Molecular Templates, Inc.

2023 Annual Report to Stockholders

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, 2022

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	**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 $0.91 of the common stock on The Nasdaq Global Select Market as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $29,380,632. 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 27, 2023 there were 56,351,647 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 2023 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days of the registrant's fiscal year ended December 31, 2022 are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

Molecular Templates, Inc.
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PART I

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K, including the sections 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 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 ("CMC") improvements;
- the timing and our ability to advance the development of our drug or 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 drug or biologic candidates;
- the anticipated progress of our drug or 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 drug or biologic candidates;
- our ability to establish and maintain intellectual property rights for our drug or biologic candidates;
- whether any drug or 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 drug or biologic candidates suitable for clinical testing;
- our ability to identify, in-license or otherwise acquire additional drug or 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 ("API") and drug or 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;
- the expected cost savings from our strategic restructuring;

- the extent to which global economic and political developments, including the impact of the COVID-19 pandemic and inflation, will affect our business operations, clinical trials, or financial condition;
- the impact of laws and regulations;
- our projected financial performance and compliance with existing debt covenants; and
- 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

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 Shiga-like Toxin A subunit ("SLTA"), a ribosome inactivating bacterial protein. In its wild-type form, SLT is thought to induce its own entry into a cell when proximal to the cell surface membrane, self-route to the cytosol, and enzymatically and irreversibly shut down protein synthesis via ribosome inactivation. SLTA is normally coupled to its cognate Shiga-like Toxin B subunit ("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 capillary leak syndrome ("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 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, CD38, and CTLA-4. 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-0169 (ETB targeting CD38) are in ongoing Phase I studies. Molecular expects to initiate a Phase I study of MT-8421 (ETB targeting CTLA-4) by mid-year 2023. Molecular expects to provide periodic updates on these studies throughout 2023.

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, Molecular's Board of Directors approved 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 would reduce Molecular's current workforce from approximately 222 full-time employees to approximately 50% of that number. The Restructuring will result in the cessation of Molecular's MT-5111 clinical development program, and will focus the majority of Molecular's pre-clinical efforts around activities related to the Bristol Myers Squibb collaboration. Molecular estimates that it will incur approximately $0.4 million of costs in connection with the reduction in workforce related to severance pay and other related termination benefits. Molecular anticipates incurring additional costs related to the Restructuring, however, such costs cannot be reasonably estimated as of the time of the filing of this Annual Report on Form 10-K.

Challenges in Oncology

Existing mechanisms of action, the specific biochemical interaction through which a drug substance produces its pharmacological effect, are subject to numerous limitations in oncology. The clinical benefit of a given drug is a function of the biological properties of the drug, the target with which the drug interacts and the tumor indication being treated, but the relative contribution of each of these factors is difficult to separate. To date, significant challenges exist in identifying the most appropriate cancer targets, applying the most effective mechanisms of action and selecting the appropriate disease indications and most responsive patient populations for a particular drug or 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 pharmacokinetic 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 fully integrated discovery-to-commercial biopharmaceutical company focused on compounds with unique and differentiated biology*. Molecular believes that differentiated mechanisms of action are crucial for improving outcomes in cancer. 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, immune-oncologics have provided substantial clinical benefit in both the relapsed and refractory setting and, when used in combinations, in earlier lines of therapy. Molecular believes that ETBs represent a new class of targeted agents with differentiated biology that are well-positioned to improve outcomes in cancer patients.

ETBs appear to induce the internalization of non- or poorly-internalizing targets, have a differentiated mechanism of action (enzymatic and irreversible ribosome inactivation), have relatively predictable PK 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 ("ADME"), and potency. ETBs possess potent direct cell killing effects via a differentiated mechanism of action, can force receptor internalization, and can be used to deliver payloads such as foreign class I antigen to the cytosol.

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 immune-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.

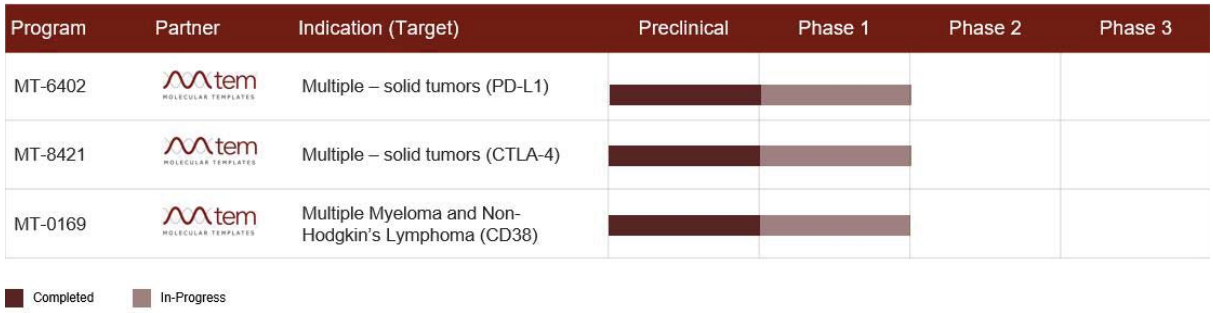
Molecular believes that its proprietary ETB technology platform represents a differentiated approach in oncology. ETBs possess the targeting specificity of antibody-based therapeutic approaches but deliver highly potent payloads that disrupt protein synthesis, a fundamental function of a cancer cell, 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:



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 single chain variable fragment ("scFv"), with affinity for PD-L1, fused to the enzymatically active de-immunized Shiga-like toxin-A subunit ("SLTA") and a 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 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 1 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 1 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 2023, patients have been treated across six dose escalation cohorts of 16 mcg/kg, 24 mcg/kg, 32 mcg/kg, 42 mcg/kg, 63 mcg/kg and 83 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.

One patient in cohort 5 (63 mcg/kg) with metastatic squamous cell nasopharynx carcinoma with disease progression after radiation therapy, chemotherapy, and pembrolizumab had a Partial Response ("PR") (RECIST) with a 63% reduction in the index lesion after cycle 2. The PR was confirmed after cycle 4 with a 66% reduction and the patient remains on treatment in cycle 5. This patient had 2% PD-L1 expression and was not HLA-A*02, suggesting the response is due to T-cell activation through the clearance of PD-L1+ immune cells. The patient showed a >250% increase in CD8/CD4 T-cell ratios.

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 1 study continues 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 without blocking of ligand-ligand interactions seen with current antibody therapeutics. The ETB approach includes potent destruction of CTLA-4+ Tregs via enzymatic ribosome destruction, a mechanism of cell kill that 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. Molecular expects to initiate a first-in-human Phase 1 study by mid-year 2023.

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.

Molecular revised the protocol for the ongoing Phase I study for MT-0169 in patients with relapsed/refractory multiple myeloma or non-Hodgkin's lymphoma 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 continues in cohort 3 at 15 mcg/kg. One patient with extramedullary IgA myeloma treated at 5 mcg/kg had a marked reduction in IgA serum protein, conversion from immunofixation positive to negative and marked improvement of hemoglobin to normal values without transfusion, demonstrating a Very Good Partial Response ("VGPR"). The patient's disease was quad-agent refractory including CD38-targeting, proteosome inhibitor, IMiD, and a BCMA bispecific antibody. The patient was assessed at cycle 8 as being in a stringent Complete Response ("CR") based on the resolution of osseous disease sites by PET scan and continues on study.

We expect to provide periodic updates on MT-6402, MT-8421, and MT-0169 throughout 2023.

ETB Research & Development Partnerships

Bristol Myers Squibb Company

On February 10, 2021, Molecular entered into a Collaboration Agreement (the "BMS Collaboration Agreement") with Bristol Myers Squibb Company ("Bristol Myers Squibb"), pursuant to which the parties agreed to enter into a strategic research collaboration to leverage Molecular's ETB technology platform to discover and develop novel products containing ETBs directed to multiple targets.

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 receive near term and development and regulatory milestone payments of up to $874.5 million. Molecular will also be 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 will be 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 will be 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 will 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 has the right to terminate the BMS Collaboration Agreement for convenience upon prior written notice to Molecular. Either party has 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 has 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.

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 SLT-A 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 November 2019, Molecular entered into a Master Collaboration Agreement ("Vertex Collaboration Agreement") with Vertex Pharmaceuticals Incorporated ("Vertex"), in which the parties agreed to enter into a strategic research collaboration to leverage Molecular's ETB technology platform to discover and develop novel targeted biologic therapies for applications outside of oncology. In October 2021, Molecular received a notice of termination from Vertex for the Vertex Collaboration Agreement. The termination of the Vertex Collaboration Agreement was effective October 29, 2021. There are no ongoing activities or economic obligations in connection with the Vertex Collaboration Agreement.

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, 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) November 30, 2023 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 not to exceed six months after the termination date if additional time is required to ensure adequate completion of the approved project, subject to the terms and conditions of the CD38 CPRIT Agreement.

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 Shiga toxin A subunit 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 Shiga toxin A subunit constructs engineered to have reduced innate and adaptive immunogenicity, including by disruption of B-cell epitopes and T-cell epitopes.

Molecular has 13 patent families that cover its proprietary platform technologies, together covering about 290 patents and pending U.S. and foreign applications worldwide, including over 200 granted U.S. and foreign patents and over 80 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 from eleven of these patent families, including in Australia, China, Europe, Hong Kong, Israel, Japan, Mexico, South Korea, and the U.S.

Molecular has 10 patent families covering ETBs in its product pipeline, including ETBs which target PD-L1 and CD38. These 10 patent families include over 95 patents and pending U.S and foreign applications worldwide, including over 45 granted U.S. and foreign patents and over 50 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. 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, 2022, 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).

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, such as MT-6402, MT-8421, MT-0169, and any future drug candidates. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Drug Development

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and its implementing regulations and biologics under the FDCA, the Public Health Service Act ("PHSA"), and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on Molecular.

MT-6402, MT-8421, MT-0169, and any ETB drug candidates must be approved by the FDA through either a New Drug Application ("NDA"), or 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 Investigational New Drug ("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 an NDA or BLA for marketing approval, including payment of application user fees;
- A determination by the FDA within 60 days of its receipt of an NDA or BLA that the NDA or BLA is sufficiently complete to permit a substantial review, in which case the NDA or BLA is filed;
- Satisfactory completion of a FDA pre-approval inspection of the manufacturing facility or facilities where the drug or biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug or biologic's identity, strength, quality and purity;
- Potential FDA audit of the nonclinical studies and/or clinical trial sites that generated the data in support of the NDA or BLA; and
- FDA review and approval of the NDA or BLA, including consideration of the views of an FDA advisory committee, if one was involved, prior to any commercial marketing or sale of the drug or biologic in the United States.

The preclinical testing, clinical trials and the approval process requires substantial time, effort and financial resources, and Molecular cannot be certain that any approvals for MT-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 an NDA or BLA are generated in two distinct developmental stages: preclinical and clinical. The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as 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. 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 that must 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 an NDA or BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

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 drugs and biologics, respectively, 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 an NDA or BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the 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, as part of the Consolidated Appropriations Act for 2023, in order to require sponsors of a Phase 3 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 3 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 on behalf of each institution that is participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct a continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to clinical trial subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific timeframes to the National Institutes of Health ("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 begun enforcing those requirements against non-compliant clinical trial sponsors.

Clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has

been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial.

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

Concurrent with clinical trials, companies may perform additional nonclinical studies and develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, potency and purity of the final drug or biologic. For biologics in particular, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined in order to help reduce the risk of the introduction of adventitious agents. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that MT-6402, MT-8421, MT-0169, and any future drug candidates do not undergo unacceptable deterioration over their respective labeled shelf lives.

NDA/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 an NDA or BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. In short, the NDA or BLA is a request for approval to market the drug or biologic for one or more specified indications and must contain proof of safety and efficacy for a drug or safety, purity, potency and efficacy for a biologic. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators 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 an NDA or BLA must be obtained before a drug or biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each NDA or BLA must be accompanied by a significant user fee, and the sponsor of an approved NDA or 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 NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs and BLAs to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may refuse to file the application and request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt and inform the sponsor by the 74th day after the FDA's receipt of the submission whether an application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months, from the filing date, in which to complete its review of a new molecular-entity ("NME") NDA or an original BLA and respond to the applicant, and six months from the filing date of an NME NDA or original BLA designated for priority review. For non-NME NDAs, the review goals are ten months from the date of receipt for a standard application and six months from the date of receipt for a priority submission. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs or BLAs, and the review process is often extended by FDA requests for additional information or clarification. After the submission is accepted for filing, the FDA begins an in-depth substantive review. As noted above, the FDA has agreed to specified performance goals in the review process of NDAs and BLAs. The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA or BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the manufacturing processes and facilities comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements by each of the entities involved in the clinical trials, including clinical investigators and any third-party clinical research organizations ("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 drug or biologic. The REMS plan could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS plan is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve an NDA or BLA without a REMS, if one is required.

The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. On the basis of the FDA's evaluation of the NDA or BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue either an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA or BLA and may require substantial additional testing or information in order for the FDA to reconsider the application. The Complete Response Letter may require additional clinical or other data, additional pivotal Phase III clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may choose either to resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or to withdraw the application. If and when all deficiencies have been addressed to the FDA's satisfaction in a resubmitted NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued Complete Response Letter in either two or six months, depending on the type of information included. Even if such data and information are submitted, however, the FDA may ultimately decide that the NDA or BLA does not satisfy the regulatory criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than 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 drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

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

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

In November 2021, the FDA granted fast-track designation to MT-6402 for the treatment of patients with advanced non-small cell lung cancer ("NSCLC") expressing PD-L1.

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

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, intended to expedite the development and review of an application for approval of a breakthrough therapy.

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

Accelerated Approval Pathway

Products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug or biologic when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM") and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product. Drugs and biologics granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

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

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

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

Pediatric Information

Under the Pediatric Research Equity Act ("PREA") amendments to the FDCA, an NDA or BLA or supplement to an NDA or BLA must contain data that are adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. 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 drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the applicant to develop additional data or conduct additional preclinical studies or clinical trials.

The FDA may also place other conditions on approvals including the requirement for 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 NDA or 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 NDAs/BLAs or supplements to approved NDAs/BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties;
- 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 mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors and dispensers over a 10-year period that is expected to culminate in November 2023. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. 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 and any future drug candidates, some of Molecular's U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments permit extension of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term extension, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term extension period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office ("USPTO") in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, Molecular may apply for 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 NDA or BLA.

Marketing Exclusivity for Small-Molecule Drug Products

In 1984, with passage of the Hatch-Waxman Amendments, Congress enacted Section 505(b)(2) of the FDCA and also authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application ("ANDA") to the agency. In support of such applications, a generic manufacturer may rely on the nonclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug ("RLD"). Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug."

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

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant submits its application to the FDA, the applicant is required to certify to the FDA concerning any patents listed for the RLD in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval.

To the extent that a Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, such an applicant also is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Section 505(b)(2) permits the filing of a new drug application, or NDA, where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, they may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. Recently, Congress directed the FDA to perform therapeutic equivalence evaluations for certain 505(b)(2) drugs no later than six months after approval when the applicant requests such an evaluation.

