restated Certificate of Incorporation of the Company, dated August 1, 2017 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on August 7, 2017). |
| 3.4 | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Molecular Templates, Inc, dated August 11, 2023 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on August 11, 2023). |
| 3.5 | 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). |
| 3.6 | 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). |
| 4.1* | Description of the Company's securities. |
| 4.2 | Registration Rights Agreement, dated June 4, 2020, by and among the Company and the selling stockholders named therein (incorporated by reference to Exhibit 4.6 to the Company's registration statement on Form S-3 Report (file No. 333-238937) filed on June 4, 2020). |

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| 4.3 | Form of Warrant issued pursuant to the Securities Purchase Agreement, 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 (File No. 001-32979) filed on August 7, 2017). |
| 4.4 | 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) filed on March 30, 2018). |
| 4.5 | Warrant to Purchase Common Stock issued to Perceptive Credit Holdings II, LP, dated February 27, 2018, (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). |
| 4.6 | 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). |
| 4.7 | 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). |
| 4.8 | Warrant, dated June 16, 2023 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on June 20, 2023). |
| 4.9 | Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on July 13, 2023). |
| 4.10 | Form of Common Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on July 13, 2023). |
| 4.11 | Form of Prefunded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on March 28, 2024). |
| 4.12 | Form of Common Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on March 28, 2024). |
| 10.1+ | 2004 Amended and Restated Equity Incentive Plan of the Company, as amended (incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 15, 2012). |
| 10.2+ | Amended and Restated 2004 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8 (File No. 333-164865) filed on February 11, 2010). |
| 10.3* | Amended and Restated Non-Employee Director Compensation Policy, adopted by the Board of Directors of the Company on October 9, 2017, amended as of May 31, 2018 and further amended as of 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). |

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| 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 (File No. 333-217993) filed on May 15, 2017, as amended on June 27, 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 (File No. 333-217993) filed on May 15, 2017, as amended on June 27, 2017). |
| 10.11 | 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). |
| 10.12 | 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). |
| 10.13 | Lease Agreement, dated October 1, 2016, and First Amendment to the Lease Agreement, dated January 30, 2017, by and between NW Austin Office Partners LLC and Molecular Templates OpCo, Inc. (incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 30, 2018). |
| 10.13.1 | Second Amendment to the Lease Agreement, dated March 29, 2017, by and between NW Austin Office Partners LLC and Molecular Templates OpCo, Inc. (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). |
| 10.13.2 | Third Amendment to the Lease Agreement, dated June 23, 2017, by and between NW Austin Office Partners LLC and Molecular Templates OpCo, Inc. (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). |
| 10.13.3 | Fourth Amendment to the Lease Agreement, dated October 18, 2022, by and between NW Austin Officer Partners LLC and Molecular Templates, 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 10, 2022). |
| 10.14+ | 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). |
| 10.15+ | 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). |
| 10.16 | 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). |
| 10.17 | 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). |
| 10.18 | 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). |

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| 10.19 | 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). |
| 10.20+ | 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). |
| 10.21+ | 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). |
| 10.22+ | 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). |
| 10.23*† | Cancer Research Grant Contract, dated September 18, 2018, by and between The Company and the Cancer Prevention and Research Institute of Texas. |
| 10.24 | Sublease Agreement, dated as of January 23, 2019, by and between the Company 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). |
| 10.25 | Registration Rights Agreement, dated February 27, 2018, by and between the Company 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). |
| 10.26 | 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). |
| 10.27 | Loan and Security Agreement, dated May 21, 2020, by and among the Company, Molecular Templates OpCo, Inc., and, K2 HealthVentures LLC and Ankura Trust Company, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on May 22, 2020). |
| 10.28 | First Amendment to Loan and Security Agreement, dated May 21, 2020, by and among the Company, Molecular Templates OpCo, Inc., and, K2 Health Ventures LLC and Ankura Trust Company, LLC, effective April 4, 2022 (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, 2022). |
| 10.29 | Sales Agreement, dated August 7, 2020, by and between the Company and Cowen and Company, LLC (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q (File No. 001-32979) filed on August 7, 2020). |
| 10.30 | CVR Agreement, dated June 16, 2023, by and between the Company and K2HV (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on June 20, 2023). |
| 10.31§ | Securities Purchase Agreement dated July 12, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on July 13, 2023). |
| 10.32+§ | Employment Agreement, dated August 1, 2023, by and between the Company and Maurizio Voi, M.D. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on September 28, 2023). |
| 10.33§ | Amended and Restated Securities Purchase Agreement, dated March 27, 2024 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on March 28, 2024). |
| 21.1* | Subsidiaries of the Company. |
| 23.1* | Consent of Ernst & Young LLP. |

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| 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. |
| 97.1+§ | Molecular Templates, Inc. Clawback Policy (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q (File No. 001-32979) filed on November 13, 2023). |
| 101.INS | Inline XBRL Instance Document |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | Inline XBRL Taxonomy Extension Labels Linkbase Document |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

ˆ 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.

† Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted by means of marking such portions with asterisks as the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

††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.

§ Certain schedules to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. Copies of the omitted schedules will be furnished to the SEC upon request.

**ITEM 16. 10-K SUMMARY**

Not applicable.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**MOLECULAR TEMPLATES, INC.**

March 29, 2024

By: /s/ ERIC E. POMA, PH.D.
**Eric E. Poma, Ph.D.**
**Chief Executive Officer and Chief Scientific Officer**

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

| Signature | Title | Date |
|---|---|---|
| /s/ Eric E. Poma, Ph.D.<br>**Eric E. Poma, Ph.D.** | Chief Executive Officer and Chief Scientific Officer (Principal Executive Officer) | March 29, 2024 |
| /s/ Jason S. Kim<br>**Jason S. Kim** | Chief Financial Officer (Principal Financial and Accounting Officer) | March 29, 2024 |
| /s/ Harold E. Selick, Ph.D.<br>**Harold E. Selick, Ph.D.** | Director | March 29, 2024 |
| /s/ David R. Hoffmann<br>**David R. Hoffmann** | Director | March 29, 2024 |
| /s/ Kevin Lalande<br>**Kevin Lalande** | Director | March 29, 2024 |
| /s/ Corazon “Corsee” Sanders, Ph.D.<br>**Corazon “Corsee” Sanders, Ph.D.** | Director | March 29, 2024 |
| /s/ Gabriela Gruia, M.D.<br>**Gabriela Gruia, M.D.** | Director | March 29, 2024 |

**Exhibit 4.1**

**DESCRIPTION OF MOLECULAR TEMPLATES, INC.'S SECURITIES**

**REGISTERED PURSUANT TO SECTION 12 OF THE**

**SECURITIES EXCHANGE ACT OF 1934**

As of December 31, 2023, Molecular Templates, Inc. had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): common stock, $0.0001 par value per share.

Unless the context otherwise requires, all references to "we" or "us" in this Exhibit 4.1 refer to Molecular Templates, Inc.

## DESCRIPTION OF CAPITAL STOCK

The following summary description of our capital stock is based on the provisions of our Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation") as well as our Amended and Restated Bylaws (the "Bylaws"), and the applicable provisions of the Delaware General Corporation Law (the "DGCL"). The following description is only a summary, and it may not contain all the information that is important to you. This information is qualified entirely by reference to the applicable provisions of our Certificate of Incorporation and Bylaws, which are exhibits to this report, and the DGCL.

As of the date of this report, our Certificate of Incorporation authorizes us to issue 150,000,000 shares of common stock, par value $0.001 per share and 2,000,000 shares of preferred stock, par value $0.001 per share.

### Common Stock

We are authorized to issue one class of common stock. Holders of our common stock are entitled to one vote for each share of common stock held of record for the election of directors and on all matters submitted to a vote of stockholders, except matters that relate only to one or more of the series of our preferred stock, and no holder has cumulative voting rights. Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends ratably, if any, as may be declared by our board of directors out of legally available funds, subject to any preferential dividend rights of any preferred stock then outstanding. Upon our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in our net assets legally available after the payment of all our debts and other liabilities, subject to the preferential rights of any preferred stock then outstanding. Holders of our common stock have no preemptive, subscription, redemption or conversion rights by virtue of holding shares of our common stock. Pursuant to the terms of the Amended and Restated Securities Purchase Agreement, dated March 28, 2024, by and among us and the persons set forth therein, certain holders of our common stock have pre-emptive rights, subject to certain customary limitations, on future issuances of our securities. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that are currently designated and issued or that we may designate and issue in the future. A majority vote of the holders of common stock is generally required to take action under our Certificate of Incorporation and our Bylaws.

### Preferred Stock

Our board of directors is authorized, without action by the stockholders, to designate and issue up to an aggregate of 2,000,000 shares of preferred stock, par value $0.001 per share, in one or more series. As of December 31, 2023, we had 250 shares of Series A Preferred Stock outstanding held by three holders of record. Our board of directors can designate the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of common stock. The

issuance of preferred stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes could, under certain circumstances, have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying, deferring or preventing a change in control of our Company, which might harm the market price of our common stock.

**Antitakeover Provisions**

Certain provisions of Delaware law, our Certificate of Incorporation and/or our Bylaws may have the effect of delaying, deferring or discouraging another person from acquiring control of our company, as described below.

***Section 203 of the DGCL***

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by (i) persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

***Certificate of Incorporation and Bylaws***

Our Certificate of Incorporation and Bylaws include a number of provisions that may discourage or delay attempts to take over the Company or effect change to our management. These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. We believe the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of

an unfriendly or unsolicited proposal to acquire or restructure the Company, outweigh the disadvantages of discouraging takeover proposals.

*Classification of Directors; Number of Directors; Removal of Directors; Vacancies*

Our Certificate of Incorporation and Bylaws provide that our board of directors is divided into three classes serving three-year terms, with one class being elected each year. The number of directors may be fixed from time to time by our board of directors. Subject to the rights of the holders of any series of preferred stock, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office, even if less than a quorum, or by a sole remaining director, and shall not be filled by a vote of the stockholders. These provisions make it difficult for stockholders to remove directors and may prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.

*Advance Notice Requirements*

Our Bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 120 days or more than 150 days prior to the first anniversary date on which we mailed our proxy materials for the preceding year's annual meeting of stockholders. The notice must contain certain information specified in our Bylaws. These provisions may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of the Company.

*Stockholder Actions; Special Meetings of Stockholders*

Our Certificate of Incorporation provides that stockholders may not take any action by written consent in lieu of a meeting. As a result, all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting. Additionally, our Bylaws provide that only a majority of the members of our board of directors then in office, the chairman of our board of directors or our president may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our Bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

*No Cumulative Voting Rights*

Our Certificate of Incorporation does not provide for cumulative voting rights in the election of our directors. Accordingly, each director shall be elected by the vote of the majority of the votes cast with respect to that director's election at any meeting of the stockholders.

*Issuance of Undesignated Preferred Stock*

The existence of authorized but unissued shares of preferred stock enables our board of directors to render more difficult or to discourage an attempt to obtain control of the Company by means of a merger, tender offer, proxy contest or otherwise.

**Exclusive jurisdiction of certain actions**

Our Certificate of Incorporation requires, to the fullest extent permitted by law, that derivative actions brought in our name, actions against our directors, officers and employees for breach of fiduciary duty and other

similar actions may be brought only in the Court of Chancery in the State of Delaware, unless we otherwise consent. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare, Trust Company, N.A., 150 Royall Street, Canton, MA 02021.

**Stock Exchange Listing**

Our common stock is listed for quotation on the Nasdaq Capital Market under the symbol “MTEM.”

**Exhibit 10.3**

**MOLECULAR TEMPLATES, INC.**
**AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION POLICY**

**ADOPTED BY THE BOARD OF DIRECTORS: OCTOBER 9, 2017 AMENDED AS OF MAY 31, 2018**
**FURTHER AMENDED EFFECTIVE AS OF DECEMBER 19, 2019**

Each member of the board of directors (the "***Board***") of Molecular Templates, Inc. (the "***Company***") who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") will be eligible to receive cash and equity compensation as set forth in this Molecular Templates, Inc. Non-Employee Director Compensation Policy (this "***Policy***"). The cash and equity compensation described in this Policy will be paid or granted, as applicable, automatically and without further action of the Board to each Non-Employee Director who is eligible to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Amended and Restated Policy became effective on October 9, 2017 (the "***Effective Date***"), was amended effective as of May 31, 2018 and amended further as of December 19, 2019, and will remain in effect until it is revised or rescinded by further action of the Board. Capitalized terms not explicitly defined in this Policy but defined in the 2018 Equity Incentive Plan (as may be amended from time to time, the "***2018 Plan***") will have the same definitions as in the 2018 Plan.

## 1. CASH COMPENSATION.

**(a) Annual Fees.** Each Non-Employee Director will be eligible to receive the annual cash retainer fees set forth below for service as (i) a member or chairperson of the Board, as applicable, and (ii) a member or chairperson of a committee of the Board (each, a "***Committee***"), as applicable, and such fees shall be paid on a quarterly basis:

| Board or Committee | Type of Fee | Amount (Per Year) |
|---|---|---|
| **Board** | Chair Retainer Fee | $ 70,000 |
| | Non-Chair Member Retainer Fee | $ 40,000 |
| **Audit Committee** | Chair Retainer Fee | $ 15,000 |
| | Non-Chair Member Retainer Fee | $ 7,500 |
| **Compensation Committee** | Chair Retainer Fee | $ 10,000 |
| | Non-Chair Member Retainer Fee | $ 5,000 |
| **Nominating and Corporate Governance Committee** | Chair Retainer Fee | $ 8,000 |
| | Non-Chair Member Retainer Fee | $ 4,000 |

**(b) Expenses.** Each Non-Employee Director will be entitled to reimbursement from the Company for all reasonable documented out-of-pocket expenses incurred by the Non-Employee Director in connection with his or her attendance at Board and Committee meetings.

To the extent that any taxable reimbursements are provided to a Non-Employee Director, they will be provided in accordance with Section 409A of the Internal Revenue Code of 1986, as amended, and the Treasury Regulations and other guidance thereunder and any state law of similar effect, including, but not limited to, the following provisions: (i) the amount of any such expenses eligible for reimbursement during the Non-Employee Director's taxable year may not affect the expenses eligible for reimbursement in any other taxable year; (ii) the reimbursement of an eligible expense must be made no later than the last day of the Non-Employee Director's taxable year that immediately follows

the taxable year in which the expense was incurred; and (iii) the right to any reimbursement may not be subject to liquidation or exchange for another benefit.

**2. EQUITY COMPENSATION.** The options described in this Policy will be granted under the 2018 Plan and will be subject to the terms and conditions of (i) this Policy, (ii) the 2018 Plan and (iii) the forms of option grant notices and option agreements approved by the Board for the grant of options to Non-Employee Directors.

**(a) Initial Grants.** Each individual who is elected or appointed for the first time after the Effective Date to be a Non-Employee Director automatically will be granted, on the date of such initial election or appointment, a non-qualified stock option to purchase 1,666 shares of Common Stock (an "***Initial Option Grant***"); and each individual who is a Non-Employee Director on the Effective Date will receive an Initial Option Grant on the Effective Date.

**(b) Annual Grants.** On the date of each annual meeting of the Company's stockholders after the Effective Date, each individual who is then a Non-Employee Director and is expected to be continuing as a Non-Employee Director following the date of such annual meeting automatically will be granted a non-qualified stock option to purchase 1,000 shares of Common Stock (an "***Annual Option Grant***"), provided that such individual has served as a Non-Employee Director for at least six (6) months prior to the date of such annual meeting.

**(c) Terms of Options**.

**(i) Exercise Price**. The exercise price of each Initial Option Grant and each Annual Option Grant will be equal to 100% of the Fair Market Value of the Common Stock subject to the option on the date that such option is granted.

**(ii) Vesting**. Subject to Section 3 below, each Initial Option Grant and each Annual Option Grant will vest and become exercisable as follows:

**(A)** Each Initial Option Grant will vest and become exercisable as to 50% of the shares of Common Stock subject to such Initial Option Grant on each of the first and second anniversaries of the date of grant, rounded down to the nearest whole share, provided that the Non-Employee Director is an Employee, director or Consultant of the Company or an Affiliate through such dates.

**(B)** Each Annual Option Grant will vest and become exercisable on the first anniversary of the date of grant, provided that the Non-Employee Director is an Employee, director or Consultant of the Company or an Affiliate through such date.

**3. CERTAIN TRANSACTIONS AND EVENTS**.

**(a) Corporate Transaction.** The provisions of this Section 3(a) (and not Paragraph 25(b) of the 2018 Plan) will apply to all outstanding Initial Option Grants and Annual Option Grants in the event of a Corporate Transaction. In the event of a Corporate Transaction while a Participant remains a Non-Employee Director, the unvested shares of Common Stock subject to each outstanding Initial Option Grant and Annual Option Grant held by such Participant at the time of such Corporate Transaction, will automatically vest in full so that all outstanding and unvested shares subject to each such Initial Option Grant and Annual Option Grant will, immediately prior to the effective date of the Corporate Transaction, become fully vested and exercisable and may be exercised for any or all of those vested shares. Immediately following the consummation of the Corporate Transaction, each unexercised Initial Option Grant and Annual Option Grant will terminate and cease to be outstanding, except to the extent assumed by the successor corporation (or Affiliate thereof).

Each Initial Option Grant and Annual Option Grant which is assumed by a successor corporation in connection with a Corporate Transaction will be appropriately adjusted immediately after such Corporate Transaction to apply to the number and class of securities which would have been issuable to the Participant as a result of the consummation of such Corporate Transaction had the Initial Option Grant or Annual Option Grant been exercised immediately prior to

such Corporate Transaction. Appropriate adjustments will also be made to the exercise price payable per share under each outstanding Initial Option Grant and Annual Option Grant, provided that the aggregate exercise price payable for such securities will remain the same. To the extent the actual holders of the Common Stock receive cash consideration for their Common Stock in consummation of the Corporate Transaction, the successor corporation may, in connection with the assumption of the outstanding Initial Option Grants and Annual Option Grants, substitute one or more shares of its own common stock with a fair market value equivalent to the cash consideration paid per share of Common Stock in such Corporate Transaction.

**(b) Change in Control.** In the event of a Change in Control while a Participant remains a Non-Employee Director, the unvested shares of Common Stock subject to each outstanding Initial Option Grant and Annual Option Grant held by such Participant at the time of such Change in Control, will automatically vest in full so that all outstanding and unvested shares subject to each such Initial Option Grant and Annual Option Grant will, immediately prior to the effective date of the Change in Control, become fully vested and exercisable and may be exercised for any or all of those vested shares. Each such Initial Option Grant and Annual Option Grant will remain exercisable for such fully vested shares until the earlier of (i) the expiration date of such Initial Option Grant or Annual Option Grant or (ii) termination of the option term in connection with a Change in Control.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

STATE OF TEXAS COUNTY OF TRAVIS

This **CANCER RESEARCH GRANT CONTRACT** ("**Contract**") is by and between the Cancer Prevention and Research Institute of Texas ("**CPRIT**"), hereinafter referred to as the "**INSTITUTE**", acting through its Chief Executive Officer, and **Molecular Templates, Inc.**, hereinafter referred to as the "**RECIPIENT**", acting through its authorized signing official.

**RECITALS**

WHEREAS, pursuant to TEX. HEALTH & SAFETY CODE, Ch. 102, the INSTITUTE may make grants to public and private persons in this state for research into the causes and cures for all types of cancer in humans; facilities for use in research into the causes and cures for cancer; research to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer; and cancer prevention and control programs.

WHEREAS, Article III, Section 67 of the Texas Constitution expressly authorizes the State of Texas to sell general obligation bonds on behalf of the INSTITUTE and for the INSTITUTE to use the proceeds from the sale of the bonds for the purposes of cancer research and prevention programs in this state.

WHEREAS, the INSTITUTE issued a request for applications for RFA P-16-TXCO-2: Texas Company Product Development Research Awards on or about January 2016.

WHEREAS, pursuant to TEX. HEALTH & SAFETY CODE § 102.251, and after a review by the INSTITUTE's scientific research and prevention program committees, the INSTITUTE has approved a Grant (defined below) to be awarded to the RECIPIENT.

WHEREAS, to ensure that the Grant provided to the RECIPIENT pursuant to this Contract is utilized in a manner consistent with Tex. Const. Article III, Section 67 and other laws, and in exchange for receiving such Grant, the RECIPIENT agrees to comply with certain conditions and deliver certain performance.

WHEREAS, the RECIPIENT and the INSTITUTE desire to set forth herein the provisions relating to the awarding of such monies and the disbursement thereof to the RECIPIENT.

**IN CONSIDERATION** of the Grant and the premises, covenants, agreements, and provisions contained in this Contract, the parties agree to the following terms and conditions:



**Article I**

**DEFINITIONS**

The following terms shall have the following meaning throughout this Contract and any Attachments and amendments. Other terms may be defined elsewhere in this Contract.

(1) **Collaborator** - any entity other than the RECIPIENT having one or more personnel participating in the Project and (a) designated as a collaborator in the application submitted by the RECIPIENT requesting the Grant funds awarded by the INSTITUTE, or (b) otherwise approved in writing as a collaborator by the INSTITUTE.

(2) **Contractor** - any person or entity, other than a Collaborator or the RECIPIENT (or their respective personnel), who is contracted by the RECIPIENT to perform activities for the Project.

(3) **Equipment** - an article of tangible, nonexpendable personal property having a useful life of more than one year and an acquisition cost of $5,000 or more per unit.

(4) **Grant** - the funding assistance authorized by TEX. HEALTH & SAFETY CODE, Ch. 102 in the amount specified in Section 2.01 and awarded by the INSTITUTE to the RECIPIENT to carry out the Project pursuant to the terms and conditions of this Contract.

(5) **Indirect Costs** - the expenses of doing business that are not readily identified with a particular grant, contract, project, function or activity, but are necessary for the general operation of the organization or the performance of the organization's activities.

(6) **Institute-Funded Activity** - all aspects of work conducted on or as part of the Project.

(7) **Non-Profit Organization** - a university or other institution of higher education or an organization of the type described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501 (c)(3)) and exempt from taxation under 501 (a) of the Internal Revenue Code (26 U.S.C. 501 (a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(8) **Principal Investigator/Program Director** - the individual designated by the RECIPIENT to direct the Project who is principally responsible and accountable to the RECIPIENT and the INSTITUTE for the proper conduct of the Project. References herein to "Principal Investigator/Program Director" include Co-Principal Investigators or Co-Program Directors as well. The Principal Investigator/Program Director and Co-Principal Investigators or Co-Program Directors are set forth on Attachment A.

(9) **Project** - the activities specified or generally described in the Scope of Work or otherwise in this Contract (including without limitation any of the Attachments to the Contract) that are approved by the INSTITUTE for funding, regardless of whether the of the INSTITUTE funding constitutes all or only a portion financial support necessary to carry them out.

(10) **Recipient Personnel** - The RECIPIENT's Principal Investigator/Program Director and RECIPIENT's employees and consultants working on the Project.

## Article II GRANT AWARD

**Section 2.01 Award of Monies.** In accordance with the provisions of this Contract and any applicable agency administrative rules, the INSTITUTE shall disburse the proceeds of the Grant to the RECIPIENT in an amount not to exceed **$ 15,200,000** to be used solely for the Project. This award is subject to compliance with the Scope of Work and demonstration of progress towards achievement of the milestones set forth in Section 2.02. This Grant is not intended to be a loan of money.

**Section 2.02 Scope of Work and Milestones.** The RECIPIENT shall perform the Project in accordance with this Agreement and as outlined in Application **DP160071** submitted by the RECIPIENT and approved by the INSTITUTE. The RECIPIENT shall conduct the Project within the State of Texas with Texas-based employees, Contractors and/or Collaborators unless otherwise specified in the Scope of Work or the Approved Budget. The INSTITUTE and the RECIPIENT hereby adopt the terms of Attachment A in their entirety, incorporate them as if fully set forth herein, and agree that the Project description, goals, timeline and milestones included as Attachment A accurately reflect the Scope of Work of the Project to be undertaken by the RECIPIENT (the "**Scope of Work**") and the milestones expected to be achieved. RECIPIENT and the INSTITUTE mutually agree that the outcome of scientific research is unpredictable and cannot be guaranteed. The RECIPIENT shall use commercially reasonable efforts to complete the goals of the Project pursuant to the timeline reflected in Attachment A and shall timely notify the INSTITUTE if circumstances occur that materially and adversely affect completion thereof. Modifications, if any, to the Scope of Work must be agreed to in writing by both parties as set forth in Section 2.06 "Amendments and Modifications" herein. Material changes to the Scope of Work include, but are not limited to, changes in key personnel involved with the Project, the site of the Project, and the milestones expected to be achieved.

**Section 2.03 Contract Term.** The Contract shall be effective as of **December 01, 2016** (the "**Effective Date**") and terminate on **November 30, 2019** or in accordance with the Contract termination provisions set forth in Article VIII herein, whichever shall occur first (the "**Termination Date**"). Unless otherwise approved by the INSTITUTE as evidenced by written communication from the INSTITUTE to the RECIPIENT and appended to the Contract, Grant funds distributed pursuant to the Contract shall be expended no earlier than the Effective Date or subsequent to the Termination Date. If, as of the Termination Date, the RECIPIENT has not used Grant money awarded by the INSTITUTE for permissible services, expenses, or costs related to the Project and has not received approval from the INSTITUTE for a no cost extension to the contract term pursuant to Section 3.11 "Carry Forward of Unspent Funds and No Cost Extension" herein, then the RECIPIENT shall not be entitled to retain such unused Grant funds from the INSTITUTE. Certain obligations as set forth in Section 9.09 of this Contract shall extend beyond the Termination Date.

**Section 2.04 Contract Documentation.** The Contract between the INSTITUTE and the RECIPIENT shall consist of this final, executed Contract, including the following Attachments to the Contract, all of which are hereby incorporated by reference:

(a) Attachment A – Project Description, Goals and Timeline

(b) Attachment B – Approved Budget, including changes approved by the INSTITUTE subsequent to execution of the Contract.

(c) Attachment C – Assurances and Certifications

(d) Attachment D – Intellectual Property and Revenue Sharing

(e) Attachment E – Reporting Requirements

(f) Attachment F – Approved Amendments to Contract, excluding budget amendments reflected in Attachment B.

**Section 2.05 Entire Agreement.** All agreements, covenants, representations, certifications and understandings between the parties hereto concerning this Contract have been merged into this written Contract. No prior contemporaneous representation, agreement or understanding, express or implied, oral or otherwise, of the parties or their agents that may have related to the subject matter hereof in any way shall be valid or enforceable unless embodied in this Contract.

**Section 2.06 Amendments and Modifications.** Requested amendments and modifications to the Contract must be submitted in writing to the INSTITUTE for review and approval (such approval shall not be unreasonably withheld.) Amendments and modifications (including alterations, additions, deletions, assignments and extensions) to the terms of this Contract shall be made solely in writing and shall be executed by both parties. The approved amendment shall be reflected in Attachment A if it is change to the Scope of Work, or as part of Attachment B if it is a budget amendment, or as part of Attachment F for all other changes.

**Section 2.07 Relationship of the Parties** The RECIPIENT shall be responsible for the conduct of the Project that is the subject of this Contract and shall direct the activities and at all times be responsible for the performance of Recipient Personnel, Collaborators, Contractors and other agents. The INSTITUTE does not assume responsibility for the conduct of the Project or any Institute-Funded Activity that is the subject of this Contract. The INSTITUTE and the RECIPIENT shall perform their respective obligations under this Contract as independent contractors and not as agents, employees, partners, joint venturers, or representatives of the other party. Neither party is permitted to make representations or commitments that bind the other party.

**Section 2.08 Subcontracting.** Any and all subcontracts entered into by the RECIPIENT in relation to the performance of activities under the Project shall be in writing and shall be subject to the requirements of this Contract. Without in any way limiting the foregoing, the RECIPIENT shall enter into and maintain a written agreement with each such permitted Contractor with terms and conditions sufficient to ensure the RECIPIENT fully complies with the terms of this Contract, including without limitation the terms set forth in Attachments C, D, and E. The RECIPIENT agrees that it shall be responsible to the INSTITUTE for the performance of and payment to any Contractor. Any reimbursements made by the RECIPIENT to a Contractor shall be made in accordance with the applicable provisions of TEX. GOV'T. CODE, Ch. 2251.

**Section 2.09 Transfer or Assignment by the Recipient.** This Contract is not transferable or otherwise assignable by the RECIPIENT, whether by operation of law or otherwise, without the prior written consent of the INSTITUTE, except as provided in this Section 2.09. Any such attempted transfer or assignment without the prior written consent of the INSTITUTE (except as provided in this Section 2.09) shall be null, void and of no effect. For purposes of this section, an assignment or transfer of this Contract by the RECIPIENT in connection with a merger, transfer or sale of all or substantially all of the RECIPIENT's assets or business related to this Contract or a consolidation, change of control or similar transaction involving the RECIPIENT shall not be deemed to constitute a transfer or assignment, so long as such action does not impair or otherwise negatively impact the revenue sharing terms in Attachment D. Nothing herein shall be interpreted as superseding the requirement that the Project be undertaken in Texas with Texas-based employees.

If the Principal Investigator leaves the employment of the RECIPIENT or is replaced by the RECIPIENT for any reason during the course of the Grant with someone who is not already designated a co-Principal

Investigator in the Application, the RECIPIENT shall notify the INSTITUTE prior to replacing the Principal Investigator. Written approval by the INSTITUTE is required for the replacement of the Principal Investigator with someone who is not already a co-Principal Investigator in the Application, which approval shall not be unreasonably withheld, conditioned or delayed.

**Section 2.10 Representations and Certifications.** The RECIPIENT represents and certifies to the best of its knowledge and belief to the INSTITUTE as follows:

(a) It has legal authority to enter into, execute, and deliver this Contract, and all documents referred to herein, and it has taken all actions necessary to its execution and delivery of such documents;

(b) It will comply with all of the terms, conditions, provisions, covenants, requirements, and certifications in this Contract, applicable statutory provisions, agency administrative rules, and all other documents incorporated herein by reference;

(c) It has made no material false statement or misstatement of fact in connection with this Contract and its receipt of the Grant, and all of the information it previously submitted to the INSTITUTE or that it is required under this Contract to submit to the INSTITUTE relating to the Grant or the disbursement of any of the Grant is and will be true and correct at the time such statement is made;

(d) It is in compliance in all material respects with provisions of its charter and of the laws of the State of Texas, and of the laws of the jurisdiction in which it was formed, and (i) there are no actions, suits, or proceedings pending, or threatened, before any judicial body or governmental authority against or affecting its ability to enter into this Contract, or any document referred to herein, or to perform any of the material acts required of it in such documents and (ii) it is not in default with respect to any order, writ, injunction, decree, or demand of any court or any governmental authority which would impair its ability to enter into this Contract, or any document referred to herein, or to perform any of the material acts required of it in such documents;

(e) Neither the execution and delivery of this Contract or any document referred to herein, nor compliance with any of the terms, conditions, requirements, or provisions contained in this Contract or any documents referred to herein, is prevented by, is a breach of, or will result in a breach of, any term, condition, or provision of any agreement or document to which it is now a party or by which it is bound; and

(f) It shall furnish such satisfactory evidence regarding the representations and certifications described herein as may be required and requested by the INSTITUTE from time to time.

**Section 2.11 Reliance upon Representations.** By awarding the Grant and executing this Contract, the INSTITUTE is relying, and will continue to rely throughout the term of this Contract, upon the truthfulness, accuracy, and completeness of the RECIPIENT's written assurances, certifications and representations. Moreover, the INSTITUTE would not have entered into this Contract with the RECIPIENT but for such written assurances, certifications and representations. The RECIPIENT acknowledges that the INSTITUTE is relying upon such assurances, certifications and representations and acknowledges their materiality and significance.