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

- the required patent information has not been filed;

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

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the ANDA applicant is not seeking approval).

If the ANDA or a 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA owner and patent holders once the ANDA or 505(b)(2) NDA in question has been accepted for filing by the FDA. The NDA owner and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or a 505(b)(2) NDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent or a decision in the infringement case that is favorable to the follow-on applicant.

In addition, under the Hatch-Waxman Amendments, the FDA may not approve an ANDA or a 505(b)(2) NDA until any applicable period of non-patent exclusivity for the reference product has expired. These market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a drug containing a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of marketing exclusivity for a NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Reference Product Exclusivity for Biological Products

In March 2010, the Patient Protection and Affordable Care Act ("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 40 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 an NDA or BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. The issuance of a Written Request does not require the sponsor to undertake the described studies.

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

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 firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against Molecular for violation of these laws, even if Molecular successfully defends against it, could cause Molecular to incur significant legal expenses, 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 drug 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.

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

European Union Orphan Designation and Exclusivity

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

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

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;

- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

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.

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 United Kingdom's Medicines and Healthcare products Regulatory Agency ("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 drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of Molecular's products will be made on a payor-by-payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require Molecular to provide scientific and clinical support for the use of Molecular's products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health

care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of 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.

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.

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 U.S. Starting in 2023, a manufacturer of drugs or biological products covered by Medicare Parts B or D must 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 but their impact on the biopharmaceutical industry in the United States remains uncertain. In addition to the IRA's drug price negotiation provisions, 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. As of mid-January 2023 the report had not been released but it is expected to further inform the current Administration's priorities and activities in this area.

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 appears to be leading to further and more aggressive efforts by states in this area. The Federal Trade Commission 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. 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. 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. 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 US health care industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other health care funding and applying new payment methodologies. For example, in March 2010, the 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 the US Centers for Medicare and Medicaid Services ("CMS") to test innovative payment and service delivery models to lower Medicare and Medicaid spending. The uncertainty related to the ACA and the 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 drug or 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).

Employees and Human Capital

In March 2023, pursuant to the Restructuring, we reduced the Company's workforce from approximately 222 full-time employees to approximately 50% of that number. 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 including team members whose objective is to locate and attract qualified experienced professionals.

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 also have an employee-led Diversity, Equity and Inclusion ("DEI") Committee which aims to support all members of our community and works to ensure all employees feel welcomed, respected and capable of performing their best work. We are also a proud equal opportunity employer and cultivate a highly collaborative and entrepreneurial culture.

Corporate Information

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 telephone number (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 and amendments to those reports on the day of filing with the SEC on our website at http://www.mtem.com or by contacting the Investor Relations Department 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 have identified conditions and events that raise substantial doubt about our ability to continue as a going concern, including our continued compliance with, and ability to avoid triggering an event of default related to, our solvency or the financial covenant in our debt facility beyond the fourth quarter of 2023. 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 may be unsuccessful in raising the capital necessary to address our going concern issues, or if we are successful, it may be on terms that are highly dilutive to existing stockholders.

- If we fail to execute successfully on our recently announced strategic reprioritization and restructuring, our business prospects and our financial condition may be adversely affected. Further, the restructuring could result in disruptions to our business during transitional periods and thereafter.

- A delisting of our common stock from Nasdaq could adversely affect our ability 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.

- 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.

- Manufacturing difficulties, disruptions or delays could limit supply of our drug or 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 drug or biologic candidates.

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

- We are heavily dependent on the success of our drug or biologic candidates, the most advanced of which is in the early stages of clinical development.

- Our drug or 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.
- 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 drug or biologic candidates and related processes for our developmental pipeline.
- We rely on third parties to conduct our clinical trials, manufacture our drug or biologic candidates and perform other services and if such third parties do not successfully carry out their contractual duties, meet expected timelines, or otherwise conduct the trials as required or perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our drug or biologic candidates when expected or at all, and our business could be substantially harmed.
- We have entered into the BMS Collaboration Agreement with Bristol Myers Squibb and, pursuant to the terms of that agreement, could become dependent on Bristol Myers Squibb for development, manufacturing, regulatory and commercialization activities with respect to certain of our ETB products directed to multiple targets.
- 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 drug or 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 have identified conditions and events that raise substantial doubt about our ability to continue as a going concern, including our continued compliance with, and ability to avoid triggering an event of default related to, our solvency or the financial covenant under our debt facility beyond the fourth quarter of 2023. 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 continue as a going concern as of the date of this Annual Report on Form 10-K. See Note 1 to our financial statements appearing elsewhere in this Annual Report on Form 10-K for additional information on our assessment. This substantial doubt relates to our future compliance with the financial covenant in our Loan and Security Agreement with K2 HealthVentures LLC (the "K2 Loan and Security Agreement") which requires us to certify monthly that we have cash, cash equivalents and marketable securities of at least five times our cash monthly burn as defined in the agreement (the "Financial Covenant"), as well as our ability to avoid triggering an event of default related to our solvency (an "Insolvency Event of Default") under the K2 Loan and Security Agreement. Currently, based on anticipated cost-savings from the Restructuring, we anticipate continued compliance with the Financial Covenant and

continued ability to avoid triggering an Insolvency Event of Default into the fourth quarter of 2023. However, we will require additional funding in order to meet our covenant requirements and ongoing operations.

If we cannot raise additional capital by then to maintain ourselves in compliance or negotiate an amendment to the Financial Covenant or the Insolvency Events of Default, then we will be in default of the K2 Loan and Security Agreement and the repayment of our indebtedness may be accelerated in full by K2 HealthVentures LLC. At December 31, 2022, we had cash, cash equivalents, and marketable securities of $61.0 million, including borrowings of $35.0 million under the K2 Loan and Security Agreement whose scheduled maturity date for repayment is June 1, 2024, but a default of the Financial Covenant or an Insolvency Event of Default may trigger accelerated repayment.

There can no assurances that we will be able to raise sufficient capital to fund ongoing operations and maintain the Financial Covenant and avoid triggering an Insolvency Event of Default beyond the fourth quarter of 2023 and/or be successful at negotiating an amendment to the K2 Loan and Security Agreement. If we are unable to obtain additional capital and continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

Our lack of cash 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 may be unsuccessful in raising the capital necessary to address our going concern issues, or if we are successful, it may be on terms that are highly dilutive to existing stockholders.

Historically, we funded our operations by raising capital from external sources, especially through the sale of common stock and our borrowings under the K2 Loan and Security Agreement. However, we are currently facing significant challenges to our ability to raise capital through the sale of common stock, including the following factors:

- in general, it is difficult for development stage companies to raise capital under current market conditions, especially those with early stage programs like ours;
- the perception that we may be unable to continue as a going concern may impede our ability to attract further equity investment;
- our common stock has been trading below $1.00 per share since July 2022 (on March 24, 2023, the closing price was $0.337 per share) and we are currently engaged in a Nasdaq hearing process regarding the potential delisting of our common stock. The potential delisting of our common stock from Nasdaq could adversely affect our ability to raise additional capital through the public or private sale of equity securities; and
- we are currently subject to the "baby shelf" limitations on our potential use of our shelf registration statement, which limits such use to an offering size of no more than $5.7 million. However, this limitation would not affect our ability to raise capital in ways other than our shelf registration statement, such as private placements and PIPEs, if investor demand exists for such offerings by us.

Given these factors, there can be no assurances we will be successful at raising sufficient capital to address our going concern issues. However, if we are successful, it may be on terms that are very highly dilutive to existing stockholders.

If we fail to execute successfully on our recently announced strategic reprioritization and restructuring, our business prospects and our financial condition may be adversely affected. Further, the Restructuring could result in disruptions to our business during transitional periods and thereafter.

There can be no assurances that we will be successful at executing on this strategic reprioritization or that the Restructuring will achieve the cost savings, operating efficiencies or other benefits that we may initially expect, which underlie our current cash runway expectations and our projection that we will remain in compliance with the Financial Covenant and avoid triggering an Insolvency Event of Default under the K2 Loan and Security Agreement into the fourth quarter of 2023. The restructuring activities may also result in a loss of continuity, accumulated knowledge and inefficiency during transitional periods and thereafter. 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 therefrom, 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.

A delisting of our common stock from Nasdaq could adversely affect our ability 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.

If our common stock is ultimately delisted by Nasdaq, our common stock may be eligible to trade on the OTC Bulletin Board or another over-the-counter 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.

Unless our common stock is listed on a national securities exchange, such as the Nasdaq Capital Market, our common stock may also be subject to the regulations regarding trading in "penny stocks," which are those securities trading for less than $5.00 per share, and that are not otherwise exempted from the definition of a penny stock under other exemptions provided for in the applicable regulations. The following is a list of the general restrictions on the sale of penny stocks:

- Before the sale of penny stock by a broker-dealer to a new purchaser, the broker-dealer must determine whether the purchaser is suitable to invest in penny stocks. To make that determination, a broker-dealer must obtain, from a prospective investor, information regarding the purchaser's financial condition, investment experience, and objectives. Subsequently, the broker-dealer must deliver to the purchaser a written statement setting forth the basis of the suitability finding and obtain the purchaser's signature on such statement.

- A broker-dealer must obtain from the purchaser an agreement to purchase the securities. This agreement must be obtained for every purchase until the purchaser becomes an "established customer."

- The Securities Exchange Act of 1934, as amended (the "Exchange Act") requires that before effecting any transaction in any penny stock, a broker-dealer must provide the purchaser with a "risk disclosure document" that contains, among other things, a description of the penny stock market and how it functions, and the risks associated with such investment. These disclosure rules are applicable to both purchases and sales by investors.

- A dealer that sells penny stock must send to the purchaser, within 10 days after the end of each calendar month, a written account statement including prescribed information relating to the security.

These requirements can severely limit the liquidity of securities in the secondary market because fewer brokers or dealers are likely to be willing to undertake these compliance activities. If our common stock is not listed on a national securities exchange, the rules and restrictions regarding penny stock transactions may limit an investor's ability to sell to a third party and our trading activity in the secondary market may be reduced.

We may seek to effect a reverse stock split, subject to obtaining stockholder approval, in order to address the $1.00 minimum bid price requirement under Nasdaq rules. In the event a reverse stock split is implemented, we cannot predict the effect that such reverse stock split would have on the market price for shares of our common stock, and the history of similar reverse stock splits for companies in like circumstances has varied. Some investors may have a negative view of a reverse stock split. Even if such reverse stock split were to have a positive effect on the market price for shares of our common stock, performance of our business and financial results, general economic conditions and the market perception of our business, and other adverse factors which may not be in our control could lead to a decrease in the price of our common stock following such reverse stock split.

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 drug or biologic candidate. We have incurred net losses in each year since 2009, including net losses attributable to common shareholders of $92.7 million for the year ended December 31, 2022. At December 31, 2022, we had an accumulated deficit of $444.8 million.

We have devoted substantially all of our financial resources to identify, acquire, and develop our drug or 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.

We have no products approved for commercialization and have never generated any revenue. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize one or more of our drug or 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 drug or biologic candidates;
- obtaining regulatory and marketing approvals for one or more of our drug or biologic candidates;
- manufacturing one or more drug or biologic candidates and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible;
- marketing, launching and commercializing one or more drug or 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 drug or biologic candidates as treatment options;
- meeting our supply needs in sufficient quantities to meet market demand for our drug or 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 drug or biologic candidates that supports profitability; and
- retaining qualified personnel.

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

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 may exceed the Federal Deposit Insurance Corporation ("FDIC") 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 ("FASB") American Institute of Certified Public Accountants, the SEC and various other regulatory and accounting bodies. A change in interpretations of, or our application of, these principles can have a significant effect on our reported results and may even affect our reporting of transactions completed before a change is announced. In addition, when we are required to adopt new accounting standards, our methods of accounting for certain items may change, which could cause our results of operations to fluctuate from period to period and make it more difficult to compare our financial results to prior periods.

Risks Related to the Development of Our Drug or Biologic Candidates

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

We currently have a current good manufacturing practices ("cGMP") manufacturing facility and we have developed the capability to manufacture drug or biologic candidates for use in the conduct of our clinical trials. We may not be able to manufacture drug or biologic candidates or there may be substantial technical or logistical challenges to supporting manufacturing demand for drug or 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 drug or 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 drug or biologic candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our drug or 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 drug or biologic candidate to complete the trial, any significant delay or discontinuity in the supply of a drug or biologic candidate, or the raw materials or other material components used in the manufacture of the drug or biologic candidate, could delay completion of our clinical trials and potential timing for regulatory approval of our drug or 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 drug or biologic candidates and our current costs to manufacture our drug products may not be commercially feasible, and the actual cost to manufacture our drug or biologic candidates could materially and adversely affect the commercial viability of our drug or biologic candidates. As a result, we may never be able to develop a commercially viable product.

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

- limited capacity of manufacturing facilities;
- contamination of drug or 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, or disease outbreaks, such as the conflict in Ukraine and the COVID-19 pandemic;
- labor disputes or shortages, including the effects of health emergencies, epidemics, pandemics, such as the COVID-19 pandemic, 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 New Drug Application ("NDA") or Biologics License Application ("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 drug or 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 drug or biologic candidates or the commercialization of our drug or 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 drug or 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 drug or 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 public health emergencies or pandemics, natural disasters, staffing shortages, or other events, which may affect our ability to initiate and/or complete preclinical studies, conduct ongoing clinical trials, and delay 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 clinical research organizations ("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 ("IRB") approval at each clinical trial site;
- failure to obtain or delays in obtaining a permit from regulatory authorities to conduct a clinical trial;
- delays in recruiting or failure to recruit sufficient eligible volunteers or 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;
- occurrence of adverse events associated with our drug or biologic candidates;

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of our drug or 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 drug or biologic candidate; and
- delays in reaching agreement on acceptable terms with third-party manufacturers or an inability to manufacture sufficient quantities of our drug or biologic candidates for use in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval for one or more of our drug or 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 drug or 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, including those caused by the COVID-19 pandemic, could also shorten any periods during which our drug or 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 drug or 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 drug or 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 drug or 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 drug or 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 drug or 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 drug or 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 drug or 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 drug or 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 drug or biologic candidates, whether appropriate or not.

We are heavily dependent on the success of our drug or biologic candidates, the most advanced of which is in the early stages of clinical development. Our ETB therapeutic drug or 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 drug or 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 drug or 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 drug or 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 drug or biologic candidates. Our future success is dependent on our ability to successfully further develop, obtain regulatory approval for, and commercialize one or more drug or biologic candidates. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a drug or 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. Our CD38-targeted ETB, MT-0169 is also being tested in a Phase I study, which began dosing patients in the first quarter of 2020 although it was paused in March 2020 due to COVID-19 and was re-initiated during the fourth quarter of 2020. The revised protocol for the ongoing Phase I study for MT-0169 in relapsed/refractory multiple myeloma and non-Hodgkin's lymphoma began dosing patients in July 2022, continues to recruit patients, has cleared the 5 mcg/kg and 10 mcg/kg doses and continues to explore the lower dose of MT-0169 at 15 mcg/kg. Our ETB candidate MT-8421 is planned to be tested in a Phase I study mid-year 2023. There can be no assurance that we will not experience problems or delays in developing our drug or 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 drug or biologic candidates in our planned indications will be sufficient to obtain regulatory approval.