**Section 2.12 Contingent upon Availability of Grant Funds.** This Contract is contingent upon funding being available for the term of the Contract and the RECIPIENT shall have no right of action against the

INSTITUTE in the event that the INSTITUTE is unable to perform its obligations under this Contract as a

result of the suspension, termination, withdrawal, or failure of funding to the INSTITUTE or lack of sufficient funding of the INSTITUTE for this Contract. If funds become unavailable to the INSTITUTE during the term of the Contract, Section 8.01(c) shall apply. For the sake of clarity, and except as otherwise provided by this Contract, if this Contract is not funded, then both parties are relieved of all of their obligations under this Contract. The INSTITUTE acknowledges and agrees that the Project is a multiyear project subject to Tex. Health & Safety Code, Ch. 102, Section 102.257.

**Section 2.13 Confidentiality of Documents and Information.** In connection with work contemplated for the Project or pursuant to complying with various provisions of this Contract, the RECIPIENT may disclose its confidential business, financial, technical, scientific information and other information to the INSTITUTE ("Confidential Information"). To assist the INSTITUTE in identifying such information, the RECIPIENT shall mark or designate the information as "confidential," provided however that the failure to so designate does not operate as a waiver to protections provided by applicable law or this Contract. The INSTITUTE shall use no less than reasonable care to protect the confidentiality of the Confidential Information to the fullest extent permissible under the Texas Public Information Act, Texas Government Code, Chapter 552 (the **"TPIA"**), and, except as otherwise provided in the TPIA to prevent the disclosure of the Confidential Information to third parties for a period of time equal to three (3) years from the termination of the contract, unless the INSTITUTE and the RECIPIENT agree in writing to extend such time period, provided that this obligation shall not apply to information that:

(a) was in the public domain at the time of disclosure or later became part of the public domain through no act or omission of the INSTITUTE in breach of this Contract;

(b) was lawfully disclosed to the INSTITUTE by a third party having the right to disclose it without an obligation of confidentiality;

(c) was already lawfully known to the INSTITUTE without an obligation of confidentiality at the time of disclosure;

(d) was independently developed by the INSTITUTE without using or referring to the RECIPIENT's Confidential Information; or

(e) is required by law or regulation to be disclosed.

The INSTITUTE shall hold the Confidential Information in confidence, shall not use such Confidential Information except as provided by the terms of this Contract, and shall not disclose such Confidential Information to third parties without the prior written approval of the RECIPIENT or as otherwise allowed by the terms of the Contract. Subject in all respects to the terms of this Contract and the TPIA, the INSTITUTE has the right to use and disclose the Confidential Information reasonably in connection with the exercise of its rights under the Contract.

In the event that the INSTITUTE is requested or required (by oral questions, interrogatories, requests for information or documents in legal proceedings, subpoena, civil investigative demand or other similar process by a court of competent jurisdiction or by any administrative, legislative, regulatory or self-regulatory authority or entity) to disclose any Confidential Information, the INSTITUTE shall provide the RECIPIENT with prompt written notice of any such request or requirement so that the RECIPIENT may seek a protective order or other appropriate remedy. If, in the absence of a protective order or other remedy, the INSTITUTE is nonetheless legally compelled to make any such disclosure of Confidential Information to any person, the INSTITUTE may, without liability hereunder, disclose only that portion of the Confidential Information that is legally required to be disclosed, provided that the INSTITUTE will use reasonable efforts to assist the RECIPIENT, at the RECIPIENT's expense, in obtaining an appropriate protective order or other reliable

assurance that confidential treatment will be accorded the Confidential Information. To the extent that such Confidential Information does not become part of the public domain by virtue of such disclosure, it shall remain Confidential Information hereunder.

## Article III
## DISBURSEMENT OF GRANT AWARD PROCEEDS

**Section 3.01 Payment of Grant Award Proceeds.** The INSTITUTE will advance Grant award proceeds upon request by the RECIPIENT, consistent with the amounts and schedule as provided in Attachment B. If the RECIPIENT does not request or the Oversight Committee does not authorize advancement of funds for some or the entire Grant award proceeds, disbursement of Grant award proceeds for services performed and allowable expenses and costs incurred pursuant to the Scope of Work will be on a reimbursement basis. To the extent that completion of certain milestones is associated with a specific tranche of funding as reflected in the Scope of Work, those milestones shall be accomplished before funding may be provided for next tranche of funding. The INSTITUTE reserves the right to terminate the Contract should a key milestone not be met.

**Section 3.02 Requests for Reimbursement and Quarterly Financial Status Reports.** If the RECIPIENT does not receive an advance disbursement of Grant proceeds, the RECIPIENT's requests for reimbursement shall be made on INSTITUTE Form 269a (Financial Status Report). If the RECIPIENT has elected to receive an advance disbursement of Grant proceeds, RECIPIENT shall submit INSTITUTE Form 269a (Financial Status Report) to document all costs and allowable expenses paid with Grant proceeds. The RECIPIENT shall submit the INSTITUTE Form 269a quarterly to the INSTITUTE within 90 days following the end of the quarter covered by the bill. A final INSTITUTE Form 269a shall be submitted by RECIPIENT not later than 90 days after the Termination Date. An extension of time for submission deadlines specified herein must be expressly authorized in writing by the INSTITUTE.

**Section 3.03 Actual Costs and Allowable Expenses.** Because the Approved budget for the Project(s) as set forth in Attachment B is only an estimate, the parties agree that the RECIPIENT's billings under this Contract will reflect the actual costs and expenses incurred in performing the Project(s), regardless of the Approved Budget, up to the total contracted amount specified in Section 2.01 "Award of Monies." The RECIPIENT shall use Grant proceeds only for allowable expenses consistent with state law and agency administrative rules. Allowable expenses for the Project(s) shall be only as outlined in the Approved Budget and any modifications to same.

**Section 3.04 Travel Expenses.** Reimbursement for travel expenditures shall be in accordance with the Approved Budget. Prior written approval from the INSTITUTE must be obtained before travel that exceeds the amount included in the Approved Budget commences. Failure to obtain such prior written approval shall result in such excess travel costs constituting expenses that may not be taken into account for the purposes of calculating expenditure of Grant funds under this Contract.

**Section 3.05 Budget Modifications.** The total Approved Budget and the assignment of costs may be adjusted based on implementation of the Scope of Work, spending patterns, and unexpended funds, but only by an amendment to the Approved Budget. In no event shall an amendment to the Approved Budget result in payments in excess of the aggregate amount specified in Section 2.01 "Award of Monies" or in approved supplemental funding for the Project, if any. The RECIPIENT may make transfers between or among lines within budget categories without prior written approval provided that:

(a) The total dollar amount of all changes of any single line item within budget categories (individually and in the aggregate) is less than 10% of the total Approved Budget;

(b) The transfer will not increase or decrease the total Approved Budget;

(c) The transfer will not materially change the nature, performance level, or Scope of Work of the Project; and

(d) The RECIPIENT submits a revised copy of the Approved Budget including a narrative justification of the changes prior to incurring costs in the new category.

All other budget changes or transfers require the INSTITUTE's express prior written approval. Transfer of funds between categories in the Project's Approved Budget may be allowed if requests are in writing, fit within the Scope of Work and the total Approved Budget, are beneficial to the achievement of the objectives of the Project, and appear to be an efficient, effective use of the INSTITUTE's funds.

**Section 3.06 Withholding Payment.** The INSTITUTE may withhold Grant award proceeds from RECIPIENT if required Financial Status Reports (Form 269a) are not on file for previous quarters or for the final period, if material program requirements are not met and remain uncured after a reasonable time period to cure, if the RECIPIENT is in breach of any material term of this Contract, or in accordance with provisions of this Contract as well as applicable state or federal laws, regulations or administrative rules, and the breach remains uncured after a reasonable time period to cure. The INSTITUTE shall have the right to withhold all or part of any future payments to the RECIPIENT to offset any prior advance payments made to the RECIPIENT for ineligible expenditures that have not been refunded to the INSTITUTE by the RECIPIENT.

**Section 3.07 Grant Funds as Supplement to Budget.** The RECIPIENT shall use the Grant proceeds awarded pursuant to this Contract to supplement its overall budget. These funds will in no event supplant existing funds currently available to the RECIPIENT that have been previously budgeted and set aside for the Project. The RECIPIENT will not bill the INSTITUTE for any costs under this Contract that also have been billed or should have been billed to any other funding source.

**Section 3.08 Buy Texas.** The RECIPIENT shall apply good faith efforts to purchase goods and services from suppliers in Texas to the extent reasonably possible, to achieve a goal of more than 50 percent of such purchases from suppliers in Texas.

**Section 3.09 Historically Underutilized Businesses.** The RECIPIENT shall use reasonable efforts to purchase materials, supplies or services from a Historically Underutilized Business (HUB). The Texas Procurement and Support Services website will assist in finding HUB vendors (http://www.window.state.tx.us/procurement.) The RECIPIENT shall complete a HUB report with each annual report submitted to the INSTITUTE in accordance with Attachment E.

**Section 3.10 Limitation on Use of Grant Award Proceeds to Pay Indirect Costs.** The RECIPIENT shall not spend more than five percent of the Grant award proceeds for Indirect Costs.

**Section 3.11 Carry Forward of Unspent Funds and No Cost Extension.** RECIPIENT may request to carry forward unspent funds into the budget for the next year. Carryover of unspent funds must be specifically approved by the INSTITUTE. The INSTITUTE may approve a no cost extension for the Contract for a period not to exceed six (6) months after the Termination Date if additional time beyond the Termination date is required to ensure adequate completion of the approved project. The Contract must be in good fiscal and programmatic standing. All terms and conditions of the Contract shall continue during any extension period and if such extension is approved, notwithstanding Section 2.03, all references to the "Termination Date" shall be deemed to mean the date of expiration of such extension period.

## Article IV
## AUDITS AND INSPECTIONS

**Section 4.01 Record Keeping.** The RECIPIENT, each Collaborator whose costs are funded in all or in part by the Grant shall maintain or cause to be maintained books, records, documents and other evidence (electronic or otherwise) pertaining in any way to its performance under and compliance with the terms and conditions of this Contract ("**Records")**. The RECIPIENT, each Collaborator and each Contractor shall use, or shall cause the entity which is maintaining such Records to use generally accepted accounting principles in the maintenance of such Records, and shall retain or require to be retained all of such Records for a period of three (3) years from the Termination Date of the Contract.

**Section 4.02 Audits.** Upon request and with reasonable notice, the RECIPIENT, each Collaborator and each Contractor whose costs are charged to the Project shall allow, or shall cause the entity which is maintaining such items to allow, the INSTITUTE, or auditors working on behalf of the INSTITUTE, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract all of its Records during regular working hours. Acceptance of funds directly under the Contract or indirectly through a subcontract under the Contract constitutes acceptance of the authority of the INSTITUTE, or auditors working on behalf of the INSTITUTE, including the State Auditor and/or the Comptroller of Public Accounts, to conduct an audit or investigation in connection with those funds for a period of three (3) years from the Termination Date of the Contract.

Notwithstanding the foregoing, any RECIPIENT expending $500,000 or more in federal or state awards during its fiscal year shall obtain either an annual single audit or a program specific audit. A RECIPIENT expending funds from only one state program may elect to obtain a program specific audit in accordance with Office of Management and Budget (OMB) Circular A-133 or with the State of Texas Uniform Grant Management Standards (UGMS). A single audit is required if funds from more than one federal or state program are spent by the RECIPIENT. The audited time period is the RECIPIENT's fiscal year, not the INSTITUTE funding period.

**Section 4.03 Inspections.** In addition to the audit rights specified in Section 4.02 "Audits", the INSTITUTE shall have the right to conduct periodic onsite inspections within normal working hours and on a day and a time mutually agreed to by the parties, to evaluate the Institute-Funded Activity. The RECIPIENT shall fully participate and cooperate in any such evaluation efforts.

**Section 4.04 On-going Obligation to Submit Requested Information.** The RECIPIENT shall, submit other information related to the Grant to the INSTITUTE as may be reasonably requested from time-to-time by the INSTITUTE, by the Legislature or by any other funding or regulatory bodies covering the RECIPIENT's activities under this Contract.

**Section 4.05 Duty to Resolve Deficiencies.** If an audit and/or inspection under this Article IV finds there are deficiencies that should be remedied, then the RECIPIENT shall resolve and/or cure such deficiencies within a reasonable time frame specified by the INSTITUTE. Failure to do so shall constitute an Event of Default pursuant to Section 8.03 "Event of Default." Upon the RECIPIENT'S request, the parties agree to negotiate in good faith, specific extensions so that the deficiencies. RECIPIENT can cure such

**Section 4.06 Repayment of Grant Proceeds for Improper Use.** In no event shall RECIPIENT retain Grant funds that have not been used by the RECIPIENT for purposes for which the Grant was intended or in violation of the terms of this Contract. The RECIPIENT shall repay any portion of Grant proceeds used by the RECIPIENT for purposes for which the Grant was not intended, as determined by the final results of an audit conducted pursuant to the provisions of this Contract. Unless otherwise expressly provided for in writing and appended to this Contract, the repayment shall be made to the INSTITUTE no

later than forty-five (45) days upon a written request by the INSTITUTE specifying the amount to be repaid and detailing the basis upon which such request is being made and the amount shall include interest calculated at an amount not to exceed five percent (5%) annually. The RECIPIENT may request that the INSTITUTE waive the interest, subject in all cases to the INSTITUTE'S sole discretion.

**Section 4.07 Repayment of Grant Proceeds for Relocation Outside of Texas.** Unless waived by a vote of the Oversight Committee, the RECIPIENT shall repay the INSTITUTE all Grant proceeds disbursed to RECIPIENT in the event that RECIPIENT relocates its principal place of business outside of the State during the Contract term or within 3 years after the final payment of the Grant funds is made by the INSTITUTE.

## Article V
## ASSURANCES AND CERTIFICATIONS

**Adoption of Attachment C.** The INSTITUTE and the RECIPIENT hereby adopt the terms of Attachment C in their entirety, incorporate them as if fully set forth herein, and agree to perform and be bound by all such terms.

## Article VI
## INTELLECTUAL PROPERTY AND REVENUE SHARING

**Adoption of Attachment D.** The INSTITUTE and the RECIPIENT hereby adopt the terms of Attachment D in their entirety, incorporate them as if fully set forth herein, and agree to perform and be bound by all such terms.

## Article VII REPORTING

**Adoption of Attachment E.** The INSTITUTE and the RECIPIENT hereby adopt the terms of Attachment E in their entirety, incorporate them as if fully set forth herein, and agree to perform and be bound by all such terms.

## Article VIII
## EARLY TERMINATION AND EVENT OF DEFAULT

**Section 8.01 Early Termination of Contract.** This Contract may be terminated prior to the Termination Date specified in Section 2.03 "Contract Term" by:

(a) Mutual written consent of all parties to this Contract; or

(b) The INSTITUTE for an Event of Default (defined in Section 8.03) by the RECIPIENT; or

(c) The INSTITUTE if allocated funds should become legally unavailable during the Contract period and the INSTITUTE is unable to obtain additional funds for such purposes; or

(d) The RECIPIENT for convenience.

**Section 8.02 Repayment of Grant Proceeds upon Early Termination.** The INSTITUTE may require the RECIPIENT to repay some or all of the disbursed Grant proceeds in the event of early termination under 8.01 (d) above or under Section 8.01(b) above, to the extent such Event of Default resulted from Grant funds being expended in violation of this Contract. To the extent that the INSTITUTE exercises this option, the INSTITUTE shall provide written notice to the RECIPIENT stating the amount to be repaid, applicable interest calculated not to exceed five percent (5%) annually, and the schedule for such repayment. The RECIPIENT may request that the INSTITUTE waive the interest, subject in all cases to the INSTITUTE'S sole discretion. In no event shall the RECIPIENT retain Grant funds that have not been used by the RECIPIENT for purposes for which the Grant was intended.