None of our ETB drug or 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 drug or 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 drug or biologic candidates. We cannot be certain that any of our drug or biologic candidates will be successful in clinical trials or receive regulatory approval. Further, our drug or biologic candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our drug or 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 drug or biologic candidates. If our ETB product candidates fail to prove to be safe, effective or commercially viable, our drug or 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 drug or biologic candidate, vary substantially according to the type, complexity, novelty and intended use and market of the drug or biologic candidate. The regulatory approval process for novel drug or biologic candidates such as ETB product candidates could be more expensive and take longer than for others, better known or more extensively studied drug or biologic candidates. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our drug or biologic candidates in either the United States or the European Union or elsewhere or how long it will take to commercialize our drug or 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 drug or 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.

During the global response to the COVID-19 pandemic, moreover, the responses of the federal, international, state and regional governments to the pandemic, including but not limited to, the redeployment of FDA and EMA resources to priority projects, could have an impact on the timeline for review and approval of new marketing applications. In particular, the FDA has told industry that it intends to be as transparent as possible about its workload and performance metrics as the situation evolves and to communicate directly with applicants and manufacturing facilities as may be necessary. The FDA also announced in July 2022 that remote regulatory assessments of facilities and other alternative approaches developed during the first two years of the pandemic will continue to be used by the agency in order to supplement its in-person inspection program. Congress has 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 may have difficulty enrolling, or fail to enroll patients, in our clinical trials given the limited number of patients who have the diseases for which our drug or biologic candidates are being studied, which could delay or prevent clinical trials of our drug or biologic candidates.

Identifying and enrolling patients to participate in clinical trials of our ETB drug or 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 drug or 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, staffing shortages, or otherwise.

The eligibility criteria of our 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 drug or 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 drug or biologic candidates may be delayed.

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

Our drug or 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.

Undesirable side effects caused by our drug or 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 adverse events ("AEs"), considered to be important or potential risks of MT-6402 include, but are not limited to, cytokine release syndrome ("CRS"), infusion-related reactions ("IRR"), immune-related adverse reactions, hepatotoxicity, acute kidney injury, hematologic toxicity, coagulation and clinical chemistry toxicity, capillary leak syndrome ("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, 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 and MT-0169, 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. Regulatory authorities may 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, 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 drug or 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 drug or 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 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 drug or biologic candidates, may carry boxed warnings or other warnings and precautions. Undesirable side effects and negative results for any of our drug or biologic candidates may negatively impact the development and potential for approval of our drug or biologic candidates for their proposed indications.

Additionally, even if one or more of our drug or 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 ("REMS") plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, or other elements to assure safe use;
- we may be required to change the way such drug or biologic candidates are distributed or administered, or change the labeling of the drug or 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 drug or 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 drug or 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 drug or biologic candidates and adversely affect our ability to conduct our business or obtain regulatory approvals for our drug or 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 drug or biologic candidates prescribing treatments that involve the use of one or more of our approved drug or 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 drug or 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 drug or 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 drug or 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 drug or biologic candidates, stricter labeling requirements for those drug or biologic candidates that are approved and a decrease in demand for any such drug or 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. 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 drug or 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 drug or biologic candidates may not be predictive of the results of larger, later-stage controlled clinical trials. Drug or 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 may publish or report interim or preliminary data from our clinical trials. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data is available.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same drug or 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 drug or biologic candidates.

We may use our financial and human resources to pursue a particular research program or drug or biologic candidate and fail to capitalize on programs or drug 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 drug 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 drug or 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 drug or biologic candidates in indications with potentially large commercial markets. If we do not accurately evaluate the commercial potential or target market for a particular drug or biologic candidate, we may relinquish valuable rights to that drug or 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 drug or biologic candidate. We may allocate internal resources to a drug or 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 drug or biologic candidates harms subjects or is perceived to harm subjects even when such harm is unrelated to our drug or 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 drug or 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 drug or biologic candidates and approved products, if any. There is a risk that our drug or 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 drug or biologic candidates may induce similar or more severe adverse events. Patients with the diseases targeted by our drug or 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 drug or 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 drug or biologic candidates, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may delay our regulatory approval process or impact and limit the type of regulatory approvals our drug or 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 drug or 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 drug or 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 drug or 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 biological drug or biologic candidates would adversely impact our business and future results of operations.

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

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

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

We have conducted and have ongoing studies in international locations and may in the future initiate additional studies in countries other than the United States. Our business activities may be subject to the Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or

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

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

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

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

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our drug or 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 drug or biologic candidate may not result in a faster development process, review or approval, compared to drugs or 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 drug or biologic candidates qualify and are designated as a breakthrough therapy, the FDA may later decide that the drugs or 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 drug or 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 drug or 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 drug or 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 drug or 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, NDA or other marketing authorization application.

Any regulatory approvals that we receive for our drug or biologic candidates may be subject to limitations on the approved indicated uses for which the drug or 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 drug or biologic candidate. In addition, if the FDA, EMA or a comparable foreign regulatory authority approves any of our drug or 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 drug or 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 drug or biologic candidates for which we hope to obtain marketing approval. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. If we are not able to comply with post-approval regulatory requirements, we could have marketing approval for any of our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

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

- impose restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- impose requirements to conduct post-marketing studies or clinical trials;
- issue warning or untitled letters if the regulator is the FDA, or comparable notice of violations from foreign regulatory authorities;
- issue consent decrees, injunctions or impose civil or criminal penalties;
- require the payment of fines, restitution or disgorgement of profits or revenues;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our 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 drug or biologic candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are otherwise not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Our commercial success will depend upon attaining significant market acceptance of our drug or 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 drug or 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 drug or 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 drug or 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 drug or biologic candidate as demonstrated through broad commercial distribution;
- the ability to offer our drug or 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 drug or 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 drug or 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 drug or 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 drug or 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 Patient Protection and Affordable Care Act (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 (the "BPCIA"), 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 Department of Health and Human Services ("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 U.S.

In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our drug or biologic candidates, restrict or regulate post-approval activities, or affect our ability to profitably sell any drug or 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 drug or 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 Inflation Reduction Act of 2022 (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. Starting in 2023, a manufacturer of drugs or biological products covered by Medicare Parts B or D must 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, the Centers for Medicare & Medicaid Services ("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 but their impact on the biopharmaceutical industry in the United States remains uncertain.

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 Federal Trade Commission's 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. As of mid-January 2023, the report had not been released but it is 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 drug or biologic pricing, including drug or 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 pharmacy benefit managers ("PBMs") and other members of the health care and pharmaceutical supply chain, an important decision that appears to be leading towards further and more aggressive efforts by states in this area. The Federal Trade Commission 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. 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.

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 drug or 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 health care providers and third-party payors will play a primary role in the recommendation, prescription and use of any drug or biologic candidates for which we obtain marketing approval. In the U.S., our future arrangements with such third parties may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain our business or financial arrangements and relationships through which we market, sell and distribute any products for which we may obtain marketing approval. 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 Statue constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") that imposes criminal and civil liability for executing a scheme to defraud any health care benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- analogous state and foreign laws and regulations relating to health care fraud and abuse, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers;
- the federal transparency requirements, sometimes referred to as the "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 drug or 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 may be subject to, or may in the future become subject to, U.S. federal and state, and foreign laws and regulations imposing obligations on how we collect, use, disclose, store and process personal information. Our actual or perceived failure to comply with such obligations could result in liability or reputational harm and could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our potential future customer base, and thereby decrease our revenue.

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

The privacy and security of personally identifiable information stored, maintained, received or transmitted, including electronically, is subject to significant regulation in the United States and abroad. While we strive to comply with all applicable privacy and security laws and regulations, legal standards for privacy continue to evolve and any failure or perceived failure to comply may result in proceedings or actions against us by government entities, 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 in the context of an establishment in the European Economic Area ("EEA") or that process the personal data of data subjects who are located in the EEA. These requirements include, for example, establishing a basis for processing, providing notice to data subjects, developing procedures to vindicate expanded data subject rights, implementing appropriate technical and organizational measures to safeguard personal data, and complying with restrictions on the cross-border transfer of personal data from the EEA to countries that the European Union does not consider to have in place adequate data protection legislation, such as the United States. The GDPR additionally establishes heightened obligations for entities that process "special categories" of personal data, such as health data. Nearly all clinical trials involve the processing of these "special categories" of personal data, and thus processing of personal data collected during the course of clinical trials is subject to heightened protections under the GDPR. Violations of the GDPR can lead to penalties of up to €20 million or 4% of an entity's annual turnover. The United Kingdom has incorporated the GDPR into its Data Protection Act 2018, and substantially equivalent requirements and penalties apply in the United Kingdom.

On July 16, 2020, the Court of Justice of the European Union (the "CJEU") issued a landmark opinion in the case *Maximilian Schrems vs. Facebook* (Case C-311/18), called *Schrems II.* This decision calls into question certain data transfer mechanisms as between the European Union member states and the United States. The CJEU is the highest court in Europe and the *Schrems II* decision heightens 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 at this early date. Consequently, there is some risk of any such data transfers from the European Union being halted by one or more European Union member states. 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 under *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 ("CMIA") 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 CMIA, California also recently 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 also creates new privacy rights for California residents and 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, which is expected to increase 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 CMIA, 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 and is expected to result in increased privacy and information security enforcement. 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 will all take effect.

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

Reliance on government funding for our programs may add uncertainty to our research and commercialization efforts with respect to those programs that are tied to such funding and may impose requirements that limit our ability to take certain actions, increase the costs of commercialization and production of drug or 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 drug or 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 Cancer Prevention & Research Institute of Texas ("CPRIT"). On September 18, 2018, we entered into our second CPRIT award grant contract for our CD38 targeted ETB program (the "CD38 CPRIT Agreement"), which was extended in September 2022. 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 drug or 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 drug or 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, such as those caused recently by the federal response to the COVID-19 pandemic and that could occur again in the event of another public health or other national emergency, 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 drug or 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 drug or 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 drug or 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 drug or 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, drug or 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, drug or 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, drug or 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, drug or biologic candidates, compositions or their uses;
- others may independently develop identical, similar or alternative methods, products, drug or biologic candidates or compositions and uses thereof;
- we 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 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, or to us and 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;
- we or our past, current or future licensors' or collaboration partners' products, drug or 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 patent term extensions available in the United States or in foreign jurisdictions or countries;
- others may design around our 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 or our past, current or future licensors' or collaboration partners' patent applications, or invalidate our 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' drug or 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, drug or 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 drug or 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, drug or 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 drug or biologic candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a drug or 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, drug or 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 drug or 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 drug or 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, drug or 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.

Patent term extensions under the Hatch-Waxman Act in the United States, and regulatory extensions in Japan and certain other countries, and under Supplementary Protection Certificates in Europe, may be available to extend the patent or market or data exclusivity terms of our drug or 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 United States Patent and Trademark Office (the "USPTO"). Although we will likely seek patent term extensions in the U.S. and in one or more foreign jurisdictions where available, we cannot provide any assurances that any such patent term extensions will be granted and, if so, for how long. As a result, we may not be able to maintain exclusivity for our drug or 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 drug or 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 recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in specified circumstances and weakened the rights of patent owners in specified situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

On September 16, 2011, the Leahy-Smith America Invents Act ("AIA") was signed into law. Under the AIA, as of March 16, 2013, the United States transitioned to a "first-inventor-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that filed or files a patent application with the USPTO after March 16, 2013 but before we file an application could therefore be granted a patent covering an invention of ours even if we had made the invention before it was made by the third party. Since 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 drug or 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 drug or 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 drug or 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 a patent term extension of up to five years beyond the expiration of a patent that covers an approved product where the permission for the commercial marketing or use of the product is the first permitted commercial marketing or use, and as long as the remaining term of the patent does not exceed 14 years. However, the applicable authorities, including the FDA in the United States, and any 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, 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, 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, drug or biologic candidates, compositions or uses could be found invalid or unenforceable if challenged in a patent office or court.

Even if our past, current or future collaboration partners' or licensors' patents do successfully issue and even if such patents cover our technologies, drug or 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, drug or biologic candidates, compositions or methods of use. Further, if we initiate legal proceedings against a third party to enforce a patent covering our technologies, drug or 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, drug or biologic candidates, compositions and associated uses.

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

Competitors may infringe our patents or the patents of any of our 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 drug or biologic candidates, the defendant could counterclaim that the patent covering our drug or 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 drug or 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 drug or 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 drug or biologic candidates to market.

If we are unable to protect the confidentiality of our trade secrets and know-how for our drug or biologic candidates or any future drug or 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 drug or 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 drug or 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 drug or biologic candidates or therapeutic uses of those ETB drug or 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 drug or biologic candidates or technologies or a requisite manufacturing process, we may not be free to manufacture or market our drug or 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 drug or 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 drug or 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 drug or biologic candidates or the use of our drug or 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 drug or biologic candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that

our drug or 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 drug or 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 drug or 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 drug or 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. Because our programs may involve a range of ETB targets and antibody domains, which in the future may include targets and antibody domains that require the use of proprietary rights held by third parties, the growth of our business may likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our drug or 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 continue to collaborate, with federal, state or international academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions grant the rights to the collaborator and retain a non-commercial license to all rights as well as 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 drug or 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 drug or 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 drug or biologic candidates, there may be times when certain patents or patent applications relating to our drug or 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 drug or biologic candidates, their compositions, uses or their manufacture, our ability to develop and commercialize those drug or 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 drug or 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 may be subject to, or may in the future become subject to, U.S. federal and state, and foreign laws and regulations imposing obligations on how we collect, use, disclose, store and process personal information. Our actual or perceived failure to comply with such obligations could result in liability or reputational harm and could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our 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 drug or 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 drug or biologic candidates. Negative posts or comments about us or our drug or 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 drug or 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 drug or 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 drug or 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 that 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 drug or 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 drug or biologic candidates for use in the conduct of our clinical trials. We may not be able to manufacture drug or biologic candidates or there may be substantial technical or logistical challenges to supporting manufacturing demand for drug or 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 drug or 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 drug or biologic candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our drug or 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 drug or biologic candidate to complete the trial, any significant delay or discontinuity in the supply of a drug or biologic candidate, or the raw materials or other material components in the manufacture of the drug or biologic candidate, could delay completion of our clinical trials and potential timing for regulatory approval of our drug or 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 drug or biologic candidates and our current costs to manufacture our drug or biologic candidates may not be commercially feasible, and the actual cost to manufacture our drug or biologic candidates could materially and adversely affect the commercial viability of our drug or 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 drug or biologic candidates on acceptable terms or at all, because the number of qualified potential manufacturers is limited. Following NDA or BLA approval, a change in the manufacturing site could require additional approval from the FDA. This approval would require new testing and compliance inspections;
- our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- our future third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our drug or biologic candidates;
- drug or 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 drug or 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 drug or biologic candidates, or the commercialization of our drug or 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 drug or 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 drug or 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 health care 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 have entered into the BMS Collaboration Agreement with Bristol Myers Squibb Company and, pursuant to the terms of that agreement, could become dependent on Bristol Myers Squibb for development, manufacturing, regulatory and commercialization activities with respect to certain of our ETB products directed to multiple targets.