**Section 8.03 Event of Default.** The following events shall, unless expressly waived in writing by the RECIPIENT INSTITUTE or fully cured by the pursuant to the provisions herein, constitute an event of default (each, an "**Event of Default**"):

(a) The RECIPIENT's failure, in any material respect, to conduct the Project in accordance with the approved Scope of Work and to demonstrate progress towards achieving the milestones set forth in Section 2.02;

(b) The RECIPIENT's failure to conduct the Project within the State of Texas to the extent required under this Contract unless as otherwise specified in the application, Scope of Work or Approved Budget;

(c) The RECIPIENT's failure to fully comply, in any material respect, with any provision, term, condition, covenant, representation, certification, or warranty contained in this Contract or any other document incorporated herein by reference;

(d) The RECIPIENT's failure to comply with any applicable federal or state law, administrative rule, regulation or policy with regard to the conduct of the Project;

(e) The RECIPIENT's material misrepresentation or false covenant, representation, certification, or warranty made by RECIPIENT herein, in the Grant application, or in any other document furnished by RECIPIENT pursuant to this Contract that was misleading at the time that it was made; or

(f) The RECIPIENT ceases its business operations, has a receiver appointed for all or substantially all of its assets, makes a general assignment for the benefit of creditors, is declared insolvent by a court of competent jurisdiction or becomes the subject, as a debtor, of a proceeding under the federal bankruptcy code, which such proceedings are not dismissed within ninety (90) days after filing.

**Section 8.04 Notice Required.** If the RECIPIENT intends to terminate pursuant to Section 8.01(d) "Early Termination of Contract", it shall provide written notice to the INSTITUTE pursuant to the notice provisions of Section 9.21 "Notices" no later than thirty (30) days prior to the intended date of termination.

If the INSTITUTE intends to terminate for an Event of Default under Section 8.01(b) by the RECIPIENT, as described in Section 8.03 "Event of Default", the INSTITUTE shall provide written notice to the RECIPIENT pursuant to Section 9.21 "Notices" and shall include a reasonable description of the Event of Default and, if applicable, the steps necessary to cure such Event of Default. Upon receiving notice from the INSTITUTE,

the RECIPIENT shall have thirty (30) days beginning on the day following the receipt of notice to cure the Event of Default. Upon request, the INSTITUTE may provide an extension of time to cure the Event of Default(s) beyond the thirty (30) day period specified herein so long as the RECIPIENT is using reasonable efforts to cure and is making reasonable progress in curing such Event(s) of Default. The extension shall be in writing and appended to the Contract. If the RECIPIENT is unable or fails to timely cure an Event of Default, unless expressly waived in writing by the INSTITUTE, this Contract shall immediately terminate as of the close of business on the final day of the allotted cure period without any further notice or action by the INSTITUTE required. **In addition, and notwithstanding the foregoing, the INSTITUTE and the RECIPIENT agree that certain events that cannot be cured shall, unless expressly waived in writing by the INSTITUTE, constitute a final Event of Default under this Contract and this Contract shall terminate immediately upon the INSTITUTE giving the RECIPIENT written "Notice of Event of Default and FINAL TERMINATION."**

In the event that the INSTITUTE terminates the Contract under Section 8.01(c) above because allocated funds become legally unavailable during the Contract period, the INSTITUTE shall immediately provide written notification to the RECIPIENT of such fact pursuant to Section 9.21 "Notices." The Contract is terminated upon the RECIPIENT's receipt of that notification, subject to Section 9.09 "Survival of Terms."

**Section 8.05 Duty to Report Event of Default.** The RECIPIENT shall notify the INSTITUTE in writing pursuant to Section 9.21 "Notices", promptly and in no event more than (30) days after it obtains knowledge of the occurrence of any Event of Default. The RECIPIENT shall include a statement setting forth reasonable details of each Event of Default and the action which the RECIPIENT proposes to take with respect thereto.

**Section 8.06 Obligations/Liabilities Affected by Early Termination.** The RECIPIENT shall not incur new obligations that otherwise would have been paid for using Grant funds after the receipt of notice as provided by Section 8.04 "Notice Required", unless expressly permitted by the INSTITUTE in writing, and shall cancel as many outstanding obligations as possible. The INSTITUTE shall not owe any fee, penalty or other amount for exercising its right to terminate the Contract in accordance with Section 8.01. In no event shall the INSTITUTE be liable for any services performed, or costs or expenses incurred, after the Termination Date of the Contract. Early termination by either party shall not nullify obligations already incurred, including the RECIPIENT's revenue sharing obligations as set forth in Attachment D, or the performance or failure to perform obligations prior to the Termination Date.

**Section 8.07 Interim Remedies.** Upon receipt by the RECIPIENT of a notice of Event of Default, and at any time thereafter until such Event of Default is cured to the satisfaction of the INSTITUTE or this Contract is terminated, the INSTITUTE may enforce any or all of the following remedies (such rights and remedies being in addition to and not in lieu of any rights or remedies set forth herein):

(a) The INSTITUTE may refrain from disbursing any amount of the Grant funds not previously disbursed; provided, however, the INSTITUTE may make such a disbursement after the occurrence of an Event of Default without thereby waiving its rights and remedies hereunder;

(b) The INSTITUTE may enforce any additional remedies it has in law or equity.

The rights and remedies herein specified are cumulative and not exclusive of any rights or remedies that the INSTITUTE would otherwise possess.

## Article IX MISCELLANEOUS

**Section 9.01 Uniform Grant Management Standards.** Unless otherwise provided herein, the RECIPIENT agrees that the Uniform Grant Management Standards (UGMS), developed by the Governor's Budget and Planning Office as directed under the Uniform Grant Management Act of 1981, TEX. GOVT. CODE, Ch. 783, apply as additional terms and conditions of this Contract and that the standards are adopted by reference in their entirety. If there is a conflict between the provisions of this Contract and UGMS, the provisions of this Contract will prevail unless expressly stated otherwise.

**Section 9.02 Management and Disposition of Equipment.** During the term of this Contract, the RECIPIENT may use Grant funds to purchase Equipment to be used for the authorized purpose of the Project, subject to the conditions set forth below. Unless otherwise provided herein, title to Equipment shall vest in the RECIPIENT upon termination of the Contract.

(a) The INSTITUTE must authorize the acquisition in advance and in writing but an acquisition is deemed authorized if included in the Approved Budget for the Project;

(b) Equipment purchased with Grant funds must stay within the State of Texas;

(c) Equipment purchased with Grant funds must be materially deployed to the uses and purposes related to the Project;

(d) In the event the RECIPIENT is indemnified, reimbursed or otherwise compensated for any loss of, destruction of, or damage to the Equipment purchased using Grant funds, it shall use the proceeds to repair or replace said Equipment;

(e) Equipment may be exchanged (trade-in) or sold without the prior written approval of the INSTITUTE if the proceeds thereof shall be applied to the acquisition cost of replacement Equipment;

(f) The RECIPIENT may use its own property management standards and procedures provided that it observes the terms of UGMS, A-102, in all material respects;

(g) The title or ownership of the Equipment shall not be encumbered for purposes other than the Project nor or transferred other than to a permitted assignee of this Contract, without the prior written approval of the INSTITUTE;

(h) If the original or replacement Equipment is no longer needed for the originally authorized purpose or for other activities supported by the INSTITUTE, the RECIPIENT shall request disposition instructions from the INSTITUTE and, upon receipt, shall fully comply therewith; and

(i) If this Contract is terminated early pursuant to Section 8.01(b), (d), (e), or (f) above, the INSTITUTE shall determine the final disposition of Equipment purchased with Grant award money.

**Section 9.03 Supplies and Other Expendable Property.** The RECIPIENT shall classify as materials, supplies and other expendable property the allowable unit acquisition cost of such property under $5,000 necessary to carry out the Project. Title to supplies and other expendable property shall vest in the RECIPIENT upon acquisition.

**Section 9.04 Acknowledgement of Grant Funding and Publicity.** The parties agree to the following terms and conditions regarding acknowledging Grant funding and publicity:

(a) The parties agree to fully cooperate and coordinate with each other in connection with all press releases and publications regarding the award of the Grant, the execution of the Contract and the Institute-Funded Activities.

(b) The RECIPIENT shall notify the INSTITUTE's Information Specialist or similar personnel at least three business days prior to any press releases, advertising, publicity, use of CPRIT logo, or other promotional activities that pertain to the Project or any Institute-Funded Activity. In the event that the INSTITUTE wishes to participate in a joint press release, the RECIPIENT shall coordinate and cooperate with the INSTITUTE's Information Specialist or similar personnel to develop a mutually agreeable joint press release.

(c) Consistent with the goal of encouraging development of scientific breakthroughs and dissemination of knowledge, publication or presentation of scholarly materials is expected and encouraged. The RECIPIENT may publish in scholarly journals or other peer-reviewed journals (including graduate theses and dissertations) and may make presentations at scientific meetings without prior notice to or consent of the INSTITUTE, except as may otherwise be set forth in this Contract. The RECIPIENT shall promptly notify the INSTITUTE when any scholarly presentations or publications have been accepted for public disclosure and shall provide the INSTITUTE with final copies of all such accepted presentations and publications. The RECIPIENT shall acknowledge receipt of the INSTITUTE funding in all publications, presentations, press releases and other materials regarding the work associated with the Institute-Funded Activities. The RECIPIENT shall promptly submit an electronic version of all published manuscripts to PubMed Central in accordance with Section 9.05 "Public Access to Research Results."

(d) When grant funds are used to prepare print or visual materials for educational or promotional purposes for the general public (e.g., patients), and excluding presentations and publications discussed above in subsection (c), the RECIPIENT shall provide a copy of such materials to the INSTITUTE at least ten (10) days prior to printing. The RECIPIENT shall also acknowledge receipt of the INSTITUTE funding on all such materials including, but not limited to, brochures, pamphlets, booklets, training fliers, project websites, videos and DVDs, manuals and reports, as well as on the labels and cases for audiovisual or videotape/DVD presentations.

**Section 9.05 Public Access to Results of Institute-Funded Activities.** The RECIPIENT shall submit an electronic version of its final peer-reviewed journal manuscripts that arise from Grant funds to the digital archive National Library of Medicine's PubMed Central upon acceptance for publication. These papers must be accessible to the public on PubMed no later than 12 months after publication. This policy is subject to the terms of Attachment D and does not supplant applicable copyright law. For clarity, this policy is not intended to require the RECIPIENT to make a disclosure at a time or in any manner that would cause the RECIPIENT to abandon, waive or disclaim any intellectual property rights that it is obligated to protect pursuant to the terms of Attachment D.

**Section 9.06 Work to be Conducted in State.** The RECIPIENT agrees that it will use reasonable efforts to direct that any new or expanded preclinical testing, clinical trials, commercialization or manufacturing that is part of or relating to any Institute-Funded Activities take place in the State of Texas, including the establishment of facilities to meet this purpose. If the RECIPIENT decides not to conduct such work in the State of Texas, the RECIPIENT shall provide a prior written explanation to the

INSTITUTE detailing the RECIPIENT's reasons for conducting the work outside of the State of Texas and the RECIPIENT's efforts made to conduct the work in the State of Texas.

**Section 9.07 Duty to Notify.** During the term of this Contract and for a period of five (5) years thereafter, the RECIPIENT is under a continuing obligation to notify the INSTITUTE's Chief Executive Officer at the same time it is required to notify any Federal or State entity of any unexpected adverse event or condition that materially impacts the performance or general public perception of the conduct or results of the Project and Institute-Funded Activities, including any impact to the Scope of Work included in the Contract and events or results that have a serious adverse impact on human health, safety or welfare. By way of example only, if clinical testing of the results of Institute-Funded Activities reveal an unexpected risk of developing serious health conditions or death, then the RECIPIENT shall, at the same time it notifies any Federal or State entity, promptly so notify the INSTITUTE's Chief Executive Officer even if such results are not available until after the term of this Contract. Notice required under this section shall be made as promptly as reasonably possible and shall follow the procedures set forth in Section 9.21 "Notices."

**Section 9.08 Severability.** If any provision of this Contract is construed to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or enforceability shall not affect any other provisions hereof. The invalid, illegal or unenforceable provision shall be deemed stricken and deleted to the same extent and effect as if never incorporated herein. All other provisions shall continue as provided in this Contract.

**Section 9.09 Survival of Terms.** Termination or expiration of this Contract for any reason will not release either party from any liabilities or obligations set forth in this Contract that: (1) the Parties have expressly agreed shall survive any such termination or expiration; or (2) remain to be performed or by their nature would be intended to be applicable following any such termination or expiration. Such surviving terms include, but are not limited to, Sections 2.13, 4.01, 4.02, 4.05, 4.06, 8.02, 8.06, 9.04, 9.05, 9.06, 9.07, 9.09, 9.14, 9.15, 9.16, 9.17, 9.18, and Attachment D.

**Section 9.10 Binding Effect and Assignment or Modification.** This Contract and all terms, provisions and obligations set forth herein shall be binding upon and shall inure to the benefit of the parties and their successors and permitted assigns, including all other state agencies and any other agencies, departments, divisions, governmental entities, public corporations or other entities which shall be successors to either of the parties or which shall succeed to or become obligated to perform or become bound by any of the covenants, agreements or obligations hereunder of either of the parties hereto. Upon a permitted assignment of this Contract by RECIPIENT, all references to "the RECIPIENT" herein shall be deemed to refer to such permitted assignee.

**Section 9.11 No Waiver of Contract Terms.** Neither the failure by the RECIPIENT or the INSTITUTE, in any one or more instances, to insist upon the complete and total observance or performance of any term or provision hereof, nor the failure of the RECIPIENT or the INSTITUTE to exercise any right, privilege or remedy conferred hereunder or afforded by law, shall be construed as waiving any breach of such term or provision or the right to exercise such right, privilege or remedy thereafter. In addition, no delay on the part of either the RECIPIENT or the INSTITUTE, in exercising any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy preclude other or further exercise thereof or the exercise of any other right or remedy.

**Section 9.12 No Waiver of Sovereign Immunity.** No provision of this Contract is in any way intended to constitute a waiver by the INSTITUTE, the RECIPIENT (if applicable), or the State of Texas of any immunities from suit or from liability that the have by INSTITUTE, the RECIPIENT, or the State of Texas may operation of law.

**Section 9.13 Force Majeure.** Neither the INSTITUTE nor the RECIPIENT will be liable for any failure or delay in performing its obligations under the Contract if such failure or delay is due to any cause beyond

the reasonable control of such party, including, but not limited to, unusually severe weather, strikes, natural disasters, fire, civil disturbance, epidemic, war, court order or acts of God. The existence of such causes of delay or failure will extend the period of performance in the exercise of reasonable diligence until after the causes of delay or failure have been removed. Each party must inform the other in accordance with Section
9.21 “Notices” within five (5) business days, or as soon as it is practical, of the existence of a force majeure event or otherwise waive this right as a defense.

**Section 9.14 Disclaimer of Damages. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, PUNITIVE, EXEMPLARY, INCIDENTAL OR CONSEQUENTIAL DAMAGES. THIS LIMITATION WILL APPLY REGARDLESS OF WHETHER OR NOT THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.**

**Section 9.15 Indemnification and Hold Harmless.** Except as provided herein, the RECIPIENT agrees to fully indemnify and hold the INSTITUTE and the State of Texas harmless from and against any and all claims, demands, costs, expenses, liabilities, causes of action and damages of every kind and character (including reasonable attorneys fees) which may be asserted by any third party in any way related or incident to, arising out of, or in connection with (1) the RECIPIENT’s negligent, intentional or wrongful performance or failure to perform under this Contract, (2) the RECIPIENT’s receipt or use of Grant funds, or (3) any negligent, intentional or wrongful act or omission committed by the RECIPIENT as part of an Institute-Funded Activity or during the Project. In addition, the RECIPIENT agrees to fully indemnify and hold the INSTITUTE and the State of Texas harmless from and against any and all costs and expenses of every kind and character (including reasonable attorneys fees, costs of court and expert fees) that are incurred by the INSTITUTE or the State of Texas arising out of or related to a third party claim of the type specified in the preceding sentence. Notwithstanding the preceding, such indemnification shall not apply in the event of the sole or gross negligence of the INSTITUTE. If the RECIPIENT is a State of Texas agency or institution of higher education, then this Section 9.15 is subject to the extent authorized by the Texas Constitution and the laws of the State of Texas.

The RECIPIENT acknowledges and agrees that this indemnification shall apply to, but is not limited to, employment matters, taxes, personal injury, and negligence.

It is understood and agreed that it is not the intent of the parties to expand or increase the liability of the State of Texas under this Article. This provision is intended to prevent the RECIPIENT, the INSTITUTE and the State of Texas from attempting or appearing to assume liability it does not have the statutory or legal power to assume.