In February 2021, we entered into the BMS Collaboration Agreement, which was amended in December 2021, pursuant to which we agreed to leverage our ETB technology platform to discover and develop novel products directed to multiple targets. Pursuant to the terms of the BMS Collaboration Agreement, we granted Bristol Myers Squibb a series of exclusive options to obtain exclusive licenses under our intellectual property to exploit products containing ETBs directed against certain targets designated by Bristol Myers Squibb. Bristol Myers Squibb may never choose to exercise its option and we cannot predict whether Bristol Myers Squibb will, if ever, exercise its option.

Under the BMS Collaboration Agreement, Bristol Myers Squibb paid us an upfront payment of $70 million. In addition to the upfront payment, we may receive near term and development and regulatory milestone payments of up to an additional $874.5 million. We will also be eligible to receive up to an additional $450 million in payments upon the achievement of certain sales milestones. We will also be 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. The milestones that trigger a payment or royalties under the BMS Collaboration Agreement may never be reached and failure to do so could harm our business and financial condition.

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

Unless earlier terminated, the BMS Collaboration Agreement will 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 has the right to terminate the BMS Collaboration Agreement for convenience upon prior written notice to Company. Either party has 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. We have 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 our patents. If Bristol Myers Squibb terminates the BMS Collaboration Agreement, it will result in a delay in or could prevent us from further developing or commercializing products directed to these targets and will delay and could prevent us from obtaining revenues for such product. Further, disputes may arise between us and Bristol Myers Squibb, which may delay or cause the termination of this collaboration, result in significant litigation, cause Bristol Myers Squibb to act in a manner that is not in our best interest or cause us to seek another collaborator or proceed with development, commercialization and funding on our own. If we seek a new collaborator but are unable to do so on acceptable terms, or at all, or do not have sufficient funds to conduct the development or commercialization of product directed to these new targets ourselves, we may have to curtail or abandon that development or commercialization, which could harm our business.

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

Our business strategy, along with our short- and long-term operating results depend in part on our ability to execute on our existing strategic collaboration and to license or partner with new strategic partners. In addition to the BMS Collaboration Agreement, we expect to seek to collaborate with other partners in the future. 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 drug or 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 drug or 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 drug or biologic candidates if the collaboration partners view our drug or biologic candidates as competitive with their own products or drug 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 drug or 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 drug or 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 drug or 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, we often indemnify them from claims arising from the good faith performance of their services.

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

Risks Related to Commercialization of Our Drug Candidates

We currently have limited marketing and sales experience. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug or 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 drug or 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 drugs or 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 drug or 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 drug or 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 drug or biologic candidates and programs on terms that are acceptable, or at all. This may be because our drug or 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 drug or 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 drug or biologic candidates could delay the development or commercialization of our drug or 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 drug or biologic candidates or bring them to market and our business may be materially and adversely affected.

If the market opportunities for our drug or biologic candidates are smaller than we believe they are, we may not meet our revenue expectations and, even if a drug or biologic candidate receives marketing approval, our business may suffer. Because the patient populations in the market for our drug or 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 drug or biologic candidates may differ significantly from the actual market addressable by our drug or 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 drug or biologic candidates may be limited or may not be amenable to treatment with our drug or 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 drug or 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, Seagen, Immunogen, Morphosys, Genmab, Bristol Myers Squibb, Novartis, Regeneron, Janssen, Xencor, Amgen, AstraZeneca, Lilly, Merck KGaA, Pfizer, Sanofi, Mentrik Biotech, Merrimack Pharmaceuticals, Spectrum Pharmaceuticals, Cogent Biosciences, Karyopharm, ADC Therapeutics, 2seventy bio, Gilead, GlaxoSmithKline, Incyte, TG Therapeutics, and Versatem. Our competitors may succeed in developing, acquiring or licensing technologies or drug or biological products that are more effective or less costly than MT-6402, MT-8421, MT-0169, or any other drug or biologic candidates that we are currently developing or that we may develop, which could render our drug or 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 drug or 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 drug or 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 drug or 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 drug or 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 drug or 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 drug or 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 drug or biologic candidates.

Although a substantial amount of our effort has focused on the continued clinical testing, potential approval and commercialization of our existing drug or 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 drug or biologic candidates. Research programs to identify new drug or biologic candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or drug or biologic candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional drug or 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 drug or biologic candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional drug or biologic candidates;

- our drug or biologic candidates may not succeed in preclinical or clinical testing;
- our drug or 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 drug or biologic candidates obsolete or less attractive;
- drug or biologic candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a drug or biologic candidate may change during our program so that such a drug or biologic candidate may become unreasonable or infeasible to continue to develop;
- a drug or biologic candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a drug or 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 drug or 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 the Centers for Medicare and Medicaid Services ("CMS") an agency within the United States Department of Health and Human Services, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel drug or biologic candidates such as ours and what reimbursement codes our drug or 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*" Congress recently 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 drug or biologic candidates, and delays or failures to obtain such approvals;
- adverse results, clinical holds, or delays in the clinical trials of our drug or biologic candidates or any future clinical trials we may conduct, or changes in the development status of our drug or biologic candidates;
- failure of any of our drug or 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 drug or biologic candidates;
- any inability to obtain adequate supply of our drug or 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, 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;
- the issuance of additional shares of our preferred stock or common stock, or the perception that such issuances may occur, including through our "at-the-market" offering program or any sales of our preferred stock or common stock by our stockholders in the future;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to ETB drugs generally, including with respect to other drugs and potential drugs in such markets;
- the introduction of technological innovations or new therapies that compete with our potential drugs;
- changes in the structure of health care payment systems;
- disruptions in the financial markets in general and more recently due to the COVID-19 pandemic;

- the impact of political instability and military conflict, such as the conflict in Ukraine, 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, 2022, a total of 56,351,647 shares of our common stock were outstanding. Any sales of those shares or any perception in the market that such sales may occur could cause the trading price of our common stock to decline.

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

We may become involved in securities litigation that could 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, or the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and executive officers provide that:

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

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

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

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

As a public company listed on The Nasdaq Capital Market, and particularly after we cease to be a "smaller reporting company," we are incurring and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company or as a public company prior to the loss of such specified statuses. We are subject to the reporting requirements of the Exchange Act, as well as various requirements imposed by the Sarbanes-Oxley Act, rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, and the Dodd-Frank Wall Street Reform and Consumer Protection Act. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which

may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. The listing requirements of The Nasdaq Capital Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct, each of which requires additional attention and effort of management and our board of directors and additional costs.

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

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

As of December 31, 2022, 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 56% 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 Delaware General Corporation Law (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, 2022, 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 recently announced 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 drug or biologic candidates may make it more challenging to recruit and retain qualified personnel. The inability to 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, breaches, unauthorized access, interruptions due to employee error or malfeasance or other disruptions, or damage from natural disasters, terrorism, war and telecommunication and electrical failures, 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. Breaches 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 security breach, if at all. If our computer systems are compromised, we could be subject to fines, damages, reputational harm, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business, in addition to possibly requiring substantial expenditures of resources to remedy. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients, 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 drug or biologic candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce data and a cybersecurity breach could adversely affect our reputation and could result in other negative consequences, including disruption of our internal operations, increased cyber security protection costs, lost revenues or litigation. Despite precautionary measures to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

In October 2016, Molecular entered into a facility lease agreement for approximately 18,000 square feet of office and laboratory space in Austin, Texas, which serves as our corporate headquarters. The lease was initially set to expire in May 2022. In January 2017, Molecular entered into a first amendment to the lease to add an additional approximately 4,000 square feet, consisting mostly of laboratory space. In March 2017, Molecular entered into a second amendment to the lease to add an additional approximately 11,000 square feet of office and laboratory space 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, TX 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 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 is traded on The Nasdaq Capital Market under the symbol "MTEM."

Stockholders

As of March 27, 2023, we had 56,351,647 outstanding shares of common stock, no outstanding shares of preferred stock, and approximately 56,351,647 holders of record of our outstanding shares of common stock.

Unregistered Sales of Equity Securities

None.

Repurchases 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 engineered toxin bodies ("ETBs"), leverages the resident biology of a genetically engineered form of Shiga-like Toxin A subunit ("SLTA") to create novel therapies with potent and differentiated mechanisms of action ("MOA") for cancer.

Recent Developments

Substantial Doubt about Going Concern related to Debt Compliance Beyond the End of 2023

We believe there is substantial doubt about our ability to continue as a going concern as of the date of this Annual Report on Form 10-K. See Note 1 to our financial statements appearing elsewhere in this Annual Report on Form 10-K for additional information on our assessment. This substantial doubt relates to our future compliance with the Financial Covenant in our K2 Loan and Security Agreement, which requires us to certify monthly that we have cash, cash equivalents and marketable securities of at least five times our cash monthly burn as defined in the agreement, and our ability to avoid triggering an Insolvency Event of Default under the K2 Loan and Security Agreement. Currently, based on the anticipated cost-savings from the Restructuring, we anticipate continued compliance with the Financial Covenant and our ability to avoid triggering an Insolvency Event of Default into the fourth quarter of 2023. If we cannot raise additional capital to maintain ourselves in compliance thereafter or negotiate an amendment to the Financial Covenant or the Insolvency Events of Default, then we will be in default of the K2 Loan and Security Agreement and the repayment of our indebtedness may be accelerated in full by K2 HealthVentures LLC. As of December 31, 2022, we had cash, cash equivalents, and marketable securities of $61.0 million, including borrowings of $35.0 million under the K2 Loan and Security Agreement, whose scheduled maturity date for repayment is June 1, 2024, but a default of the Financial Covenant or an Insolvency Event of Default may trigger accelerated repayment. There can no assurances that we will be able to raise sufficient capital to fund ongoing operations and maintain our Financial Covenant or avoid triggering an Insolvency Event of Default beyond the fourth quarter of 2023 and/or be successful at negotiating an amendment to the K2 Loan and Security Agreement thereafter.

Strategic Reprioritization

On March 29, 2023, our Board of Directors approved 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 our collaboration with Bristol Myers Squibb. The Restructuring would reduce our current workforce from approximately 222 full-time employees to approximately 50% of that number. The Restructuring will result in the cessation of our MT-5111 clinical development program, and will focus the majority of our pre-clinical efforts around activities related to the Bristol Myers Squibb collaboration. We estimate that we will incur approximately $0.4 million of costs in connection with the reduction in workforce related to severance pay and other related termination benefits. We expect the majority of the costs associated with the Restructuring to be incurred during the quarter ending June 30, 2023. We anticipate incurring additional costs related to the Restructuring, however, such costs cannot be reasonably estimated as of the time of the filing of this Annual Report on Form 10-K.

Nasdaq Hearing Process regarding Potential Delisting of Common Stock

On August 31, 2022, we received a deficiency letter from the Listing Qualifications Department (the "Staff") of Nasdaq notifying us that because the closing bid price of our common stock was below $1.00 for 30 consecutive days, we no longer met the bid price requirement. We did not regain compliance with the bid price requirement by the Compliance Date and, as a result, on February 28, 2023, we received notice (the "Notice") from the Staff that our securities would be subject to delisting, unless we timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). Specifically, the Notice indicated that we were not eligible for an automatic second 180 day grace period for the bid price rule, as we did not comply with the $5 million stockholders' equity initial listing requirement for The Nasdaq Capital Market. As of the date of this Annual Report on Form 10-K, we had a stockholders' deficit of approximately $(15.1) million.

We timely requested a hearing before the Panel, with such request implementing a stay against any further action by Nasdaq at least pending the issuance of a decision by the Panel and the expiration of any extension the Panel may grant to us following the hearing. Our hearing is currently scheduled for mid-April 2023, at which time, pursuant to Nasdaq listing and hearing regulations, the Panel has the discretion to grant or deny an extension of up to an additional 180 days from the date of the Notice. We continue to work diligently to regain compliance. Our plan with respect to the bid price requirement may include seeking to effect a reverse stock split, subject to obtaining stockholder approval, and to regain compliance with the stockholders' equity requirement by raising capital. However, there can be no assurance that the Panel will determine to continue our listing, or that we will be able to raise sufficient capital to regain compliance with the applicable listing criteria such as the stockholders' equity requirement, within any extension that may be granted by the Panel.

Collaboration Agreements

Bristol Myers Squibb Company

On February 10, 2021, we entered into a Collaboration Agreement ("BMS Collaboration Agreement") with Bristol Myers Squibb Company ("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.

Pursuant to the BMS Collaboration Agreement, Bristol Myers Squibb paid us an upfront payment of $70.0 million. We might receive near term and development and regulatory milestone payments of up to an additional $874.5 million and will be eligible to receive up to an additional $450.0 million in milestone payments upon the achievement of certain sales milestone events. We will also be 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 will be 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 will be 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, 2022, included in this Annual Report on Form 10-K.

Previous Agreements

In September 2018, we entered into the Development Collaboration and Exclusive License Agreement (the "Collaboration 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 SLT-A fusion proteins ("Licensed Products") for the treatment of patients with diseases such as multiple myeloma.

In April 2021, we received a notice of termination from Takeda for the Collaboration 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 Collaboration Agreement. The termination of the Collaboration 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 Collaboration 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 November 2019, we entered into a Master Collaboration Agreement ("Vertex Collaboration Agreement") with Vertex Pharmaceuticals Incorporated ("Vertex"), in which the parties agreed to enter into a strategic research collaboration to leverage our ETB technology platform to discover and develop novel targeted biologic therapies for applications outside of oncology.

In October 2021, we received a notice of termination from Vertex for the Vertex Collaboration Agreement. The termination of the Vertex Collaboration Agreement was effective in October 2021. There are no ongoing activities or economic obligations in connection with the Vertex Collaboration Agreement.

In June 2017, we entered into a Multi-Target Collaboration and License Agreement with Takeda (the "Takeda Multi-Target Agreement"), pursuant to which we 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 a Cancer Research Grant Contract (the "CD38 CPRIT Agreement") with the Cancer Prevention and Research Institute of Texas ("CPRIT"), which was extended in September 2022, in connection with a grant of approximately $15.2 million awarded by CPRIT to us in November 2016 to fund research of a cancer therapy involving an ETB that is targeting CD38 (the "Award"). Pursuant to the CD38 CPRIT Agreement, we 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 (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) November 30, 2023 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 not to exceed six months after the termination date if additional time is required to ensure adequate completion of the approved project, subject to the terms and conditions of the CD38 CPRIT Agreement.

For more information about our grant agreements, please see Note 3, "Research and Development Agreements" to our audited consolidated financial statements for the year ended December 31, 2022, 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, 2022, included in this Annual Report on Form 10-K.

Research and Development Expenses

Research and development expenses consist principally of:

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

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including the initiation and enrollment of subjects in clinical trials and manufacture of drug or biologic materials for clinical trials. We expect research and development 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 research and development activities;
- clinical trials and early-stage results;
- the terms and timing of regulatory approvals; and
- the ability to market, commercialize and achieve market acceptance for MT-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 European Medicines Agency ("EMA") or other regulatory authority were to require us to conduct pre-clinical and clinical studies beyond those which we currently anticipate will be required for the completion of clinical development or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of our clinical development programs.

General and Administrative Expenses

Our general and administrative expenses consist principally of:

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

In March 2023, we implemented certain initiatives as part of our strategic reprioritization efforts to improve operating efficiency, including cessation of the MT-5111(HER2) clinical development program and the reduction of our headcount by approximately 50%. While we expect to incur certain legal, accounting and other expenses in connection with the Restructuring, we expect that such measures will decrease our general and administrative expenses.

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,			
	2022	2021	Change ($)	Change (%)
Research and development revenue, related party	$ —	$ 13,136	$ (13,136)	-100%
Research and development revenue, other	19,754	25,561	(5,807)	-23%
Total revenue	$ 19,754	$ 38,697	$ (18,943)	-49%

Research and Development Revenue – from related party

The decrease in research and development revenue – from related parties for the year ended December 31, 2022 compared to the year ended December 31, 2021 was due to Takeda ceasing to be a related party in 2021.

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, 2022, included in this Annual Report on Form 10-K.

Research and Development Revenue – other

The decrease in research and development revenue – other for the year ended December 31, 2022 compared to the year ended December 31, 2021 is primarily due to the cessation of the Vertex Collaboration Agreement during 2021.

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, 2022, 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,			
	2022	2021	Change ($)	Change (%)
Research and development expenses	$ 82,425	$ 84,665	$ (2,240)	-3%
General and administrative expenses	26,200	34,106	(7,906)	-23%
Total operating expenses	$ 108,625	$ 118,771	$ (10,146)	-9%

Research and Development Expenses

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

	Years ended December 31,			
	2022	2021	Change ($)	Change (%)
Program costs	$ 24,408	$ 28,514	$ (4,106)	-14%
Employee compensation	37,398	41,694	(4,296)	-10%
Laboratory costs	9,962	5,131	4,831	94%
Other research and development costs	10,657	9,326	1,331	14%
Total research and development expenses	$ 82,425	$ 84,665	$ (2,240)	-3%

Research and development ("R&D") expenses decreased $2.2 million during the year ended December 31, 2022 compared to the year ended December 31, 2021. This decrease is primarily due to decreased program costs related to our collaboration agreements and decreases in headcount partially offset by an increase in laboratory costs.

Program costs decreased $4.1 million during the year ended December 31, 2022 compared to the year ended December 31, 2021. The programs driving the decrease were $3.1 million for MT-0169, $2.1 million for other programs, $1.9 million for MT-3724, $1.3 million for Vertex and $0.2 for SLAMF7 which is partially offset by an increase of $1.7 million for MT-8421, $1.2 million for BMS, $0.9 million for MT-5111 and $0.7 million for MT-6402.

Headcount decreased in R&D by 14% from December 31, 2021 to December 31, 2022. This staffing decrease resulted in a decrease in employee compensation costs of $4.3 million for the year ended December 31, 2022 compared to the year ended December 31, 2021.

Laboratory costs increased by $4.8 million during the year ended December 31, 2022 compared to the year ended December 31, 2021, which is due to laboratory equipment and supplies. The increase in expense reflects the costs of outfitting, supplying and maintaining laboratory facilities.

Other R&D costs increased by $1.3 million during the year ended December 31, 2022 compared to the year ended December 31, 2021 due to higher depreciation expense related to the lab buildouts and related equipment.

General and Administrative Expenses

General and administrative expenses decreased by $7.9 million during the year ended December 31, 2022 compared to the year ended December 31, 2021. The main driver of this decrease is related to a decrease of headcount resulting in a decrease of employee compensation expenses and decrease in legal services.

Nonoperating activities

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

	Years ended December 31,			
	2022	2021	Change ($)	Change (%)
Interest and other income, net	$ 988	$ 434	$ 554	128%
Interest expense	(4,782)	(3,369)	(1,413)	42%
Total nonoperating activities	$ (3,794)	$ (2,935)	$ (859)	29%

Interest and Other Income and Interest Expense

The increase in interest and other income for the year ended December 31, 2022, compared to the year ended December 31, 2021 was primarily due to higher interest related to our marketable securities.

The increase in interest expense for the year ended December 31, 2022, compared to the year ended December 31, 2021 was primarily due to higher interest paid for our debt holdings.

Liquidity and Capital Resources

Sources of Funds and Liquidity

Historically, we have funded our operations by raising capital from external sources, especially through the sale of common stock and our borrowings under the K2 Loan and Security Agreement. However, we are currently facing substantial doubt about our ability to continue as a going concern, given that our continued compliance with the Financial Covenant in our K2 Loan and Security Agreement and our ability to avoid triggering an Insolvency Event of Default beyond the fourth quarter of 2023 is dependent on us raising capital before such time or being successful at negotiating an amendment to the K2 Loan and Security Agreement, see "*−Recent Developments− Substantial Doubt about Going Concern related to Future Debt Compliance"*. If we cannot raise additional capital by then to maintain ourselves in compliance or negotiate an amendment to the Financial Covenant or the Insolvency Events of Default, then we will be in default of the K2 Loan and Security Agreement and the repayment of our indebtedness may be accelerated in full by K2 HealthVentures LLC. At December 31, 2022, we had cash, cash equivalents, and marketable securities of $61.0 million, including borrowings of $35.0 million under the K2 Loan and Security Agreement whose scheduled maturity date for repayment is June 1, 2024, but a default of the Financial Covenant or an Insolvency Event of Default would potentially trigger accelerated repayment. There can no assurances that we will be able to raise sufficient capital to fund ongoing operations and maintain compliance with the Financial Covenant and avoid triggering an Insolvency Event of Default beyond the fourth quarter of 2023 and/or be successful at negotiating an amendment to the K2 Loan and Security Agreement thereafter.

Future Funding Requirements and Liquidity

Based on our cash, cash equivalents and marketable securities as of December 31, 2022 (approximately $61.0 million) and the anticipated cost-savings of Restructuring and other assumptions, we anticipate that we will be able to fund our planned operating expenses and capital expenditure requirements pursuant to the priorities of our strategic refocusing into the second quarter of 2024. However, the foregoing is subject to our continued compliance with the Financial Covenant in the K2 Loan and Security Agreement, which requires us to certify monthly that we have cash, cash equivalents and marketable securities of at least five times our cash monthly burn as defined in the agreement, as well as our ability to avoid triggering an Insolvency Event of Default under the K2 Loan and Security Agreement. Currently, based on anticipated cost-savings from the Restructuring, we are anticipating continued compliance with the Financial Covenant and our ability to avoid triggering

an Insolvency Event of Default, into the fourth quarter of 2023. If we cannot raise additional capital to maintain itself in compliance thereafter or negotiate an amendment to the Financial Covenant or to the Insolvency Events of Default, then we will be in default of the K2 Loan and Security Agreement and the repayment of our indebtedness may be accelerated in full by K2 HealthVentures LLC. As of December 31, 2022, we had $35.0 million outstanding under K2 Loan and Security Agreement, whose maturity date for repayment is June 1, 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. 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, 2022 and 2021

The table below summarizes our cash flows for the years ended December 31, 2022 and 2021:

	Years ended December 31,			
	2022	2021	Change ($)	Change (%)
Net cash used in operating activities	$ (89,024)	$ (30,387)	$ (58,637)	193%
Net cash provided by/(used in) investing activities	95,317	(62,440)	157,757	-253%
Net cash provided by/(used in) financing activities	(265)	92,592	(92,857)	-100%
Net increase/(decrease) in cash, cash equivalents, and restricted cash	$ 6,028	$ (235)	$ 6,263	-2665%

The increase in net cash used in operating activities for the year ended December 31, 2022 compared to the year ended December 31, 2021 was primarily due to the decrease in revenue recognized during 2022.

The increase in net cash provided by investing activities for the year ended December 31, 2022 compared to the year ended December 31, 2021 was primarily due to investment activity in marketable securities.

The changes in net cash used in financing activities for the year ended December 31, 2022 compared to the year ended December 31, 2021 was primarily due to common stock, warrants and long term debt issued in 2021.

Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and had an accumulated deficit of $444.8 million at December 31, 2022. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our ETB candidates.

We expect our expenses to increase substantially in connection with our ongoing development activities related to MT-6402, MT-8421, MT-0169, and our collaboration with Bristol Myers Squibb. In addition, we expect to incur additional costs associated with operating as a public company. We anticipate that our expenses will increase substantially if and as we:

- support the PD-L1 program and the ongoing Phase I study for MT-6402;
- support the planned Phase I study of MT-8421;
- support the ongoing Phase I study of MT-0169;
- research activities through the designation of the development candidate(s) with Bristol Myers Squibb;
- 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 debt.

Because of the numerous risks and uncertainties associated with the development of MT-6402, MT-8421, MT-0169, and our collaboration with Bristol Myers Squibb 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.

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

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

Critical Accounting Policies and Use of Estimates

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

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

Revenue Recognition

Our revenue has consisted principally of research and development revenue from collaboration partners and grant revenue.

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

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

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

For further information regarding our revenue recognition, please see Note 1, "Organization and Summary of Significant Accounting Policies" to our audited consolidated financial statements for the year ended December 31, 2022, 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.

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, 2022, 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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, 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, 2022, the Company has recognized $19.8 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 30, 2023

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

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,190	$ 24,983
Marketable securities, current	28,859	118,061
Prepaid expenses	3,459	3,917
Other current assets	3,790	1,254
Total current assets	68,298	148,215
Marketable securities, non-current	—	8,986
Operating lease right-of-use assets	11,132	8,608
Property and equipment, net	14,632	19,309
Other assets	3,486	7,244
Total assets	$ 97,548	$ 192,362
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 504	$ 1,612
Accrued liabilities	8,823	9,515
Deferred revenue, current	45,573	32,937
Other current liabilities	2,182	2,606
Total current liabilities	57,082	46,670
Deferred revenue, long-term	5,904	33,350
Long-term debt, net of current portion	36,168	35,491
Operating lease liabilities	12,231	9,564
Other liabilities	1,295	1,625
Total liabilities	112,680	126,700
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $0.001 par value:		
Authorized: 2,000,000 shares at December 31, 2022 and December 31, 2021; issued and outstanding: 250 shares at December 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value:		
Authorized: 150,000,000 shares at December 31, 2022 and December 31, 2021; issued and outstanding: 56,351,647 December 31, 2022 and 56,305,049 shares at December 31, 2021	56	56
Additional paid-in capital	429,646	417,704
Accumulated other comprehensive loss	(66)	(48)
Accumulated deficit	(444,768)	(352,050)
Total stockholders' (deficit) equity	(15,132)	65,662
Total liabilities and stockholders' (deficit) equity	$ 97,548	$ 192,362

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,	
	2022	2021
Research and development revenue, related party	$ —	$ 13,136
Research and development revenue, other	19,754	25,561
Total revenue	19,754	38,697
Operating expenses:		
Research and development	82,425	84,665
General and administrative	26,200	34,106
Total operating expenses	108,625	118,771
Loss from operations	88,871	80,074
Interest and other income, net	988	434
Interest and other expense, net	(4,782)	(3,369)
Loss before provision for income taxes	92,665	83,009
Provision for income taxes	53	—
Net loss	92,718	83,009
Net loss attributable to common shareholders	$ 92,718	$ 83,009
Net loss per share attributable to common shareholders:		
Basic and diluted	$ 1.65	$ 1.50
Weighted average number of shares used in net loss per share calculations:		
Basic and diluted	56,334,456	55,297,798

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,	
	2022	2021
Net loss	$ 92,718	$ 83,009
Other comprehensive income:		
Unrealized loss on available-for-sale securities	(18)	(65)
Comprehensive loss	$ 92,736	$ 83,074

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances, December 31, 2020	250	—	49,984,333	50	328,314	17	(269,041)	59,340
Issuance of common stock pursuant to stock plans	—	—	320,716	—	1,620	—	—	1,620
Issuance of common stock in at-the-market offering, net of issuance costs of $4.8 million	—	—	6,000,000	6	71,139	—	—	71,145
Stock-based compensation	—	—	—	—	16,631	—	—	16,631
Other comprehensive loss	—	—	—	—	—	(65)	—	(65)
Net loss	—	—	—	—	—	—	(83,009)	(83,009)
Balances, December 31, 2021	250	—	56,305,049	56	417,704	(48)	(352,050)	65,662
Issuance of common stock pursuant to stock plans	—	—	46,598	—	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	—	56,351,647	56	429,646	(66)	(444,768)	(15,132)

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,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ 92,718	$ 83,009
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and other	7,383	6,630
Loss on disposal of property and equipment	66	442
Stock-based compensation expense	11,909	16,631
Interest due on long-term debt	121	146
Amortization of debt discount and accretion related to debt	975	737
Impairment of fixed assets and intangibles	430	—
Accretion of asset retirement obligations	124	135
Changes in operating assets and liabilities:		
Prepaid expenses	458	223
Accounts receivable, related party	—	234
Other assets	(438)	(289)
Operating lease right-of-use assets and liabilities	(550)	243
Accounts payable	(1,108)	(757)
Accrued liabilities	(866)	(3,268)
Other liabilities, related party	—	(11,853)
Other liabilities	—	(472)
Deferred revenue	(14,810)	47,735
Deferred revenue, related party	—	(3,895)
Net cash used in operating activities	(89,024)	(30,387)
Cash flows from investing activities:		
Purchases of property and equipment	(3,198)	(3,996)
Purchase of marketable securities	(55,525)	(210,994)
Sales of marketable securities	154,040	152,550
Net cash provided by/(used in) investing activities	95,317	(62,440)
Cash flows from financing activities:		
Payments of capital and finance lease obligations	—	(1)
Proceeds from issuance of long-term debt and warrants, net	—	19,828
Proceeds from stock option exercises	33	1,620
Proceeds from issuance of common stock and warrants, net offering expenses	—	71,145
Fees paid on loan modification	(298)	—
Net cash provided by/(used in) financing activities	(265)	92,592
Net increase/(decrease) in cash, cash equivalents, and restricted cash	6,028	(235)
Cash, cash equivalents and restricted cash, beginning of period	28,651	28,886
Cash, cash equivalents and restricted cash, end of period	$ 34,679	$ 28,651
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 32,190	$ 24,983
Restricted cash included in Other assets	2,489	3,668
Total cash, cash equivalents and restricted cash	$ 34,679	$ 28,651
Supplemental Cash Flow Information		
Cash paid for interest	$ 3,495	$ 2,248
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	$ 81

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

NOTE 1—ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Nature of the Business

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

Basis of Presentation

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

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 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.