**Section 9.16 Alternative Dispute Resolution.** If applicable, the dispute resolution process provided for in TEX. GOVT. CODE, Ch. 2260 shall be used, as further described herein, to resolve any claim for breach of contract made against the INSTITUTE (excluding any uncured Event of Default). The submission, processing and resolution of a party's claim are governed by the published rules adopted by the Attorney General pursuant to TEX. GOVT. CODE, Ch. 2260, as currently effective, hereafter enacted or subsequently amended.

**Section 9.17 Applicable Law and Venue.** This Contract shall be construed and all disputes shall be considered in accordance with the laws of the State of Texas, without regard to its principles governing the conflict of laws. Provided that the RECIPIENT first complies with procedures set forth in Section 9.16 “Alternative Dispute Resolution,” exclusive venue and jurisdiction for the resolution of claims arising from or related to this Contract shall be in the federal and state courts in Travis County, Texas.

**Section 9.18 Attorneys’ Fees.** In the event of any litigation, appeal or other legal action to enforce any provision of the Contract, the RECIPIENT shall pay all expenses of such action, including attorneys' fees

and costs, if the INSTITUTE is the prevailing party. If the RECIPIENT is a State of Texas agency or institution of higher education, then this Section 9.18 is subject to the extent authorized by the Texas Constitution and the laws of the State of Texas.

**Section 9.19 Counterparts.** This Contract may be executed in any number of counterparts, each of which when so executed and delivered shall be an original, but such counterparts shall together constitute one and the same instrument.

**Section 9.20 Construction of Terms** The headings used in this Contract are inserted only as a matter of convenience and for reference and shall not affect the construction or interpretation of this Contract. Where context so indicates, a word in the singular form shall include the plural, a word in the masculine form the feminine, and vice-versa. The word "including" and similar constructions (such as "includes", "included", "for example", "such as", and "e.g.") shall mean "including, without limitation" throughout this Contract. The words “and” and “or” are not intended to convey exclusivity or nonexclusivity except where expressly indicated or where the context so indicates in order to give effect to the intent of the parties.

**Section 9.21 Notices.** All notices, requests, demands and other communications will be in writing and will be deemed given on the date received as demonstrated by (i) a courier’s receipt or registered or certified mail return receipt signed by the party to whom such notice was sent, provided that such notice was sent to the Authorized Signing Official (ASO) at the address provided in the CPRIT Grants Management System, (ii) a fax confirmation page showing that such fax was successfully transmitted to the fax number provided in the CPRIT Grants Management System, or (iii) via correspondence in the CPRIT Grants Management System.

# DP160071, Contract Attachment A

## Abstract and Significance

Multiple myeloma accounts for 10% of all hematological malignancies in the United States. An estimated 26,850 people were diagnosed with the disease in the United States in 2015 with an estimated 11,200 deaths resulting from the disease (SEER Cancer Statistics, 2015). The five-year survival rate for myeloma is only 45%.

Historically, there have been three major classes of therapeutics used to treat multiple myeloma: steroids, proteasome inhibitors, and the thalidomide-derived immunomodulatory drugs (IMiDs). In 2015, daratumumab, an antibody to CD38, and elotuzumab, an antibody to CS1, became the first biologics approved for multiple myeloma. Daratumumab in particular has shown robust single-agent activity (29% response rate) in relapsed/refractory patients indicating that CD38 plays an important role in myeloma disease progression.

Because of the generally poor outcome in myeloma patients, there is a high need for new therapeutics to treat the disease. Molecular Templates has developed a novel scaffold of biologics against cancer by fusing the single chain variable fragment of an antibody (scFv) to a proprietarily modified form of the Shiga-like toxin A subunit (SLTA), an enzymatic inactivator of ribosome activity. These compounds combine the specificity of an antibody with a novel and potent direct mechanism of cell-kill. Molecular Templates' first compound, MT-3724 targets CD20 and is in a first-in-human dose-escalation study at MD Anderson and Memorial Sloan Kettering in heavily pre-treated patients with non-Hodgkins lymphoma (NHL). To date, there have been twelve patients treated with no dose-limiting toxicities seen. Of the eleven patients evaluable for efficacy, there has been one complete metabolic response (patient to undergo allogeneic transplant), one partial response, one mixed response, three stable diseases (all with tumor regression), and five patients with progressive disease. This efficacy is especially impressive since MT-3724 has not yet reached linear pharmacokinetics in its dose escalation.

Molecular Templates has designed MT-4019ND for the treatment of multiple myeloma. MT-4019ND has a high-affinity scFv that specifically targets CD38 fused to a proprietary de-immunized form of SLTA.
MT-4019ND has shown extremely potent in vitro and in vivo activity against tumor cells expressing CD38. MT-4019ND has shown potent synergistic activity in combination with pomalidomide, the standard of care for refractory myeloma patients. MT-4019ND mirrors MT-3724 in terms of scaffold construction with similar absorption, distribution, metabolism and excretion (ADME) and pharmacokinetics (PK) characteristics.

CD38 was chosen as a target because of the clinical activity of daratumumab. Daratumumab works primarily by directing complement dependent cytotoxicity (CDC) and antibody-dependent cell-mediated cytotoxicity (ADCC) to CD38+ myeloma cells. Although immune recruitment can be a potent mechanism of cell-kill, roughly 70% of CD38+ refractory patients fail to respond to daratumumab monotherapy.

There is strong precedence in oncology for developing different mechanisms of action against the same validated target. There is an approved antibody, small molecule, and antibody-drug conjugate targeting

HER2 in breast cancer, for example as well as multiple small molecules and antibodies to EGFR. In multiple myeloma, three different IMiDs (lenalidomide, pomalidomide, and thalidomide) are used sequentially in treatment. MT-4019ND was engineered to provide a different mechanism of destruction targeting CD38+ myelomas. In in vitro and in vivo studies, MT-4019ND shows excellent specificity, potency and safety as well as synergistic activity in combination with an IMiD. MT-3724 is administered as an infusion and has predictable PK and ADME characteristics. MT-4019ND shares a scaffold with MT-3724 which has shown excellent safety and notable efficacy in its first-in-human study.

This application outlines a strategy to move MT-4019ND into clinical studies and rapidly characterize its activity in myeloma patients with no other treatment options. The development plan outlined in this application follows that of daratumumab and has the potential to show early signs of safety and efficacy and to form the basis of an accelerated FDA approval. Molecular Templates has successfully demonstrated that it can efficiently move pre-clinical leads into first-in-human studies. The early clinical data seen the company’s lead compound MT-3724 strongly suggest the scaffold used to construct MT-4019ND is safe and effective.

## Layperson's Summary

In 2015, there were approximately 27,000 new cases of multiple myeloma diagnosed in the US making it the second most prevalent blood cancer. The five-year survival rate for multiple myeloma is 45% and the median survival is approximately 4 years.
CD38 is a protein expressed on the surface of myeloma cells. Recently, daratumumab, an antibody that specifically targets CD38, was approved for the treatment of patients with multiple myeloma. Daratumumab works primarily by binding myeloma cells and recruiting an immune response to them. Most patients' immune system will ultimately stop responding to daratumumab allowing the disease to progress.

Molecular Templates, a venture-backed biopharmaceutical company in Georgetown, TX, has developed a novel multiple myeloma drug that targets CD38 but works in a different way from daratumumab.
MT-4019ND is a fusion of an antibody fragment that binds CD38 with a highly toxic bacterial protein. MT-4019ND binds CD38 on the surface of myeloma cells but instead of recruiting an immune response, it directly kills the myeloma cell through its toxin component. MT-4019ND has shown a potent ability to kill myeloma cell lines in the laboratory and in animal models of myeloma.
Molecular Templates has a similar compound in the clinic for lymphoma that appears safe and effective in patients.
Molecular Templates seeks $15.3M in CPRIT financing to move MT-4019ND through clinical studies in patients with refractory multiple myeloma.

Timelines: project_timeline.pdf

**Goal 1:**

O pen MT-4019 IND Upon funding, Molecular Templates would initiate IND-required studies. These studies would include two GLP repeat dose toxicity studies in the appropriate rodent and

ADDED non-human primate species, non-GLP studies in rodent and non-human primate, a GLP TCR assay, all required assay development and validation, and establishment of the PK profile for MT-4019ND. In parallel, process development and expression of MT-4019ND for GMP materials will commence upon funding. Molecular Templates has considerable experience in conducting IND-enabling studies and in the manufacture of GMP material for its scFv-SLTA fusions.

**Objective 1:** Satisfy FDA requirements for successful IND application

ADDED

**Objective 2:**

ADDED

Use toxicology studies to establish a starting dose in humans that is expected to be safe and may potentially provide benefit

**Objective 3:** Create sufficient GMP material to cover drug needs in Phase I
**ADDED**

**Goal 2:** Initiation of Phase I First-in-Man Clinical Trial in Relapsed/Refractory Multiple Myeloma A first-in-man Phase I study in relapsed or refractory myeloma patients (n=30) is targeted to begin a
**ADDED** year after the receipt of CPRIT funding with an estimated study completion timeline of 18 months including data read-out and analysis. Up to four clinical sites will be selected for participation in the Phase I study with at least one site located in Texas. Patients will be deemed refractory if they have failed at least three lines of therapy, including both a proteasome inhibitor, an IMiD, and a CD38 antibody. An efficacy analysis will be conducted at the conclusion of the Phase I study; if a response rate of 10% or greater is not seen, the project will be halted. If the response rate in the Phase I is 10% or greater, the Phase II portion of the study will commence. During the Phase I, a second GMP manufacturing campaign will commence based on an early interim evaluation of drug activity in the ongoing Phase I in preparation for the Phase II portion of the study.

**Objective 1:** Initiate Phase I study for MT-4019ND
**ADDED**

**Objective 2:**
**ADDED**

| | |
|---|---|
| Based on | early ad hoc read of efficacy and safety data from Phase I, initiate second GMP manufacturing campaign for Phase II drug materials |

**Objective 3:** Establish Phase II dose
**ADDED**

**Goal 3:**

Ini tiation of Phase II Clinical Trial in Relapsed/Refractory Multiple Myeloma In the event that a 10% or greater response rate is seen in the Phase I, the study will be expanded to a Phase II study.

**ADDED** The Phase II expansion (n=110) would be expected to start within 30 months of receiving CPRIT financing and could be expected to complete in 24 months. The Phase I clinical sites would be expanded with an estimated 10 to 12 clinical sites participating in the Phase II portion of the study.

At least three of the expansion sites will be in Texas. The Phase II will examine the safety and efficacy of MT-4019ND in relapsed or refractory multiple myeloma patients. As seen with daratumumab, the Phase II study could form the basis of a registration study. The goal would be to demonstrate substantial clinical benefit in patients with CD38+ relapsed/refractory multiple myeloma to support approval of MT-4019ND.

**Objective 1:** Initiate Phase II expansion study for MT-4019ND
**ADDED**

**Objective 2:** Determination of whether Phase II study can be pivotal
**ADDED**

**TIMELINE**

**AIM 1**

Objective: A successful IND submission for MT-4019ND

Methods: Fully characterize MT-4019ND on the following parameters:

- GMP manufacturing
- IND-enabling studies including (but not limited to) toxicology

Time/Cost: 12 months/$4,100,000

Go/No-go: An inability to establish a starting dose for Phase I or any significant unexpected toxicity in the non-human primate model will end development of MT-4019ND

Month 1-2: Tech transfer to GMP manufacturer Month 3-4: 100L process development run
Month 5: Engineering run (240L scale); Non-GLP studies (murine and NHP) Month 6: GMP run (2 X 300L scale); pre-IND meeting
Month 7-8: GLP repeat dose toxicology studies (murine and NHP) Month 8-11: Chronic toxicology study (if required)
Month 12: IND filing

**AIM 2**

Objective: Complete a first-in-man Phase I study with MT-4019ND

Methods: Conduct a multi-institution Phase I study in CD38+ relapsed/refractory multiple myeloma patients

- Dose-escalation study
- Major endpoints are establishing dose, safety, and PK parameters
- Initiate GMP campaign for Phase II study based on interim read of Phase I study

Time/Cost: 18 months/$5,150,000

Go/no-go: A response rate of < 10% or severe toxicity will result in termination of the project

Month 1-4: Site selection and IRB approval
Month 5-15: Determine MTD; PK and ADA analysis; response rate assessment; initiate Phase II GMP campaign based on interim efficacy and safety read
Month 15: FDA discussion for Breakthrough Therapy Designation Month 18: Initiation of Phase II expansion

**AIM 3**

Objective: Conduct Phase II expansion study in CD38+ relapsed/refractory multiple myeloma patients

Methods: Expansion to a multi-institution Phase II study in CD38+ relapsed/refractory multiple myeloma patients

- Expand cohort after MTD is defined
- Major endpoints are evaluation of response rates, duration of response, a progression-free survival

Time/Cost: 18 months/$6,050,000

Month 1-6: Expansion of sites; initiation of accrual

## ATTACHMENT B - Detailed Budget Form

| Budget | Budget Year 1 | Budget Year 2 | Budget Year 3 | Total Budget |
|---|---|---|---|---|
| a. Personnel | $0.00 | $0.00 | $0.00 | $0.00 |
| b. Fringe Benefits | $0.00 | $0.00 | $0.00 | $0.00 |
| c. Travel | $0.00 | $0.00 | $0.00 | $0.00 |
| d. Equipment | $0.00 | $0.00 | $0.00 | $0.00 |
| e. Supplies | $50,000.00 | $750,000.00 | $0.00 | $800,000.00 |
| f. Contractual | $4,050,000.00 | $4,400,000.00 | $5,950,000.00 | $14,400,000.00 |
| g. Other | $0.00 | $0.00 | $0.00 | $0.00 |
| **h. Total Direct Charges** | **$4,100,000.00** | **$5,150,000.00** | **$5,950,000.00** | **$15,200,000.00** |
| i. Indirect Charges (doesn't apply to prevention grants awarded prior to 01 Sep 2016) | $0.00 | $0.00 | $0.00 | $0.00 |
| **j. Total Charges** | **$4,100,000.00** | **$5,150,000.00** | **$5,950,000.00** | **$15,200,000.00** |

* Note:

For purposes of contract initiation only:

| | |
|---|---|
| **Federal ID#:** | 90-0549423 |
| **Vendor ID#:** | 19005494232000 |
| **ASO Contact:** | Kim, Jason |
| **Address:** | 9301 Amberglen Boulevard, Suite 100 |
| **Address 2:** | |
| **City, State, ZIP** | Austin, TX 78729 |
| **Phone:** | 5126390206 |
| **Fax:** | 5122332709 |
| **Email:** | jason.kim@moleculartemplates.com |

# ATTACHMENT C ASSURANCES AND

# CERTIFICATIONS

This Attachment C is hereby incorporated into and made a part of that certain **CANCER RESEARCH GRANT CONTRACT** ("**Contract**") by and between the Cancer Prevention and Research Institute of Texas ("**CPRIT**" or the "**INSTITUTE**") and the RECIPIENT. A capitalized term used in this Attachment shall have the meaning given to term in the Contract or in the Attachments to the Contract, unless otherwise defined herein. In the event of a conflict between the provisions of this Attachment and the provisions of the Contract, this Attachment shall control.

**By signing this Contract, RECIPIENT certifies compliance with the following assurances and certifications required by the INSTITUTE (listed below). RECIPIENT further acknowledges that its obligations pursuant to the following assurances and certifications are ongoing.**

**Section C1.01 Demonstration of Matching Funds.** Pursuant to TEX. HEALTH & SAFETY CODE § 102.255(d) and T.A.C. 25 § 703.11, RECIPIENT has an amount of funds equal to one-half of the amount of the Grant to be disbursed each fiscal year of the Contract term dedicated to the research that is the subject of the Grant as demonstrated by the form incorporated herein to Attachment C. The RECIPIENT shall update the matching funds certification and verficiation annually for each fiscal year that Grant funds are disbursed.

**Section C1.02 Payment of Taxes.** RECIPIENT's payment of franchise taxes is current or, if the RECIPIENT is exempt from payment of franchise taxes, that it is not subject to the State of Texas franchise tax. If franchise tax payments become delinquent during the Contract term, payments under this Contract will be withheld until the RECIPIENT's delinquent franchise tax is paid in full. The RECIPIENT also acknowledges that it is not otherwise exempt from state sales or occupancy tax as a result of this Contract.

**Section C1.03 Compliance with Confidentiality Guidelines Relating to Personal and Medical Information.** RECIPIENT complies with all applicable laws, rules and regulations relating to personal and medical information. Without in any way limiting the foregoing, RECIPIENT maintains and enforces appropriate facility and information technology access rules and procedures to protect against inappropriate disclosure of patient records and all other documents deemed confidential by law, which are maintained in connection with the Project and Institute-Funded Activities, including provisions that comply with the requirements of the INSTITUTE's rules, 25 T.A.C. Section 703.14. Upon request from the INSTITUTE, RECIPIENT will timely furnish a copy of the RECIPIENT's facility and information technology access rules and procedures, as well as any other applicable confidentiality guidelines.

If RECIPIENT, including any Collaborators or Contractors, works directly with patients or otherwise has access to or maintains patient personal and medical information, RECIPIENT specifically addresses Health Insurance Portability and Accountability Act of 1996 regulations concerning confidentiality of personal and medical information. Any disclosure of confidential information in any way related to the Project (including information that may be required by reports and inspections) must be in accordance with all applicable laws.

**Section C1.04 Conduct of Research or Service Provided.** RECIPIENT understands that the Project must be conducted with full consideration for the ethical and medical implications of the research

performed or services delivered and comply with all federal and state laws regarding the conduct of the research or service.

**Section C1.05 Regulatory Certificates, Licenses and Permits.** All personnel, facilities and equipment involved or to be involved in the Project are certified, licensed, permitted, registered or approved by the appropriate regulating agency, where applicable. Any revocation, surrender, expiration, non-renewal, inactivation or suspension of any such certification, license, permit, registration or approval shall constitute grounds for Contract termination.

**Section C1.06 Assurances and Certifications in Accordance with the NIH *Grants Policy Statement***:

(a) Civil Rights. Compliance with Title VI of the Civil Rights Act of 1964.

(b) Handicapped Individuals. Compliance with Section 504 of the Rehabilitation Act of 1973 as amended.

(c) Sex Discrimination. Compliance with Section 901 of Title IX of the Education Amendments of 1972 as amended.

(d) Age Discrimination. Compliance with the Age Discrimination Act of 1975, as amended.

(e) Patents, Licenses and Inventions. Compliance with the Standard Patent Rights clauses as specified in 37 CFR, Part 401 or 35 U.S.C. 203, if appropriate and applicable, in a manner that adequately protects the INSTITUTE'S rights in the Project Results.

(f) Human Subjects. Compliance with the requirements of federal policy concerning the safeguarding of the rights and welfare of human subjects who are involved in activities supported by federal funds. Before any funding may be released for any Project involving human subjects, RECIPIENT must receive approval from RECIPIENT's Institutional Review Board (IRB). Upon request, a copy of RECIPIENT's IRB approval must be provided to the INSTITUTE.

(g) Human Biological/Anatomical Material. Compliance with the recommendations of the NIH Office of Human Subject Research Medical Administrative Series (MAS) #MO1-2 entitled "Procurement and Use of Human Biological Materials for Research," and any other federal or state requirements.

(h) Use of Animals. Compliance with applicable portions of the Animal Welfare Act (PL 89-544 as amended) and appropriate Public Health Service Policy on Humane Care and Use of Laboratory Animals regulations. Before any funding may be released for any Project involving animal subjects, RECIPIENT must receive approval from RECIPIENT's Institutional Animal Care and Use Committee (IACUC). Upon request, a copy of RECIPIENT's IACUC approval must be provided to the INSTITUTE.

(i) Debarment and Suspension. RECIPIENT certifies that neither it nor the Principal Investigator/Project Director or any other Recipient Personnel or personnel of any Collaborator or Contractor assigned to work on the Project are debarred, suspended, proposed for debarment, declared ineligible or otherwise excluded from participation in the Project by any federal or state department or agency.

(j) Non-Delinquency on Federal or State Debt. RECIPIENT certifies that neither it, nor any person to be paid from funds under this Contract, is delinquent in repaying any Federal debt as defined by OMB Circular A-129 or any debt to the State of Texas.

(k) Eligibility to Receive Payments on State Contracts. RECIPIENT certifies that it and the Principal Investigator/Project Director are not ineligible to receive the Grant award under this Contract pursuant to Tex. Fam. Code Ann. Section 231.006 and acknowledges that this Contract may be terminated and payment may be withheld if this certification is inaccurate.

(l) Drug-Free Workplace. Compliance with the Drug-Free Workplace Act of 1988 (45 CFR 82).

(m) Misconduct in Science. Compliance with 42 CFR Part 50, Subpart A, and Final Rule as published at 54 CFR 32446, August 8, 1989.

(n) Objectivity of Research/Conflict of Interest. Compliance with the NIH requirement to maintain a written standard of conduct and comply with 42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research. RECIPIENT must notify the INSTITUTE of any conflicting financial interests and assure that the interest has been managed, reduced or eliminated.

(o) Trafficking in Persons. Compliance with the NIH regulations on trafficking in persons as published at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-055.html.

(p) Criminal Misconduct. RECIPIENT shall promptly report issues to the INSTITUTE involving potential civil or criminal fraud related in any way to the Project, the Institute-Funded Activity or this Contract, such as false claims or misappropriation of federal or state funds.

**Section C1.07 Tobacco Free Workplace Policy.** Pursuant to T.A.C. 25 § 703.20, RECIPIENT certifies that its board of directors, governing body, or similar has adopted and enforces a Tobacco-Free Workplace Policy that meets or exceeds all of the following minimum standards:

(a) Prohibits the use of all forms of tobacco products, including but not limited to cigarettes, cigars, pipes, water pipes (hookah), bidis, kreteks, electronic cigarettes, smokeless tobacco, snuff and chewing tobacco;

(b) Designates the property to which the policy applies ("designated area"). The designated area(s) must at least comprise all buildings and structures where the CPRIT project is taking place, as well as the sidewalks, parking lots, walkways, and attached parking structures immediately adjacent but only to the extent the CPRIT Grant Recipient owns, leases as the sole tenant, or controls the building, sidewalks, parking lots and/or parking structures. In the event that the RECIPIENT does not own, lease as the sole tenant, or control the building, sidewalks, parking lots and/or parking structures, then the designated area(s) must include all areas under the RECIPIENT's control;

(c) Applies to all employees and visitors in the designated area(s); and

(d) Provides for or refers employees to tobacco use cessation services.

If RECIPIENT cannot meet the minimum standards as set forth in this section, RECIPIENT certifies that it has received an approved waiver from the INSTITUTE's CEO for the current fiscal year.

**Section C1.08 No Donations to the Institute or a Foundation Established to Support Institute.** RECIPIENT certifies that as of June 14, 2013, it has not made and will not make a contribution, during the term of the Contract, to the INSTITUTE or to any foundation established specifically to support the INSTITUTE.

**DP160071 - Product Development Research Contract Attachment C Part 2 Matching Compliance Certification (MCC) - Initial**

**For Public or Private Institutions of Higher Education ONLY (all other entities proceed to the section below):** The grant recipient may credit toward the matching funds requirement the dollar equivalent to the difference between the institution's federally approved indirect cost rate for research projects and CPRIT's five percent (5%) indirect cost allowance. If a Public or Private Institution of Higher Education intends to fulfill its match requirement using expended funds only (no federally approved indirect cost rate credit), then choose "No" on the first question and proceed with the form submission.

If the grant recipient's Federally Approved Indirect Cost Rate is greater than or equal to 55% (the 50% matching funds requirement and the 5% CPRIT Indirect Cost Rate), then no further action is required once the appropriate information has been entered in lines "a" through "d" and in the "Enter Certification of Initial Matching Funds Encumbered" field below.

If the combined Federally Approved Indirect Cost Rate and the CPRIT Indirect Cost Rate calculated for the Project is less than 55%, then the grant recipient must use the section below to demonstrate that it has encumbered funds available and not yet expended that are dedicated to the
CPRIT-funded project for the portion of the match requirement not met by the Federally Approved Indirect Cost Rate credit.

| | |
|---|---|
| **Public or Private Institution of Higher Education: (Choose 'No' if You Are Using Encumbered Funds)** | No |
| **Matching funds Requirement + CPRIT Indirect Cost Rate:** | **50.0%** |
| Federally Approved Cost Rate for Project for Year 1: | - 0.0% |
| Percentage to fulfill match requirement for Year 1: | 50.0% |
| **Certified Year 1 Approved Budget:** | **$4,100,000.00** |
| Remaining Dollar amount to fulfill match requirement for the Award year 1: | $2,050,000.00 |
| Match based on prior year credit/deficiency: | $2,050,000.00 |
| Enter Certification of Initial Matching Funds Encumbered: | $2,050,000.00 |

The information above is the entity/Institution's demonstration of encumbered available funds pursuant to its certification in Attachment C. The information in the certification shall be updated annually. **By approving this form the grant recipient certifies that it has the matching funds available as reflected on the form.**

# ATTACHMENT D

# INTELLECTUAL PROPERTY AND REVENUE SHARING

This Attachment D is hereby incorporated into and made a part of that certain **CANCER RESEARCH GRANT CONTRACT** ("**Contract**") by and between the Cancer Prevention and Research Institute of Texas ("**CPRIT**" or the "**INSTITUTE**") and the RECIPIENT. A capitalized term used in this Attachment shall have the meaning given the term in the Contract or in the Attachments to the Contract, unless otherwise defined herein. In the event of a conflict between the provisions of this Attachment and the provisions of the Contract, this Attachment shall control.

## PART 1
## OWNERSHIP AND INTELLECTUAL PROPERTY PROTECTION

**Section D1.01 Ownership of Project Results.** RECIPIENT and its Collaborators, and (to the extent applicable) any third party participating in the development of the Project Results, shall retain ownership of the Institute-Funded Technology and the Institute-Funded IPR, subject to the terms of the Contract. A Collaborator as defined in the Contract is not a third party that engages with RECIPIENT as a licensing partner.

**Section D1.02 Transfer or Assignment of Rights to a Third Party.** RECIPIENT shall notify the INSTITUTE of any proposed transfer or assignment of rights in any Project Results to a third party and provide to INSTITUTE a copy of the agreement under which the proposed transfer or assignment is to occur. RECIPIENT shall ensure that, in any assignment or transfer of Project Results, the transferee or assignee agrees in writing to: (i) recognize that the Institute-Funded IPR and Institute-Funded Technology, as applicable, is transferred or assigned subject to the licenses, interests and other rights in such Project Results provided to the INSTITUTE in the Contract and any applicable law or regulation, (ii) take all actions necessary to protect all such licenses, interests and other rights, and (iii) be responsible for and pay all amounts required under Part 4 of this Attachment D. Any attempted transfer or assignment of rights in any Project Results to a third party without written agreement to the conditions in (i) – (iii) above shall be null, void and of no effect.

**Section D1.03 Protection of Institute-Funded IPR.** Subject to Section D5.01, RECIPIENT shall use commercially reasonable efforts to appropriately protect the Institute-Funded IPR, including without limitation, diligently seeking registration and maintenance of patents and copyrights covering the Institute-Funded Technology, as appropriate. If RECIPIENT elects to abandon any patent applications filed or patents issued covering any Institute-Funded Technology in any Major Market Country, RECIPIENT shall provide the INSTITUTE with prior written notice of such election, with sufficient time (but no less than 60 days) for the INSTITUTE to exercise its rights under this Section D1.03 with respect thereto. Upon notice of the aforesaid, the INSTITUTE shall have the right, but not the obligation, to pursue protection of the applicable Institute-Funded Technology on its own behalf in such Major Market Country, including directing the filing, prosecution and maintenance of patent applications or patents covering the applicable Institute-Funded Inventions in any of such Major Market Countries for which the INSTITUTE exercises its rights under this Section D1.03. In the Major Market Countries where the INSTITUTE pursues protection of the Institute-Funded Technology under this Section D1.03, RECIPIENT agrees to grant, and does hereby grant, to the INSTITUTE a non-exclusive, irrevocable, royalty-free, perpetual license with right to sublicense in the applicable Major Market Countries to the applicable Instituted-Funded Technology and

any applicable Project Results. For clarification, a determination by RECIPIENT to (i) abandon a patent application in favor of a continuation or divisional application or the like, or (ii) narrow the scope of the claimed subject matter, shall not be deemed an election to abandon such Institute-Funded IPR.

**Section D1.04 Cost of Protection.** The INSTITUTE shall not be responsible for, and no Grant funds may be used to pay for, any costs or expenses associated with RECIPIENT's efforts to protect the Institute- Funded IPR.

**Section D1.05 Inventions.**

**(a) Disclosures and Patent Applications.** RECIPIENT shall notify INSTITUTE of each Institute-Funded Invention by delivering to INSTITUTE a copy of the invention disclosure within thirty (30) days after RECIPIENT receives or generates it. In the event that a patent application is filed on the invention disclosure, RECIPIENT shall provide the INSTITUTE with a complete copy of such patent application and associated filing documents within (30) days of its filing.

**(b) Patent Prosecution and Maintenance.** For all Institute-Funded Inventions for which patent protection is pursued, RECIPIENT shall provide an annual written report to the INSTITUTE regarding the status of pending applications and issued patents that are Institute-Funded IPR.

**Section D1.06 Required Agreements with Recipient Personnel and Contractors.** The RECIPIENT shall have, maintain and enforce written policies or agreements applicable to Recipient Personnel and Contractors with terms sufficient to enable RECIPIENT to fully comply with all terms and conditions of this Contract, including that Recipient Personnel and Contractors agree to and hereby assign any Institute- Funded Inventions to RECIPIENT. RECIPIENT shall promptly report to INSTITUTE any material breach of such policies or agreements relating to or affecting any of the provisions of this Contract.

**Section D1.07 Agreements with Collaborators.** All agreements between RECIPIENT and a Collaborator, or a third party participating in the development of the Project Results, relating to or affecting joint ownership of any Project Result shall recognize the licenses, interests and other rights provided to the INSTITUTE in the Contract. RECIPIENT shall provide to the INSTITUTE a copy of each such agreement affecting joint ownership of any Project Result.

## PART 2
## NON-COMMERCIAL LICENSES

**Section D2.01 RECIPIENT License.** In granting an Exclusive License to any Project Results, RECIPIENT shall retain the right to Exploit all Project Results (including material embodiments thereof) for education, research and other non-commercial purposes, and the right to grant the licenses pursuant to Section D2.02 below.

**Section D2.02 INSTITUTE License.** RECIPIENT agrees to grant, and does hereby grant, to the INSTITUTE a non-exclusive, irrevocable, royalty-free, perpetual, worldwide license with right to sublicense under the Project Results and, subject to any existing third party rights, any Necessary Additional IPR to Exploit all Project Results (including material embodiments of Project Results) by the INSTITUTE, other governmental entities and agencies of the State of Texas, and private or independent institutions of higher education (as defined by Texas law) located in Texas, for education, research and other non-commercial purposes only pursuant to industry-standard confidentiality and/or material transfer agreements to be entered into between the parties, as applicable. RECIPIENT shall make the Institute-Funded Technology available by reasonable means to the INSTITUTE in order for the INSTITUTE to exercise its rights under this Section D2.02, at no cost to RECIPIENT. A copy of any written license granted by INSTITUTE under this Section D2.02 will be provided to RECIPIENT by INSTITUTE within ten (10) days of the effective date of such license.

**Section D2.03 No Implied Licenses.** No implied licenses are granted under this Agreement including without limitation any license to any Intellectual Property Rights owned or controlled by RECIPIENT

outside of the Institute-Funded IPR. Nothing in this Agreement shall be construed to impose an obligation on RECIPIENT to license or otherwise make available any of its Intellectual Property Rights or other resources owned or controlled by it except as expressly provided in this Agreement.