There is substantial doubt about the Company's ability to continue as a going concern as of the date of this Annual Report on Form 10-K. This substantial doubt relates to the Company's future compliance with the financial covenant in its Loan and Security Agreement with K2 HealthVentures LLC (the "K2 Loan and Security Agreement"), which requires the Company to certify monthly that its has cash, cash equivalents and marketable securities of at least five times the Company's cash monthly burn as defined in the agreement (the "Financial Covenant"), as well as the Company's ability to avoid triggering an event of default related to its solvency (an "Insolvency Event of Default") under the K2 Loan and Security Agreement. Currently, based on anticipated cost-savings from the restructuring, discussed in Note 15 "Subsequent Events," the Company anticipates continued compliance with, and the ability to avoid triggering an event of default related to, an Insolvency Event of Default or the Financial Covenant into the fourth quarter 2023. However, the Company will require additional funding in order to meet its covenant requirements and ongoing operations. If the Company cannot raise additional capital to maintain its compliance thereafter or negotiate an amendment to the Financial Covenant or the Insolvency Events of Default, then the Company will be in default of the K2 Loan and Security Agreement and the repayment of the Company's indebtedness may be accelerated in full by K2 HealthVentures LLC. The Company has not yet established an ongoing source of revenues sufficient to cover its operating costs and to provide sufficient certainty that it will continue as a going concern. As of December 31, 2022, the Company had an accumulated deficit of $444.8 million.

At December 31, 2022, the Company had cash, cash equivalents, and marketable securities of $61.0 million, including borrowings of $35.0 million under the K2 Loan and Security Agreement whose scheduled maturity date for repayment is June 1, 2024, but a default of the Financial Covenant or an Insolvency Event of Default would potentially trigger accelerated repayment. There can be no assurances that the Company will be able to raise sufficient capital to fund ongoing operations and maintain compliance with, and avoid triggering an event of default related to, an Insolvency Event of Default or the Financial Covenant beyond the fourth quarter of 2023 and/or be successful at negotiating an amendment to the K2 Loan and Security Agreement. If the Company is unable to obtain additional capital and continue as a going concern, it might have to 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.

Accounting Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 $2.5 million and $3.7 million of restricted cash at December 31, 2022 and December 31, 2021, 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 to measure fair value for its financial assets and liabilities. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities. For Level 2 securities that have market prices from multiples sources, a "consensus price" or a weighted average price for each of these securities can be derived from a distribution-curve-based algorithm which includes market prices obtained from a variety of industrial standard data providers (e.g. Bloomberg), security master files from large financial institutions, and other third-party sources. Level 2 securities with short maturities and infrequent secondary market trades are typically priced using mathematical calculations adjusted for observable inputs when available.

Marketable Securities

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

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

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash and cash equivalents, investments, long term debt and accounts receivable.

The Company's cash 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. The Company's exposure to credit risk associated with non-payment will be affected principally by conditions or occurrences within Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda"), Vertex Pharmaceuticals Incorporated ("Vertex") and Bristol Myers Squibb Company ("Bristol Myers Squibb"). Takeda accounted for approximately 13% and 34% of total revenues for the years ended December 31, 2022 and December 31, 2021, respectively. Vertex accounted for approximately 0% and 48% of total revenues for the years ended December 31, 2022 and December 31, 2021, respectively. Bristol Myers Squibb accounted for approximately 87% and 18% of total revenues for the years ended December 31, 2022 and December 31, 2021, respectively.

Drug or biologic candidates developed by the Company may require approvals or clearances from the U.S. Food and Drug Administration ("FDA") or international regulatory agencies prior to commercial sales. There can be no assurance that the Company's drug or 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 seven years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the assets.

Patents

The gross value of Patents was $0.7 million and $1.1 million at December 31, 2022 and December 31, 2021, respectively, and are recorded in Other assets. The Company recorded $0.1 million of amortization expense for the years ended December 31, 2022 and December 31, 2021, with estimated expense to remain $0.1 million for each of the four successive years subsequent to December 31, 2022. For the year ended December 31, 2022, the Company recorded impairments of $0.4 million 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, 2022 and 2021.

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. 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 SEC Staff Accounting Bulletin No. 107, *"Share-Based Payment"*. To determine the risk-free interest rate, the Company utilized an average interest rate based on U.S. Treasury instruments with a term consistent with the expected term of the Company's stock-based awards. To determine the expected stock price volatility for the Company's stock-based awards, the Company considers its historical volatility and its industry peers. The fair value of all the Company's stock-based awards assumes no dividends as the Company does not anticipate paying cash dividends on its common stock.

Warrants

In conjunction with certain financing transactions, the Company issued warrants to purchase the Company's common stock. The Company determines whether the warrants should be classified as a liability or equity according to ASC 480, "*Distinguishing Liabilities from Equity*". For warrants classified as equity, the Company records the value of the warrants in additional paid-in capital on the balance sheet. Upon issuance of the outstanding warrants, the Company determined that equity classification was appropriate. There were no warrants issued for the years ended December 31, 2022 or 2021.

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 of America.

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 November 2021, the FASB issued ASU No. 2021-10, "Government Assistance: Disclosures by Business Entities about Government Assistance". The amendments in this Update improve financial reporting by requiring disclosures that increase the transparency of transactions with a government. The amendments require the following annual disclosures about transactions with a government that are accounted for by applying a grant or contribution accounting model by analogy (i) the type of transaction, (ii) the accounting for the transaction, and (iii) the effect of the transaction on the entity's financial statements. The Company adopted this standard as of January 1, 2022, using a prospective approach and it did not have a material impact on the Company's financial statements and related disclosures.

NOTE 2—NET LOSS PER SHARE

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period utilizing the two-class method. As discussed further in Note 11 "Stockholders' Equity", Preferred Stock Shareholders participate equally with Common Stock Shareholders in earnings, but do not participate in losses, and are excluded from

the Basic net loss calculation. Diluted net loss per share is computed by giving effect to all potential dilutive common shares, including outstanding options, warrants and convertible preferred stock. More specifically, at December 31, 2022 and December 31, 2021, stock options, warrants and if converted preferred stock totaling approximately 11,841,000 and 11,249,000 common shares, 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 our collaboration partner's parent company headquarters. Research and Development revenues disaggregated by location were as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Japan	$ 2,586	$ 13,136
United States	17,168	25,561
Total research and development revenue	$ 19,754	$ 38,697

Bristol Myers Squibb Collaboration Agreement

In February 2021, the Company entered into a Collaboration Agreement (the "BMS Collaboration Agreement"), as amended, with Bristol Myers Squibb to perform strategic research collaboration leveraging the Company's ETB technology platform to discover and develop novel products containing ETBs directed to multiple targets.

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 may receive near term and development and regulatory milestone payments of up to $874.5 million. The Company will also be 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 will be 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 will be responsible for all development, manufacturing, regulatory and commercialization activities with respect to that development candidate.

Unless earlier terminated, the BMS Collaboration Agreement will 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 has the right to terminate the BMS Collaboration Agreement for convenience upon prior written notice to the Company. Either party has 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 has 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 will be recognized over time as the underlying research and development services are performed.

The Company recognizes 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 will use actual costs incurred relative to budgeted costs expected to be incurred. These costs consist primarily of internal employee efforts and third-party contract costs. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligation over the estimated service period.

The Company had $45.3 million of deferred revenue, current and $5.9 million of deferred revenue, non-current, at December 31, 2022 related to the BMS Collaboration Agreement. The Company had $32.8 million of deferred revenue, current and $30.7 million of deferred revenue, non-current, at December 31, 2021 related to the BMS Collaboration Agreement.

Vertex Collaboration Agreement

In November 2019, the Company entered into a Master Collaboration Agreement (the "Vertex Collaboration Agreement") with Vertex, to perform strategic research leveraging the Company's ETB technology platform to discover and develop novel targeted biologic therapies for applications outside of oncology.

In October 2021, the Company received a notice of termination from Vertex for the Vertex Collaboration Agreement. The termination of the Vertex Collaboration Agreement was effective in October 2021. There are no ongoing activities or economic obligations in connection with the Vertex Collaboration Agreement. With the termination of the agreement, the Company's performance obligations under the Vertex Collaboration Agreement were completed in the fourth quarter of 2021 and the remaining unrecognized transaction price of $14.6 million was recognized as research and development revenue.

As of December 31, 2022 and December 31, 2021, there was no deferred revenue related to the Vertex Collaboration Agreement, respectively.

Takeda Pharmaceutical Company Limited Collaboration Agreements

Research and development revenue from a previously related party was with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda") and were as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Takeda Development and License Agreement	$ —	$ 13,114
Takeda Multi-Target Agreement	2,586	22
Total research and development revenue, previously related party	$ 2,586	$ 13,136

Takeda Development and License Agreement

In September 2018, the Company entered into a Development Collaboration and Exclusive License Agreement, as amended, with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda, for the development and commercialization of products incorporating or comprised of one or more CD38 SLT-A fusion proteins ("Licensed Products") for the treatment of patients with diseases such as multiple myeloma (the "Takeda Development and License Agreement"). In April 2021, the Company received a notice of termination from Takeda for the Takeda Development and License Agreement. Following receipt of the termination notice from Takeda, the Company 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, the Company 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 the Company, the Company may owe low-single digit royalties on future net sales of MT-0169 to Takeda as well as to certain third-party licensors. The Company may also owe certain third-party licensors potential aggregate clinical and regulatory milestone payments of up to $22.25 million.

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

As of December 31, 2022 and December 31, 2021, the Company had no deferred revenue related to the Takeda Development and License Agreement.

Takeda Multi-Target Agreement

In June 2017, the Company entered into a Multi-Target Collaboration and License Agreement with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda (the "Takeda Multi-Target Agreement"), in which the Company agreed to collaborate with

Takeda to identify and generate ETBs, against two targets designated by Takeda. 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.

As of December 31, 2022, there was no deferred revenue related to the performance obligation. As of December 31, 2021, deferred revenue was $2.6 million and the remaining unrecognized transaction price of $2.6 million was recognized as research and development revenue in the first quarter of 2022.

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 2022, under which CPRIT awarded a $15.2 million product development grant to fund research of a cancer therapy involving a CD38 targeting ETB. Pursuant to the CD38 CPRIT Agreement, the Company may also use such funds to develop a replacement CD38 targeting ETB, with or without a partner.

During the twelve months ended December 31, 2022 and December 31, 2021, the Company recognized no grant revenue under these awards. Qualified expenditures submitted for reimbursement in excess of amounts received are recorded as receivables in Grant revenue receivable. At December 31, 2022 and December 31, 2021, the Company had no grant revenue receivable.

NOTE 4—MARKETABLE SECURITIES AND FAIR VALUE MEASUREMENTS

The following table sets forth the Company's financial assets (cash equivalents and available-for-sale marketable securities) at fair value on a recurring basis as of December 31, 2022 and 2021:

	December 31, 2022	Basis of Fair Value Measurements		
		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			

	December 31, 2021	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	$ 24,058	$ 24,058	$ —	$ —
Commercial paper	103,113	—	103,113	—
United States Treasury Bills	14,023	—	14,023	—
Government-related debt securities	5,185	—	5,185	—
Corporate Bonds	5,726	—	5,726	
Total	$ 152,105	$ 24,058	$ 128,047	$ —
Amounts included in:				
Cash and cash equivalents	$ 25,058			
Marketable securities, current	118,061			
Marketable securities, non-current	8,986			
Total cash equivalents and marketable securities	$ 152,105			

The Company invests in highly-liquid, investment-grade securities. The following is a summary of the Company's available-for-sale securities at December 31, 2022 and 2021:

	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

	December 31, 2021			
	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Cash equivalents - money market funds, commercial paper and corporate bonds	$ 25,058	$ —	$ —	$ 25,058
Marketable securities, current - commercial paper, Treasury bills and corporate bonds	118,084	6	(29)	118,061
Marketable securities, non-current - Treasury bills	9,011	—	(25)	8,986

The following summarized the contractual maturities of the Company's available-for-sale investments at December 31, 2022 and 2021:

	December 31, 2022	
	Cost Basis	Fair Value
Due in one year or less	$ 58,948	$ 58,882
Due after one year through five years	—	—
Total	$ 58,948	$ 58,882

	December 31, 2021	
	Cost Basis	Fair Value
Due in one year or less	$ 143,142	$ 143,119
Due after one year through five years	9,011	8,986
Total	$ 152,153	$ 152,105

The Company received no proceeds from the sale of available-for-sale securities for the years ended December 31, 2022 and 2021, respectively, with no realized gain for the years ended December 31, 2022 and 2021. The basis on which the cost of the security sold was determined is by specific share identification.

NOTE 5—PROPERTY AND EQUIPMENT

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

	December 31,	
	2022	2021
Laboratory equipment	$ 21,831	$ 19,211
Leasehold improvements	12,971	12,822
Furniture and fixtures	518	471
Computer and equipment	658	658
	35,978	33,162
Less: Accumulated depreciation	(21,346)	(13,853)
Total property and equipment, net	$ 14,632	$ 19,309

Depreciation expense was $7.7 million and $6.6 million for the years ended December 31, 2022 and 2021, respectively.

In connection with the continued expansion of the Company's facilities, at December 31, 2022 and 2021, the Company had net Asset Retirement Obligation (ARO) assets totaling $0.3 million and $0.6 million, respectively. The ARO assets are included in

Leasehold improvements. For the year ended December 31, 2022 and December 31, 2021, the Company recorded a non-cash adjustment related to the ARO assets of $0.2 million and zero million, respectively. See Note 9 “Leases” for further discussion.

NOTE 6—BALANCE SHEET COMPONENTS

Accrued liabilities comprise the following (in thousands):

	December 31, 2022	December 31, 2021
Accrued liabilities:		
General and administrative	$ 855	$ 794
Clinical trial related costs	1,327	1,134
Non-clinical research and manufacturing operations	1,779	2,153
Payroll related	4,828	5,388
Other accrued expenses	34	46
Total Accrued liabilities	$ 8,823	$ 9,515

NOTE 7 — RELATED PARTY TRANSACTIONS

Takeda

In connection with the Takeda Multi-Target Agreement described in Note 3, “Research and Development Collaboration Agreements”, Takeda became a related party, pursuant to a stock purchase agreement. Refer to Note 11, “Stockholders’ Equity”, for more detail about the Takeda Stock Purchase Agreement. Additionally, Jonathan Lanfear, a director of the Company, was the Vice President and Global Head of Oncology and Neuroscience Business Development for Takeda until September 25, 2020. In August 2021, Takeda ceased to be a related party after a sale of the above-mentioned shares.

NOTE 8 — BORROWING ARRANGEMENTS

K2 Health Ventures Loan and Security Agreement

In May 2020, the Company entered into 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 to date the Company has 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 accrues 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 will be interest only until the loan’s maturity date of June 1, 2024 and (ii) the minimum cash covenant will 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.

The K2 Loan and Security Agreement includes both financial and non-financial covenants including the minimum cash covenant. The Company was in compliance with the debt covenants at December 31, 2022.

The Company recorded the debt net of $2.8 million comprised of deferred financing costs, debt discount and associated exit fee which are being accreted to interest expense over the term of the K2 Loan and Security Agreement using the effective interest method. Additionally, the Company incurred $0.2 million in facilities fee related to the second tranche which was previously classified as a prepaid asset.

As of December 31, 2022 and December 31, 2021, the K2 Loan principal balance was $35.0 million and $35.0 million, respectively.