## PART 3 COMMERCIALIZATION OF PROJECT RESULTS

**Section D3.01 Commercialization Strategy.** RECIPIENT shall be under a continuing obligation throughout the term of this Contract to enhance and improve the commercial development plan submitted with the Application and to provide an annual written report to the INSTITUTE regarding the RECIPIENT's and its licensee's efforts to commercialize or otherwise bring to practical application Project Results. The INSTITUTE may, at its option and at any time, provide RECIPIENT with comments regarding the RECIPIENT's commercial development plan and strategy, in which case RECIPIENT shall consider in good faith and, if appropriate, use reasonable efforts to account for and incorporate the INSTITUTE's input into such commercial development plan and strategy.

**Section D3.02 Commercialization Efforts.** The RECIPIENT shall, including whether through its own efforts or the efforts of a licensee under a License Agreement allowed by the terms of this Attachment, use diligent and commercially reasonable efforts to commercialize at least one Commercial Product or Commercial Service or otherwise bring to practical application the Project Results in accordance with the commercial development plan submitted with the Application and including any changes to such commercial development plan in accordance with Section D3.01. For the avoidance of doubt, partnering or licensing activities shall be considered to be efforts to commercialize.

**Section D3.03 Licensing of Project Results.** Each License Agreement entered into by the RECIPIENT shall include an acknowledgement by the licensee that (i) such License Agreement is subject to the INSTITUTE's licenses, interests and other rights under this Contract, and (ii) to the extent that there is a conflict between the terms of the License Agreement and the terms of this Contract, the terms of this Contract shall prevail. In addition, all License Agreements shall include terms obligating the licensee to report to the RECIPIENT such information as is required for the RECIPIENT to fully comply with the terms of the Contract, including without limitation the reporting obligations set forth in Attachment E, and to allow RECIPIENT to make the grants specified in Sections D2.02. The RECIPIENT shall monitor the performance of its licensees and such licensees' compliance with the terms of the License Agreements and shall take commercially reasonable actions to enforce the terms of all License Agreements. The RECIPIENT shall promptly report to the INSTITUTE any material breach of a License Agreement relating to or affecting any of the material provisions of this Contract.

**Section D3.04 Cost of Licensing Activities.** The INSTITUTE shall not be responsible for, and no Grant funds may be used to pay for, any costs or expenses associated with the RECIPIENT's Licensing Activities.

**Section D3.05 Survival.** The licenses, rights and obligations set forth in this Attachment D, except Section D3.01, shall survive any termination of this Contract, including any termination for convenience by RECIPIENT.

**Section D3.06 Recipient Opt-Out.** In the event RECIPIENT determines, after diligently attempting to comply with the terms of Section D3.02, to cease its efforts, either directly or through a licensee, to commercialize or otherwise bring to practical application the Project Results, it will so notify the INSTITUTE in writing promptly thereafter. Such written notice must identify the Project Results and provide a reasonable explanation of the reasons for the RECIPIENT's election. Upon receipt of such notice, the INSTITUTE and RECIPIENT shall meet within thirty (30) days to review the Project Results and rationale for the RECIPIENT's election. Provided that RECIPIENT's determination to cease its efforts was not based on material safety concerns related to the Project Results, the INSTITUTE and RECIPIENT shall engage in good faith negotiations regarding an alternative commercialization strategy and/or revenue sharing approach.

The INSTITUTE and RECIPIENT may consider, among other options, an award of equity in the RECIPIENT, expansion or modification of the Institute Funded Activity to cover other commercial products or commercial services being advanced by the RECIPIENT, or some combination thereof. Unless otherwise agreed, if the INSTITUTE and RECIPIENT are unable to achieve an alternative strategy or agreement within one-hundred and eighty (180) days of the RECIPIENT's initial notice of election, and provided that RECIPIENT's determination to cease its efforts was not based on material safety concerns related to the Project Results, the INSTITUTE shall have the right, but not the obligation, to exercise its rights in Section D5.01 in relation to the Project Results at the INSTITUTE's expense. If the INSTITUTE elects to exercise its rights under Section D5.01 in relation to the Project Results, the INSTITUTE shall notify the RECIPIENT in writing within the later of 220 days of INSTITUTE's receipt of the RECIPIENT's initial notice of election or thirty (30) days following a declaration by one of the Parties that good faith negotiations have failed. In the event that the INSTITUTE exercises its option under this Section D3.06, the RECIPIENT shall cooperate with the INSTITUTE's efforts and provide to INSTITUTE sufficient information such as relevant feasibility studies, trial results, regulatory summaries, and pertinent schedules or deadlines in relation to the Project Results, in commercializing or otherwise bringing to practical application the applicable Project Results at the INSTITUTE's cost. For clarity, so long as the RECIPIENT is making efforts to commercialize at least one Commercial Product or Commercial Service, RECIPIENT shall have no obligation to provide the written notice as described in this Section D3.06.

## PART 4 REVENUE SHARING

**Section D4.01 Revenue Sharing Percentages.** In consideration for the Grant Award Proceeds paid to the RECIPIENT by the INSTITUTE under the Contract:

a. RECIPIENT shall pay to the INSTITUTE during the Revenue Term the following payments until the INSTITUTE receives the aggregate amount of four hundred percent (400%) of the Grant Award Proceeds:

(i) a revenue sharing percentage of three percent (3%) of Revenue for Cumulative Revenue greater than five million U.S. dollars (USD$ 5,000,000) and less than or equal to five hundred million U.S. dollars (USD$ 500,000,000);

(ii) a revenue sharing percentage of four percent (4%) of Revenue for Cumulative Revenue greater than five hundred million U.S. dollars (USD$ 500,000,000) and less than or equal to one billion U.S. dollars (USD $1,000,000,000); and

(iii) a revenue sharing percentage of five percent (5%) of Revenue for Cumulative Revenue greater than one billion U.S. dollars (USD $1,000,000,000).

For clarity, no payments will be made by the RECIPIENT to the INSTITUTE under this Section D4.01(a) until the Cumulative Revenue of the Recipient is greater than five million U.S. dollars (USD $5,000,000).

b. In the event the RECIPIENT and/or its licensee is required to obtain a license under Intellectual Property Rights of one or more Third Parties in order to make Sales of Commercial Products and/or Commercial Services in any given country ("**Participating License Sources**"), then the revenue sharing percentages set forth under Section D4.01(a)(i)-(iii) may be reduced by one-half percent (0.5%) for every one percent (1%) royalty paid to such Third Parties on Commercial Products and/or Commercial Services in such country, as applicable, provided that in no event will the payments otherwise due to the INSTITUTE under Section D4.01(a) be less than fifty percent (50%) of the payments that would be

payable to the INSTITUTE absent the effects of this Section D4.01(b). By way of example, if the RECIPIENT is required to obtain such a license from a Third Party in a country wherein the RECIPIENT pays a four percent (4%) royalty for Intellectual Property Rights that cover Commercial Products and Commercial Services in such country, the revenue sharing percentages under Section D4.01(a)(i), (ii), and (iii) would be reduced to one and one-half percent (1.5%), two percent (2%), and three percent (3%) in such country, respectively.

**Section D4.02 Continued Revenue Sharing.** In the event the INSTITUTE receives during the Revenue Term the aggregate amount of four hundred percent (400%) of the Grant Award Proceeds from the RECIPIENT, the RECIPIENT will continue to pay the INSTITUTE a revenue sharing percentage of one-half percent (0.5%) of Revenue for all Revenue generated during the remainder of the Revenue Term. For clarity, this revenue sharing percentage cannot be reduced as set forth in Section D4.01(b).

**Section D4.03 Equity.** Nothing herein prohibits the INSTITUTE from negotiating with the RECIPIENT for an equity share in the RECIPIENT in addition to or in lieu of the revenue sharing set forth in Sections D4.01 and D4.02, when mutually agreed to by the INSTITUTE and the RECIPIENT. But under no circumstances is the INSTITUTE obligated to negotiate for an equity share in the RECIPIENT in lieu of the revenue sharing set forth herein.

**Section D4.04 Statements and Timing of Payments.** All payments owed pursuant to this Part 4 shall be made to the Cancer Prevention and Research Institute of Texas, and are payable on or before the thirtieth day following the end of the calendar quarter in which the Revenue is received or, in the case of Section D4.05, the monetary recovery is received. For each payment specified in Sections D4.01 and D4.02, the payment shall be accompanied by a statement specifying for such calendar quarter: (i) the Contract to which the payment relates, (ii) the identities of, royalty percentages, and amounts actually paid to any Participating License Sources, (iii) the License Agreements, if any, to which the payment relates, (iv) the quantity of all Sales of each Commercial Product and Commercial Service since the last payment, if Sales are applicable to the current payment, (v) the gross consideration from all such Sales, if Sales are applicable to the current payment, and (vi) a calculation of the amount of the payment to the Cancer Prevention and Research Institute of Texas.

**Section D4.05 Recoveries in Enforcement Actions.** In the event that the RECIPIENT receives any monetary recovery from its enforcement of Institute-Funded IPR against infringement by a third party, then it shall pay to the State of Texas a share of such monetary recovery, including any punitive damages, less the documented fees and expenses that are directly associated with such enforcement and are paid by RECIPIENT to third parties, at the same rate and in the same manner as it shares Revenue pursuant to Sections D4.01 and D4.02 (including any adjustments allowed by Section D4.01(b)). For clarity, if the enforcement action is resolved by way of the execution of a License Agreement with the allegedly infringing third party and such License Agreement is consistent with this Part 4, then this Section D4.05 is not intended to apply to such License Agreement or the consideration specified therein.

**Section D4.06 Revenue-Related Records.** In addition to satisfying the requirements of Article IV of the Contract and Section E1.03 of Attachment E, the RECIPIENT shall keep complete and accurate Revenue- related records until the fourth anniversary of the date of the payment of the last payment owed hereunder, in sufficient detail to permit the INSTITUTE to confirm the accuracy of the statements delivered to the INSTITUTE under Section D4.04 and the calculation of the payments owed hereunder.

**Section D4.07 Audit of Revenue-Related Records.** Upon at least fifteen (15) days' advance written notice, the RECIPIENT shall permit the INSTITUTE or its representatives or agents, at the INSTITUTE's expense, to examine the Revenue-related records of the RECIPIENT pursuant to Section D4.06 once per calendar year during regular business hours for the purpose of and to the extent necessary to verify the RECIPIENT's compliance with this Part 4. The rights of the INSTITUTE under this Section D4.07 shall

terminate on the fourth anniversary of the date of the payment of the last payment owed hereunder. In the event that any such examination reveals an underpayment to the INSTITUTE of greater than five percent (5%) of the amounts previously paid by the RECIPIENT to the INSTITUTE, then the RECIPIENT shall reimburse the INSTITUTE for the cost of such examination.

## PART 5
## OPT-OUT AND DEFAULT

**Section D5.01 RECIPIENT Opt-Out.** If the INSTITUTE elects to exercise its rights in relation to the Project Results under Section D3.06, the INSTITUTE shall have the right, but not the obligation, to pursue protection of the Applicable Institute-Funded IPR on its own behalf, including directing the filing, prosecution and maintenance of patents covering the applicable Institute-Funded Inventions and/or to commercialize or otherwise bring to practical application Project Results covered by the Applicable Institute-Funded IPR, at its own cost, either directly or through one or more licensees. For the purposes of this Part 5, "Applicable Institute-Funded IPR" shall mean all Project Results. If the INSTITUTE elects to exercise any such rights under this Section D5.01, it shall notify RECIPIENT in writing pursuant to the notification requirements in Section D3.06 and RECIPIENT shall thereafter comply with the terms of Section D5.03 with regard to the Applicable Institute-Funded IPR.

**Section D5.02 RECIPIENT Default.** In the event that the INSTITUTE notifies RECIPIENT in writing of RECIPIENT's failure to materially comply with its obligations under Section D3.02, and RECIPIENT fails within sixty (60) days of such notice either: (a) to cure such failure, or in the event that such failure cannot be reasonably cured within such 60-day period, to provide to INSTITUTE a plan to cure such failure that INSTITUTE deems acceptable, (b) to provide written notice to the INSTITUTE that such failure was due to material safety concerns, or (c) to provide proper notice pursuant to Section 3.06, then without further action on the part of the RECIPIENT or INSTITUTE, the RECIPIENT shall be deemed to have provided the INSTITUTE the complete, written notice of its cessation of efforts as described in Section 3.06, and the INSTITUTE shall be free to exercise its rights under Section 3.06.

**Section D5.03 RECIPIENT Cooperation upon Opt-Out or Default.** In the event that the INSTITUTE exercises any of its rights under Section D5.01, the RECIPIENT shall:

(1) subject to any existing third party rights, transfer and assign, and does hereby assign, all of its right, title and interest in and to the applicable Project Results to the INSTITUTE or the INSTITUTE's designee, to the maximum extent allowed by law, including where relevant and necessary to facilitate the foregoing transfer, requesting and diligently attempting to obtain any approvals required by law or otherwise in relation to such transfer, and subject to any existing third party rights, hereby grants to the INSTITUTE a non-exclusive, royalty-free, perpetual, fully transferable and sublicensable license under any Institute-Funded Technology and Necessary Additional IPR to Exploit the Project Results for the development, manufacture and sale of Commercial Products and Commercial Services and for all other purposes reasonably related thereto;
(2) to the extent that RECIPIENT is unable to transfer all of its right, title and interest in and to the applicable Project Results to the INSTITUTE as specified in Section D5.03(1), and subject to any existing third party rights, RECIPIENT hereby grants to the INSTITUTE an exclusive, royalty-free, perpetual, fully transferable and sublicensable license under the Applicable Institute-Funded IPR to Exploit the Project Results for the development, manufacture and sale of Commercial Products and Commercial Services and for all other purposes reasonably related thereto, provided that the INSTITUTE may exercise the foregoing rights only after exercising its right under Section D5.01;
(3) cooperate with the INSTITUTE's efforts, and at the INSTITUTE's cost, in protecting Applicable Institute-Funded IPR and Institute-Funded Technology, and in commercializing or otherwise bringing to practical application the applicable Project Results, including making relevant Recipient Personnel (to the extent still obligated to RECIPIENT), Contractors, Collaborators,

records (including without limitation, laboratory notebooks, electronic records and data), papers, information, samples, specimens and other materials related to the applicable Project Results reasonably available for such purposes and executing any documents and taking any further action reasonably necessary to effectuate the intent of this Section D5.03; and

(4) subject to applicable law, not take any action that would oppose or impede the INSTITUTE's ability to protect the applicable Project Results.

If the INSTITUTE exercises its rights under Sections D5.01, the RECIPIENT shall have no further claim to or interest in the applicable Project Results, except as set forth in Section D2.01 of this Attachment and shall not be entitled to any share of Revenue or any other compensation with respect to such Project Results, except to the minimum extent required by law, if any. To the extent that the INSTITUTE has exercised its rights under Section D5.01 and RECIPIENT is unable to transfer all of its right, title and interest in and to the applicable Project Results to the INSTITUTE as specified in D5.03(1), then the INSTITUTE's license set forth in D5.03(2) includes the right, but not the obligation, for the INSTITUTE at its cost to: (i) direct the filing, prosecution and maintenance of patents covering the applicable Project Results, and (ii) enforce all Applicable Institute-Funded IPR relevant to the Project Results against any infringement by a third party. Subject to the statutory duties of the Texas Attorney General, if any, RECIPIENT shall cooperate fully with the INSTITUTE in any action brought by the INSTITUTE to enforce the Institute-Funded IPR in the applicable Project Results, at the INSTITUTE's cost, including without limitation, joining the enforcement action in name as a party plaintiff after all required approvals are obtained; provided that the INSTITUTE or its designee shall have full control over such enforcement action and shall receive and retain all monetary and other recoveries resulting from such enforcement actions, including any punitive damages.

## PART 6 DEFINITIONS

Throughout this Attachment D, the following underlined terms shall have the meanings given below.

(1) **Commercial Product** means anything that is based on, utilizes or is developed from, or materially incorporates, the Project Results and that is capable of being sold, licensed, transferred or conveyed to another party or is capable of otherwise being Exploited or disposed of, whether in exchange for consideration or not.

(2) **Commercial Service** means any service performed that is based on, utilizes or is developed from, or materially incorporates, the Project Results. For clarity, Commercial Service does not include non- commercial research and development performed by RECIPIENT or its Collaborators or licensees.

(3) **Cumulative Revenue** means after the First Commercial Sale worldwide of a Commercial Product or Commercial Service, the sum of all Revenue in all years and calendar quarters up to the calendar quarter in which the applicable revenue sharing percentage in Section D4.01 is being paid.

(4) **Exclusive License** means a License Agreement under which the specific rights granted to the licensee with respect to the Project Results, including without limitation scope of use and territorial rights, are granted on an exclusive basis.

(5) **Exclusivity** means any exclusivities granted by the government in a country to provide an entity with protection from competitors in the commercial market for a defined period of time, including but not limited to patent-based exclusivities (and any patent term extensions, supplementary protection certificates or patent term adjustments thereof, and the like), and market-based "data" exclusivities (e.g., orphan drugs, new chemical entities, biologics, new formulations or combinations, and pediatric, and the like). For the avoidance of doubt, Exclusivity shall not mean any protection gained solely from either trade secrets or trademarks.

(6) **Exploit** or **Exploitation** means make, have made, use, sell, offer to sell, import, export, or otherwise commercialize, dispose of, practice, copy, distribute, create derivative works of, publicly perform or publicly display.

(7) **First Commercial Sale** means the first bona fide arm's length Sale of a Commercial Product or Commercial Service to a Third Party by or on behalf of RECIPIENT or its licensees for monetary value, for use or consumption by the end user of such Commercial Product or Commercial Service. For clarity, Sales of a Commercial Product or Commercial Service for registration samples, clinical trial purposes or compassionate use sales, named patient use, test marketing, sampling and promotional uses, inter- company transfers to affiliates of RECIPIENT or its licensees, shall not constitute a First Commercial Sale.

(8) **Grant Award Proceeds** means the sum of all monies paid by INSTITUTE to RECIPIENT under the Contract. For clarity, Grant Award Proceeds will not be diminished by the amount of any funds repaid to INSTITUTE by RECIPIENT under Section 4.07 of the Contract.

(9) **Institute-Funded IPR** means any and all Intellectual Property Rights in and to Institute-Funded Technology. In no event shall Institute-Funded IPR include any intellectual property rights and/or technology in existence and owned/controlled by the RECIPIENT prior to the receipt of funds from the INSTITUTE or arising from activities conducted independently of the Project or acquired independently of the Project.

(10) **Institute-Funded Invention** means an Invention conceived or first reduced to practice by or on behalf of RECIPIENT, including by Recipient Personnel, Contractor(s) and/or Collaborator(s) in the performance of Institute-Funded Activity.

(11) **Institute-Funded Technology** means any and all of the following resulting or arising, in whole or in part, from Institute-Funded Activity during the Contract term: (a) proprietary and confidential information, including but not limited to data, trade secrets, materials and know-how; (b) databases, compilations and collections of data; (c) tools, methods and processes; and (d) works of authorship, excluding all scholarly works, but including, without limitation, computer programs, source code and executable code, whether embodied in software, firmware or otherwise, documentation, files, records, data and mask works; and all instantiations of the foregoing in any form and embodied in any form, including but not limited to therapeutics, drugs, drug delivery systems, drug formulations, devices, diagnostics, biomarkers, reagents, methodologies and research tools. Institute-Funded Technology includes Institute-Funded Inventions. Institute-Funded Technology shall not include items that were conceived of, in existence, or owned/controlled by RECIPIENT prior to receipt of funds from the INSTITUTE or arising from activities conducted independently of the Project or acquired independently of the Project, such as: (a) proprietary and confidential information, including but not limited to data, trade secrets, materials and know-how; (b) databases, compilations and collections of data; (c) tools, methods and processes; and (d) works of authorship, excluding all scholarly works, but including, without limitation, computer programs, source code and executable code, whether embodied in software, firmware or otherwise, documentation, files, records, data and mask works; and all instantiations of the foregoing in any form and embodied in any form, including but not limited to therapeutics, drugs, drug delivery systems, drug formulations, devices, diagnostics, biomarkers, reagents, methodologies and research tools.

(12) **Intellectual Property Rights** or **IPR** means any and all of the following and all rights in, arising out of, or associated therewith: (a) all United States and foreign patents and utility models and applications therefor, and all reissues, re-examinations, divisionals, renewals, substitutions, extensions, provisionals, continuations and continuations-in part thereof, and equivalent or similar rights anywhere in the world in inventions and discoveries; (b) all trade secrets and rights in know-how, materials and proprietary information; (c) all copyrights, copyright registrations and applications therefor, and all other rights corresponding thereto throughout the world; (d) all mask works, mask work registrations and applications

therefor, and any equivalent or similar rights in semiconductor masks, layouts, architectures or topology; and (e) any similar, corresponding or equivalent rights to any of the foregoing anywhere in the world.

(13) **Invention** means any idea, composition of matter, method, device, process or discovery that is conceived and/or reduced to practice, whether patentable or not.

(14) **License Agreement** means an agreement by which an owner of a Project Result grants any right to Exploit such Project Result to a Third Party in exchange for consideration.

(15) **Licensing Activities** means the efforts of RECIPIENT or its Collaborator to negotiate, execute or enforce a License Agreement.

(16) **Major Market Country** means one or more of the following: Canada, France, Germany, Italy, Japan, Spain, Switzerland, United Kingdom, and United States of America.

(17) **Necessary Additional IPR** means any Intellectual Property Rights (a) owned by RECIPIENT, and (b) identified by the Institute and agreed to in writing by RECIPIENT, that are not Project Results but are necessary to Exploit the Project Results for the specific purposes set forth in the applicable Section of this Attachment D.

(18) **Project Results** means any and all Institute-Funded Technology and Institute-Funded IPR.

(19) **Revenue** means the gross consideration, whether cash (for example, but not by way of limitation, any milestone fees, license fees, sublicense fees, or assignment fees) or non-cash (for example, but not by way of limitation, securities, direct equity interest, indirect equity interest, trade or barter considerations, and the like), received from Sales to a Third Party by or on behalf of the RECIPIENT and its licensees (including RECIPIENT's affiliates and sublicensees of RECIPIENT's licensee), net of: (a) trade or quantity discounts or rebates, credits, allowances or refunds given for rejected or returned Commercial Products or Commercial Services, (b) any sales, value-added or other tax or governmental charge levied on the sale, transportation or delivery of a Commercial Product or Commercial Service (but excluding any income tax owed by the RECIPIENT), and (c) any separately stated charges for freight, postage, shipping and insurance. The foregoing notwithstanding, any consideration: (i) received and used by RECIPIENT or its licensees for the purpose of research or development of Commercial Products and Commercial Services, or (ii) received from Sales made solely in the performance of clinical trials designed to obtain regulatory approval for a Commercial Product or Commercial Service, or (iii) received by RECIPIENT or its licensees from Sales made for compassionate use where no profit was obtained by RECIPIENT or its licensees shall not be included in this term.

(20) **Revenue Term** means the period commencing on the date of the First Commercial Sale of a Commercial Product or Commercial Service and ending, on a country-by-country basis, when there is not, or there no longer exists, any Exclusivity for the Commercial Product or Commercial Service in such country. If there is no Exclusivity for a Commercial Product or Commercial Service in any Major Market Country, the Revenue Term shall mean the period commencing on the date of the First Commercial Sale of such Commercial Product or Commercial Service and ending twelve (12) years later.

(21) **Sale** or **Sales** means any sale, license, lease, transfer, conveyance or other Exploitation or disposition of a Commercial Product or Commercial Service for which consideration from a first Third Party is received. For clarity, transfer or assignment of a Commercial Product or Commercial Service in connection with a merger, consolidation, transfer or sale of all, or substantially all, of RECIPIENT's business or assets, or change of control or similar transaction involving the RECIPIENT will not constitute a Sale.

(22) **Third Party** means a party other than (a) the RECIPIENT, (b) any affiliate or licensee of the RECIPIENT, either directly or through any sublicenses, or (c) an entity that enjoys any special course of dealing with any of (a) or (b) above.

Other terms may be defined elsewhere in this Attachment or in the Contract.

# ATTACHMENT E REPORTING REQUIREMENTS

This Attachment E is hereby incorporated into and made a part of that certain **CANCER RESEARCH GRANT CONTRACT** ("**Contract**") by and between the Cancer Prevention and Research Institute of Texas ("**CPRIT**" or the "**INSTITUTE**") and the RECIPIENT. A capitalized term used in this Attachment shall have the meaning given to term in the Contract or in the Attachments to the Contract, unless otherwise defined herein. In the event of a conflict between the provisions of this Attachment and the provisions of the Contract, this Attachment shall control.

INSTITUTE and RECIPIENT agree as follows:

## ANNUAL REPORTING

**Section E1.01 Annual Reports.** The RECIPIENT shall submit reports annually to the INSTITUTE within 60 days of the anniversary of the Effective Date of this Contract or at such other time as may be specified herein. The reports shall be submitted by the means and in the form(s) required by the INSTITUTE and shall be signed by the Principal Investigator/Program Director and the RECIPIENT's Authorized Signing Official. To the extent possible, the reports shall only include information that may be shared publicly. However, if it is necessary to submit information in the reports that the RECIPIENT considers confidential in order to fully comply with the terms of this Contract, then the RECIPIENT shall use reasonable efforts to mark such information as "confidential" and shall, to the extent practicable , to segregate such information within the reports to facilitate its redaction should redaction ever be necessary or appropriate.

**Section E1.02 Contents of Reports.** Each report shall contain a signed verification (electronic signature is acceptable) of RECIPIENT's compliance with each of its obligations as set forth in the Contract and shall include the following for the period covered by such report, as may then be applicable:

**(a) Project Data.** During the term of the Contract, RECIPIENT shall include in its annual report each of the following (except that the final annual report due under this part (a) shall be due within ninety (90) days after the end of the term of the Contract):

(1) A brief statement of the progress made to under the Scope of Work, including the progress to achieve the Project Goals and Timelines set forth in Attachment A.
(2) A brief statement of the Project Goals for the twelve months following submission of the report.
(3) New jobs created in the preceding twelve month period as a result of the Grant funds awarded to RECIPIENT.
(4) An inventory of the Equipment purchased for the Project using Grant funds.
(5) A HUB report in accordance with Section 3.08 "Historically Underutilized Businesses" of the Contract.

**(b) Commercialization Data.** During the term of the Contract and continuing thereafter for so long as RECIPIENT has ongoing obligations to the INSTITUTE with respect to protection, development, commercialization and licensing of Project Results pursuant to Attachment D, RECIPIENT shall provide information about commercialization activities in a format specified by the INSTITUTE.

**c) Revenue Sharing Data.** During the term of the Contract and continuing thereafter for so long as RECIPIENT has ongoing obligations to the INSTITUTE with respect to revenue sharing pursuant to Attachment D:

(1) A statement of the identities of the funding sources, amounts and dates of funding for all funding sources for the Project.
(3) A brief statement of the RECIPIENT's efforts to secure additional funds to support the Project.
(4) All financial information necessary to verify the calculation of the revenue sharing amounts specified in Attachment D.

**(d) Additional Data.** In addition to the foregoing, RECIPIENT shall use commercially reasonable efforts to also promptly report any other information required by this Contract or otherwise reasonably requested by the INSTITUTE, the Legislature, or any other funding or regulatory bodies covering the RECIPIENT's activities under this Contract.

**Section E1.03 Record Keeping and Audits.** The provisions of Article IV of the Contract shall apply fully to all information reported to the INSTITUTE pursuant to this Attachment, except that the right of the State of Texas to audit and the RECIPIENT's obligation to maintain Records shall continue until four years after the date of each such report made by RECIPIENT hereunder.

**Section E1.04 Confidentiality of Documents and Information.** The provisions of Section 2.13 "Confidentiality of Documents and Information" of the Contract shall apply fully to all Confidential Information reported, delivered or submitted to the INSTITUTE pursuant to this Attachment E.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## Approved Contract Documents

| Title | Approved By | Approved Date |
|---|---|---|
| Product Development Base Contract | Kim, Jason | 04 Sep 2018 |
| Attachment A - Goals and Objectives | Nelson, Lisa | 06 Sep 2018 |
| Attachment B - Verification Request of Contract Document | Kim, Jason | 07 Sep 2018 |
| Attachment C Part 1 - Assurances and Certifications | Kim, Jason | 31 Aug 2018 |
| Attachment C Part 2 - Matching Compliance Certification | Lansdowne, Bob | 07 Sep 2018 |
| Attachment D - Intellectual Property and Revenue Sharing | Kim, Jason | 04 Sep 2018 |
| Attachment E - Reporting Requirements | Kim, Jason | 04 Sep 2018 |
| Chief Executive Officer Approval | Roberts, Wayne | 18 Sep 2018 |

**Exhibit 21.1**

**SUBSIDIARIES OF MOLECULAR TEMPLATES, INC.**

| Subsidiary | Jurisdiction |
|---|---|
| Molecular Templates OpCo, Inc. | Delaware |
| THLD Enterprises (UK), Limited | United Kingdom |

**Exhibit 23.1**

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. 333-273864) of Molecular Templates, Inc.,
2. Registration Statement (Form S-3 No. 333-242078) of Molecular Templates, Inc.,
3. Registration Statement (Form S-3 No. 333-238937) of Molecular Templates, Inc.,
4. Registration Statement (Form S-3 No. 333-225223) of Molecular Templates, Inc.,
5. Registration Statement (Form S-3 No. 333-220477) of Molecular Templates, Inc.,
6. Registration Statement (Form S-3 No. 333-162719) of Threshold Pharmaceuticals, Inc.,
7. Registration Statement (Form S-3 No. 333-153475) of Threshold Pharmaceuticals, Inc.,
8. Registration Statement (Form S-8 No. 333-271071) of Molecular Templates, Inc. pertaining to the Molecular Templates, Inc. 2018 Equity Incentive Plan,
9. Registration Statement (Form S-8 No. 333-263928) of Molecular Templates, Inc. pertaining to the Molecular Templates, Inc. 2018 Equity Incentive Plan,
10. Registration Statement (Form S-8 No. 333-254484) of Molecular Templates, Inc. pertaining to the Molecular Templates, Inc. 2018 Equity Incentive Plan,
11. Registration Statement (Form S-8 No. 333-237148) of Molecular Templates, Inc. pertaining to the Molecular Templates, Inc. 2018 Equity Incentive Plan,
12. Registration Statement (Form S-8 No. 333-230617) of Molecular Templates, Inc. pertaining to the Molecular Templates, Inc. 2018 Equity Incentive Plan,
13. Registration Statement (Form S-8 No. 333-225826) of Molecular Templates, Inc. pertaining to the Molecular Templates, Inc. 2018 Equity Incentive Plan,
14. 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,
15. Registration Statement (Form S-8 No. 333-210089) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Employee Stock Purchase Plan,
16. Registration Statement (Form S-8 No. 333-202476) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Employee Stock Purchase Plan,
17. 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,
18. 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,
19. 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,
20. 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,
21. Registration Statement (Form S-8 No. 333-167260) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Equity Incentive Plan,
22. 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,
23. Registration Statement (Form S-8 No. 333-156733) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Equity Incentive Plan,
24. Registration Statement (Form S-8 No. 333-143130) of Threshold Pharmaceuticals, Inc. pertaining to the Amended and Restated 2004 Equity Incentive Plan,
25. 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
26. Registration Statement (Form S-8 No. 333-126276) of Threshold Pharmaceuticals, Inc. pertaining to the 2001 Equity Incentive Plan, the 2004 Equity Incentive Plan, and the 2004 Employee Stock Purchase Plan;

of our report dated March 29, 2024, with respect to the consolidated financial statements of Molecular Templates, Inc. included in this Annual Report (Form 10-K) of Molecular Templates, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Austin, Texas
March 29, 2024

**Exhibit 31.1**

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 29, 2024

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

**Exhibit 31.2**

CERTIFICATIONS UNDER SECTION 302

I, Jason S. Kim, 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 29, 2024

/s/ Jason S. Kim
Jason S. Kim
Chief Financial Officer

**Exhibit 32.1**

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Molecular Templates, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2023 (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 29, 2024

/s/ Eric E. Poma Ph.D.

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

Date: March 29, 2024

/s/ Jason S. Kim

Jason S. Kim
Chief Financial Officer