As of December 31, 2022 and December 31, 2021, the carrying value of the long-term debt was $36.2 million and $35.5 million, respectively.

Future required principal and final payments on the K2 Loan were as follows at December 31, 2022 ($ in thousands):

2023	$ —
2024	35,000
Total Principal Amounts	35,000
Final Fee Due at Maturity	2,357
Unamortized discount, deferred costs and final fee	(1,189)
Total Long-Term Debt, net	36,168

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 four years to less than seven 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 ROU asset as they are not reasonably certain to be exercised. Certain finance leases also include options to purchase the leased equipment. The depreciable life of assets and leasehold improvements are limited by the expected lease term, unless there is a transfer of title or purchase option reasonably certain of exercise. The leases do not contain any residual value guarantees or material restrictive covenants.

In September 2021, the Company permanently vacated its office space of approximately 10,000 square feet in Jersey City, New Jersey. The space was vacated because employees have transitioned to long-term remote working arrangements or the Company's office space in New York, New York. The abandonment of leased space is an indicator of impairment and the Company assessed the lease ROU asset for impairment.

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 by and between the Company and NW Austin Office Partners LLC, dated October 1, 2016, as previously amended (the "Lease Agreement").

On October 18, 2022, the Company entered into that certain Fourth Amendment to Lease between the Company and NW Austin Office Partners LLC (the "Lease Amendment") which amended the Lease Agreement to document the exercise of its option to extend the term of its lease of the Property for an additional six-year term beginning August 31, 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, 2022 and 2021 are shown below (in thousands):

	2022	2021
Balance at beginning of year	$ 1,625	$ 1,490
Revisions in estimated cash flows	(454)	—
Accretion expense	124	135
Balance at end of year	$ 1,295	$ 1,625

In connection with the extension of the lease term for the Property, the original estimated cash flows for the related asset retirement obligation (ARO) was reduced by $0.5 million for the year ended December 31, 2022.

Due to the 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 year ended December 31, 2022, the Company recorded non-cash adjustment to the ROU assets for $0.3 million related to the decrease of the ARO.

For the year ended December 31, 2021, the Company recorded a non-cash impairment charges related to the lease ROU assets of $0.6 million, which is recorded in general and administrative expenses.

As of December 31, 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, 2022 and 2021 were as follows (in thousands):

	2022	2021
Operating leases		
Operating lease expense	$ 2,611	$ 2,778
Variable lease expense	524	476
Total operating lease expense	$ 3,135	$ 3,254

The following table summarizes the balance sheet classification of leases at December 31, 2022 (in thousands):

Operating leases	
Operating lease right-of-use assets	$ 11,132
Operating lease liabilities, current[1]	$ 2,182
Operating lease liabilities, non-current	12,231
Total operating lease liabilities	$ 14,413

1. Included in other current liabilities.

The following table presents other information on leases as of December 31, 2022 and December 31, 2021 (in thousands):

	2022	2021
Weighted average remaining lease term, operating leases	5.54 years	5.65 years
Weighted average discount rate, operating leases	8.21%	7.02%

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, 2022 (in thousands):

	Operating Leases
2023	3,255
2024	3,369
2025	3,299
2026	2,564
Thereafter	5,509
Total lease payments	17,996
Less:	
Imputed interest	(3,583)
Total lease liabilities	$ 14,413

Supplemental cash flow information related to the Company's leases were as follows for the years ended December 31, 2022 and 2021 (in thousands):

	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows operating leases	$ 3,252	$ 3,204
Financing cash flows finance leases	$ —	$ 1

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 $0.5 million at December 31, 2022. The Company has entered into agreements with CROs and other external service providers for services, primarily in connection with the clinical trials and development of the Company's drug candidates. The Company was contractually obligated for up to approximately $46.7 million of future services under these agreements at December 31, 2022, 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 which in total range from $4.9 million to $5.5 million and includes signed orders for capital equipment.

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

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 5,793,063 units (the "Units") having an aggregate purchase price of $40.0 million ("PIPE Financing"), each such Unit consisting of (i) one (1) share (the "Shares") of our common stock and (ii) a warrant (the "Private Placement Warrants") to purchase 0.5 shares of our common stock (the "Private Placement"). The Private Placement was pursuant to equity commitment letter agreements entered into by and between the Company and investors in March 2017 and June 2017. The purchase price per Unit was $6.9048. The Warrants are exercisable for a period of seven years from the date of their issuance at a per-share exercise price of $6.8423 (which exercise price shall be payable in cash or through a cashless exercise mechanic), subject to certain adjustments as specified in the Warrants. At December 31, 2022, there were warrants outstanding under this agreement to purchase 2,896,528 shares of common stock. The warrants were valued at $16.3 million using the Black-Scholes model and recorded in additional paid-in capital. The Black-Scholes inputs used were: expected dividend rate of 0%, expected volatility of 147%, risk free interest rate of 2.07%, and expected term of 7.0 years. The warrants were exercisable upon issuance and expire August 1, 2024.

In December 2015, the Company entered into an agreement with Wedbush ("Wedbush Agreement"), which was subsequently amended in December 2017, related to Wedbush's services associated with the equity financing under the Longitude Securities Purchase Agreement. As part of the Wedbush Agreement, the Company issued warrants to purchase 57,930 shares of 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 $6.8423 (which exercise price shall be payable in cash or through a cashless exercise mechanic), subject to certain adjustments as specified in the Warrants. At December 31, 2022, there were Wedbush Warrants outstanding to

purchase 57,930 shares of common stock. The Wedbush Warrants were valued at $0.4 million using the Black-Scholes model. The Black-Scholes inputs used were: expected dividend rate of 0%, expected volatility of 108%, risk free interest rate of 2.3%, and expected term of 7.0 years. The warrants were exercisable upon issuance and expire December 1, 2024.

Subsequent Private Placements_

In connection with the execution of the Takeda Multi-Target Agreement, the Company entered into 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 2,922,993 shares of the Company common stock, at a price per share of $6.8423, for an aggregate purchase price of $20.0 million.

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

Public Offerings

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

On November 25, 2019, the Company closed its underwritten public offering (the "2019 Public Offering") of 6,900,000 shares of its common stock at a price to the public of $8.00 per share, and 250 shares of newly designated Series A Convertible Preferred Stock ("Series A Preferred Stock") at a price to the public of $8.00 per share. The offering included the exercise in full by the underwriters of their option to purchase up to 900,000 additional shares of common stock. The net proceeds to the Company from the offering, after deducting the underwriting discounts and commissions and offering expenses payable by the Company, were approximately $53.4 million. Each share of Series A Preferred Stock is convertible to 1,000 shares of Common Stock, provided that the holder of Series A Preferred Stock will be prohibited from converting the Series A Preferred Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of the Company's common stock then issued and outstanding. In the event of the Company's liquidation, dissolution, or winding up, holders of Series A Preferred Stock will receive a payment equal to $0.001 per share of Series A Preferred Stock before any proceeds are distributed to the holders of the Company's common stock and *pari passu* with any distributions to the holders of the Company's Series A Preferred Stock. 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 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 3.6 million shares of the Company's common stock at a purchase price of $12.00 per share and 0.5 million shares at a purchase price of $12.70, 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 Securities and Exchange Commission ("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 6.0 million shares of common stock at an offering price of $12.65 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 190,000 shares of the Company's common stock with an exercise price of $9.58 (the "2018 Warrants"). The 2018 Warrants are exercisable for a period of seven years from the date of issuance, subject to certain adjustments as specified in the Warrants. The 2018 Warrants were classified as equity and recorded in additional paid-in capital. They were valued at $1.5 million using the Black-Scholes model. The Black-Scholes inputs used were: expected dividend rate of 0%, expected volatility of 105%, risk free interest rate of 2.8%, and expected term of 7.0 years.

NOTE 12—EQUITY INCENTIVE PLANS AND STOCK-BASED COMPENSATION

2018 Equity Incentive Plan

In May 2018, the Company adopted the 2018 Equity Incentive Plan ("2018 Plan"). The 2018 Plan serves as a successor to the 2004 Amended and Restated Equity Incentive Plan ("2004 Plan"), 2009 Stock Plan, as amended ("2009 Plan") and 2014 Equity Incentive Plan ("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) 2,000,000 newly reserved shares, which included, as of April 30, 2018, 104,184 shares reserved and unallocated under the 2009 Stock Plan, as amended, and 335,040 shares reserved and unallocated under the 2014 Equity Incentive Plan, as amended, plus (ii) up to 2,885,121 additional shares that may be added to the 2018 Plan in connection with the forfeiture, 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, 2022, options to purchase 2,814,408 shares of common stock were available for future grants under the 2018 Plan.

2004 Employee Stock Purchase Plan

On January 1, 2017, an additional 9,091 shares were authorized for issuance under the 2004 Employee Stock Purchase Plan ("2004 Purchase Plan") pursuant to the annual automatic increase to the authorized shares under the 2004 Purchase Plan. The 2004 Purchase Plan contains consecutive, overlapping 24 month offering periods. Each offering period includes four six-month purchase periods. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of the purchase period. For the years ended December 31, 2022 and 2021, no shares were purchased by employees under the 2004 Purchase Plan. At December 31, 2022 and December 31, 2021, there were 8,636 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, 2022 and 2021:

	Outstanding Options Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in millions):
Balances, December 31, 2020	6,697,927	$ 9.13	7.76	$ 13.79
Granted	2,683,818	$ 12.84		
Exercised	(320,716)	$ 5.05		
Cancelled	(1,206,556)	$ 11.46		
Balances, December 31, 2021	7,854,473	$ 10.21	6.72	$ 0.95
Granted	2,920,189	$ 2.21		
Exercised	(46,598)	$ 0.71		
Cancelled	(2,281,601)	$ 9.44		
Balances, December 31, 2022	8,446,463	$ 7.70	7.09	$ -
Vested and expected to vest, December 31, 2022	8,446,463	$ 7.70	7.09	$ -
Exercisable at December 31, 2022	4,852,746	$ 8.91	6.07	$ -

At December 31, 2022, 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
$ 0.33-1.27	1,058,749	7.43	$ 0.92	298,909	$ 1.27
$ 1.70-2.35	87,053	8.97	$ 2.30	3,453	$ 1.85
$ 2.77-2.77	1,643,051	8.63	$ 2.77	232,303	$ 2.77
$ 3.08-5.81	815,521	6.29	$ 4.71	733,059	$ 4.75
$ 6.31-6.31	913,037	5.41	$ 6.31	913,037	$ 6.31
$ 6.52-9.40	1,082,012	6.08	$ 8.80	945,395	$ 8.95
$ 10.78-13.99	454,814	6.04	$ 12.35	310,753	$ 12.39
$ 14.05-14.05	1,259,793	7.63	$ 14.05	584,120	$ 14.05
$ 14.50-14.94	961,442	7.08	$ 14.57	685,157	$ 14.57
$ 15.43-61.27	170,991	7.12	$ 16.79	146,560	$ 16.89
$ 0.33-61.27	8,446,463	7.09	$ 7.70	4,852,746	$ 8.91

The total intrinsic value of stock options exercised during the years ended December 31, 2022 and 2021 was zero and $1.2 million, respectively, as determined at the date of the option exercise.

Cash received from stock option exercises was zero and $1.6 million for the years ended December 31, 2022 and 2021, respectively. 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,	
	2022	2021
Research and development	$ 6,096	$ 8,839
General and administrative	5,813	7,792
Total stock-based compensation	$ 11,909	$ 16,631

At December 31, 2022, the total unrecognized compensation cost related to unvested stock-based awards granted to employees under the Company's 2018 equity incentive plan was approximately $17.0 million. This cost will be recorded as compensation expense on a ratable basis over the remaining weighted average requisite service period of approximately 2.24 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,	
	2022	2021
Employee Stock Options:		
Risk-free interest rate	2.35%	0.93%
Expected term (in years)	6.08	6.08
Dividend yield	—	—
Volatility	88.59%	113.25%
Weighted-average fair value of stock options granted	$ 1.65	$ 10.81

NOTE 13—INCOME TAXES

For the years ended December 31, 2022 and 2021, the Company recorded an income tax provision expense of $0.1 million and zero, 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):

	2022	2021
U.S. federal taxes (benefit) at statutory rate	$ (19,459)	$ (17,431)
State federal income tax benefit	(8,653)	(3,834)
Permanent differences	3	15
Stock compensation	1,964	1,666
Research and development credits	(2,494)	(2,840)
Change in valuation allowance due to operations	30,619	24,219
Change in state rate and carryovers	(1,927)	(1,795)
Total	$ 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,	
	2022	2021
Deferred tax assets		
Net operating loss carryforward	$ 53,957	$ 63,372
Interest	—	603
Research and development credits	15,235	12,422
Deferred stock compensation	8,086	5,916
Deferred revenue	16,127	699
Lease liability	4,516	3,095
Accrued expenses and other	1,846	1,636
Capitalized Research & Experimental Expenditures	19,764	—
Total deferred tax assets	119,531	87,743
Total deferred tax liabilities		
Depreciable and amortizable assets	(1,329)	(1,459)
Right-of-use asset	(3,488)	(2,189)
Total deferred tax liabilities	(4,817)	(3,648)
Less: Valuation allowance	(114,714)	(84,095)
Net deferred tax assets	$ —	$ —

At December 31, 2022, the Company had federal net operating loss carryforwards of approximately $506.7 million and state net operating loss carryforwards of approximately $13.0 million available to offset future taxable income. $286.7 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. $220.0 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 NOLs to expire unutilized due to a previous section 382 limitation.

At December 31, 2022, the Company had federal research and development tax credits available to offset future taxes of approximately $22.4 million, which expire in the year beginning 2022, and state research and development tax credits of approximately $2.9 million, which expire beginning 2033. The Company currently anticipates $9.5 million of 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 increased by $30.6 million from continuing operations.

The Company has no uncertain tax positions as of December 31, 2022 and 2021. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2022 and 2021, 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 $0.7 million and $0.8 million for the years ended December 31, 2022 and 2021, respectively.

NOTE 15—SUBSEQUENT EVENTS

Strategic Reprioritization

On March 29, 2023, the Company's Board of Directors approved 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 the Company's collaboration with Bristol Myers Squibb. The Restructuring will reduce the Company's current workforce from approximately 222 full-time employees to approximately 50% of that number. The Restructuring will result in the cessation of the Company's MT-5111 clinical development program, and will focus the majority of the Company's pre-clinical efforts around activities related to the Bristol Myers Squibb collaboration. The Company estimates that it will incur approximately $0.4 million of costs in connection with the reduction in workforce related to severance pay and other related termination benefits. The Company communicated the workforce reduction on March 30, 2023 and expects the majority of the costs associated with the Restructuring to be incurred during the quarter ending June 30, 2023. The Company anticipates incurring additional costs related to the Restructuring, however, such costs cannot be reasonably estimated as of the time of the filing of this Annual Report on Form 10-K.

Collaboration Agreements

In March 2023, the research program for one of the collaboration's targets has been completed and the related performance obligation has been deemed complete by the Company. At December 31, 2022, the Company had $25.8 million of deferred revenue, current related to the completed performance obligation.

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, 2022. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to its management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2022, 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 Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. 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 at December 31, 2022 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, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Strategic Reprioritization and Reduction in Workforce

On March 29, 2023, the Company's Board of Directors approved 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 the Company's collaboration with Bristol Myers Squibb. The Restructuring would reduce the Company's current workforce

from approximately 222 full-time employees to approximately 50% of that number. The Restructuring will result in the cessation of the Company's MT-5111 clinical development program, and will focus the majority of the Company's pre-clinical efforts around activities related to the Bristol Myers Squibb collaboration. The Company estimates that it will incur approximately $0.4 million of costs in connection with the reduction in workforce related to severance pay and other related termination benefits. The Company expects the majority of the costs associated with the Restructuring to be incurred during the quarter ending June 30, 2023. The Company anticipates incurring additional costs related to the Restructuring, however, such costs cannot be reasonably estimated as of the time of the filing of this Annual Report on Form 10-K. For a discussion of our recently announced Restructuring, see "*Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments – Strategic Reprioritization*".

Departure of Scott Morenstein from the Board of Directors

On March 27, 2023, Scott Morenstein notified the Company that he is resigning from the Board of Directors of the Company effective on March 30, 2023. Prior to his resignation, Mr. Morenstein served as a Class II director of the Company and as a member of the Audit Committee of the Board of Directors. The Company expressed gratitude to Mr. Morenstein for his contributions to the Board of Directors and the Company. Mr. Morenstein's resignation did not involve a disagreement with the Company on any matter relating to the Company's operations, policies or practices.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

The information required by Part III is omitted from this report because we will file a definitive proxy statement within 120 days after the end of our 2022 fiscal year pursuant to Regulation 14A for our 2023 Annual Meeting of Stockholders, or the 2023 Proxy Statement, will be filed pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended. If the 2023 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Management and Corporate Governance," "Section 16(a) Beneficial Ownership Reporting Compliance," and "Code of Business Conduct and Ethics" in the Company's Proxy Statement for the 2023 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Executive Officer and Director Compensation" in the Company's Proxy Statement for the 2023 Annual Meeting of Stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Security Ownership of Certain Beneficial Owners and Management," and "Equity Compensation Plan Information" in the Company's Proxy Statement for the 2023 Annual Meeting of Stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Certain Relationships and Related Person Transactions" and "Management and Corporate Governance" in the Company's Proxy Statement for the 2023 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Independent Registered Public Accounting Firm" in the Company's Proxy Statement for the 2023 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

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

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

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

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

EXHIBIT NUMBER	DESCRIPTION
2.1^	Agreement and Plan of Merger and Reorganization, dated March 16, 2017, by and among the Company, Molecular Templates OpCo, Inc. and Trojan Merger Sub, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, as amended (File No. 001-32979) filed on March 17, 2017).
3.1	Amended and Restated Certificate of Incorporation of the Company, as subsequently amended (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 6, 2014).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Company, dated August 1, 2017 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-32979) 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 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).
3.5	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	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).
4.2	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).
4.3	Form of Warrant issued to Wedbush Securities, dated December 1, 2017 (incorporated by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 30, 2018).
4.4	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).
4.5	Form of Senior Indenture (incorporated by reference to Exhibit 4.7 to the Company's registration statement on Form S-3 (File No. 333-228975) filed on December 21, 2018).
4.6	Form of Subordinated Indenture (incorporated by reference to Exhibit 4.8 to the Company's registration statement on Form S-3 (File No. 333-228975) filed on December 21, 2018).

10.1+	2004 Amended and Restated Equity Incentive Plan of the Company, as amended (incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 15, 2012).
10.2+	Amended and Restated 2004 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8 (File No. 333-164865) filed on February 11, 2010).
10.3	Amended and Restated Non-Employee Director Compensation Policy, adopted by the Board of Directors of the Company on October 9, 2017, amended as of May 31, 2018 and further amended as of December 19, 2019 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on December 19, 2019).
10.4	2014 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on October 13, 2017).
10.5+	Form of Indemnification Agreement between the Company and each of its directors and executive officers (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on August 7, 2017).
10.6+	Form of Notice of Grant of Stock Options and Option Agreement under the 2004 Equity Incentive Plan (incorporated by reference to Exhibit 10.25 to the Company's Current Report on Form 8-K (File No. 000-51136) filed on March 17, 2006).
10.7+	Form of Stock Option Grant Notice and Option Agreement for employees under the 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 30, 2018).
10.8+	Form of Stock Option Grant Notice and Option Agreement for non-employee directors under the 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 30, 2018).
10.9+	Amended and Restated Executive Employment Agreement, dated April 22, 2016, between Molecular Templates OpCo, Inc. and Eric E. Poma, Ph.D. (incorporated by reference to Exhibit 10.43 to the Company's Registration Statement on Form S-4 (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 May 15, 2017).
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).
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†	Cancer Research Grant Contract, dated as of November 7, 2012, by and between the Cancer Prevention & Research Institute of Texas and Molecular Templates OpCo, Inc. (incorporated by reference to Exhibit 10.33 to the Company's Current Report on Form 8-K (File No. 001-32979), filed on June 22, 2018).
10.21+	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).
10.22+	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).
10.24+	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 (incorporated by reference to Exhibit 10.3 to the Company Quarterly Report on Form 10-Q/A (File No. 001-32979) filed on February 13, 2019).
10.24	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+	Executive Employment Agreement, dated January 3, 2019, by and between Roget J. Waltzman, M.D. and the Company (incorporated by reference to Exhibit 10.48 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 13, 2020).
10.28	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).
10.29	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).
10.30	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).

10.31††	Collaboration Agreement, dated February 10, 2021, by and between the Company and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-32979) filed on May 14, 2021).
10.32††	Amendment No. 1 to Collaboration Agreement, dated December 2, 2021, by and between the Company and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.54 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 29, 2022.
21.1*	Subsidiaries of the Company.
23.1*	Consent of Ernst & Young LLP.
31.1*	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act of 1934, as amended, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act of 1934, as amended, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	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)

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

* Filed herewith.

** Furnished herewith. This certification is not deemed filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and is not deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.

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

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

+ Indicates a management contract or compensatory plan or arrangement.

ITEM 16. 10-K SUMMARY

Not applicable.

SIGNATURES

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

MOLECULAR TEMPLATES, INC.

March 30, 2023

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. **Eric E. Poma, Ph.D.**	Chief Executive Officer and Chief Scientific Officer (Principal Executive Officer)	March 30, 2023
/s/ Jason S. Kim **Jason S. Kim**	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2023
/s/ Harold E. Selick, Ph.D. **Harold E. Selick, Ph.D.**	Director	March 30, 2023
/s/ Jonathan Lanfear **Jonathan Lanfear**	Director	March 30, 2023
/s/ David R. Hoffmann **David R. Hoffmann**	Director	March 30, 2023
/s/ David Hirsch, M.D., Ph.D. **David Hirsch, M.D., Ph.D.**	Director	March 30, 2023
/s/ Kevin Lalande **Kevin Lalande**	Director	March 30, 2023
/s/ Scott Morenstein **Scott Morenstein**	Director	March 30, 2023
/s/ Corazon “Corsee” Sanders, Ph.D. **Corazon “Corsee” Sanders, Ph.D.**	Director	March 30, 2023
/s/ Gabriela Gruia, M.D. **Gabriela Gruia, M.D.**	Director	March 30, 2023

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

FORM 10-K/A
(Amendment No. 1)

(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, 2022

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	**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 $0.91 of the common stock on The Nasdaq Global Select Market as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $29,380,632. 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 April 24, 2023 there were 56,351,647 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

None.

EXPLANATORY NOTE

This Amendment No. 1 on Form 10-K/A (this "Amendment") amends the Annual Report on Form 10-K of Molecular Templates, Inc. (the "Company," "we," "our," "us" or "Molecular") for the fiscal year ended December 31, 2022, as originally filed with the Securities and Exchange Commission (the "SEC") on March 30, 2023 (the "Original 10-K"). The purpose of this Amendment is to include information required by Part III of the Annual Report on Form 10-K that was intentionally omitted from Part III of the Original 10-K. In addition, this Amendment amends Item 15 of Part IV of the Original 10-K to update the exhibit list and to include new certifications by our principal executive officer and principal financial officer under Section 302 of the Sarbanes-Oxley Act of 2002, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Except as described above, no other changes have been made to the Original 10-K. The Original 10-K continues to speak as of the dates described in the Original 10-K, and we have not updated the disclosures contained therein to reflect any events that occurred subsequent to such dates. Accordingly, this Amendment should be read in conjunction with the Company's filings made with the SEC subsequent to the filing of the Original 10-K, as information in such filings may update or supersede certain information contained in this Amendment.

In this Amendment, unless the context specifically indicates otherwise, "the Company", "we", "us", "our" and "MTEM" refer to Molecular Templates, Inc. and its subsidiaries following the Merger, effective on August 1, 2017, and to Private Molecular and its subsidiaries prior to the Merger. References to "Pre-Merger Threshold" means Threshold prior to the Merger effective on August 1, 2017.

Special Note Regarding Forward-Looking Statements

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

- the implementation of our business strategies, including our ability to pursue development pathways and regulatory strategies for MT-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; via de-immunization of the Shiga-like Toxin A subunit as well as chemistry, manufacturing, and controls improvements;
- the timing and our ability to advance the development of our drug or 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 drug or biologic candidates;
- the anticipated progress of our drug or 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 drug or biologic candidates;
- our ability to establish and maintain intellectual property rights for our drug or biologic candidates;
- whether any drug or 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 drug or biologic candidates suitable for clinical testing;
- our ability to identify, in-license or otherwise acquire additional drug or 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 drug or 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;
- the expected cost savings from our strategic restructuring;
- the extent to which global economic and political developments, including the impact of the COVID-19 pandemic and inflation, will affect our business operations, clinical trials, or financial condition;
- the impact of laws and regulations;
- our projected financial performance and compliance with existing debt covenants; and
- the sufficiency of our cash resources; and other risks and uncertainties, including those listed under Part I, Item 1A, "Risk Factors" of the Original 10-K.

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

Molecular Templates, Inc.
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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The Board of Directors

Our certificate of incorporation, as amended and restated, provides that our business is to be managed by or under the direction of a classified board of directors. This means our Board of Directors is divided into three classes for purposes of election, with each class having as nearly as possible an equal number of directors. One class is elected at each annual meeting of stockholders to serve for a three-year term. The term of service of each class of directors is staggered so that the term of one class expires at each annual meeting of stockholders.

Our Board currently consists of eight (8) members, classified into three classes as follows:

- Class I is comprised of Eric E. Poma, Ph.D., Harold E. Selick, Ph.D. and Gabriela Gruia, M.D., with a term ending at the 2023 annual meeting of stockholders;
- Class II is comprised of Jonathan Lanfear and Corsee Sanders, Ph.D, with a term ending at the 2024 annual meeting of stockholders; and
- Class III is comprised of David Hirsch, M.D., Ph.D., David R. Hoffmann and Kevin Lalande, with a term ending at the 2025 annual meeting of stockholders.

Our certificate of incorporation and bylaws, each as amended and restated, provide that the authorized number of directors may be changed only by resolution of a majority of the Board of Directors. The Board of Directors makes an effort to distribute additional directorships resulting from an increase in the number of directors among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our Board of Directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our Company. Our directors may be removed only for cause by the affirmative vote of the holders of a majority of shares then entitled to vote at an election of directors. Any vacancy on our Board of Directors, including a vacancy resulting from an enlargement of our Board of Directors, may be filled only by the vote of a majority of our directors then in office.

Set forth below are the names of our directors, their ages, their offices in the Company, if any, their principal occupations or employment for at least the past five years, the length of their tenure as directors and the names of other public companies in which such persons hold or have held directorships during the past five years. Additionally, information about the specific experience, qualifications, attributes or skills that led to our Board's conclusion that each person listed below should serve as a director is set forth below:

Name	Age	Position with the Company
Eric E. Poma, Ph.D.	51	Chief Executive Officer and Chief Scientific Officer, Director
Harold E. Selick, Ph.D.(2)(3)	68	Chairman of the Board
Gabriela Gruia, M.D.(3)	66	Director
David Hirsch, M.D., Ph.D.(1)(3)	52	Director
David R. Hoffmann(1)	78	Director
Kevin Lalande(2)	50	Director
Jonathan Lanfear(1)	54	Director
Corsee Sanders, Ph.D.(2)	66	Director

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Corporate Governance Committee

Eric E. Poma, Ph.D.

Dr. Poma has been a director of the Company since August 2017, effective as of the Merger. Dr. Poma is the Chief Executive Officer and Chief Scientific Officer of the Company and founded Private Molecular in February 2009,

serving on its board of directors since its inception. From March 2005 until September 2008, Dr. Poma was Vice President of Business Development of Innovive Pharmaceuticals (acquired by Cytrx Corporation), a biotechnology company. As the founder of Private Molecular and in his role as Chief Scientific Officer, he led the invention of technology underlying the Company's platform technology and what constitutes the whole of the Company's current pipeline of candidates. Dr. Poma received his Ph.D. in Microbiology and Immunology and B.S. in Biology from the University of North Carolina at Chapel Hill and his M.B.A. from New York University. Our Board has concluded that Dr. Poma should serve as a director of the Company based on Dr. Poma's direct involvement in the creation of, and knowledge of, our technology platform and extensive experience in the industry, which provides invaluable insight to our Board on matters involving the Company and its future goals. Additionally, having the Chief Executive Officer as a director is an optimal way, in the Company's opinion, of ensuring the most efficient execution and development of the Company's business goals and strategies.

Harold E. "Barry" Selick, Ph.D.

Dr. Selick is chairman of the Company's Board and has served as a director of the Company since August 2017, effective as of the Merger, and served as a Pre-Merger director of Threshold since June 2002. He is currently the Vice Chancellor of Business Development, Innovation and Partnerships at the University of California, San Francisco, a position that he has held since April 2017. Previously, Dr. Selick served as Pre-Merger Threshold's Chief Executive Officer from June 2002 until March 2017. Dr. Selick previously served as director of Amunix Pharmaceuticals, lead director and chairman of PDL Biopharma, chairman of the board of directors of Catalyst Biosciences and currently serves as chairman of the board of Protagonist Therapeutics, the latter two of which are currently public drug discovery and development companies. Dr. Selick received his B.A. in Biophysics and Ph.D. in Biology from the University of Pennsylvania and was a Damon Runyon-Walter Winchell Cancer Fund Fellow and an American Cancer Society Senior Fellow at the University of California, San Francisco. Our Board has concluded that Dr. Selick should serve as a director of the Company based on Dr. Selick's extensive experience and industry knowledge. In addition, Dr. Selick brings an understanding of our Company and business, previously serving as Pre-Merger Threshold's Chief Executive Officer.

Gabriela Gruia, M.D.

Dr. Gruia has been a director of the Company since 2022. Dr. Gruia is an oncologist with over 25 years of experience in oncology drug development, spanning cell and gene therapy, bi-specifics, biologics, immunotherapy, and small molecules and currently serves as the Founder and Principal of Gabriela Gruia Consulting, LLC. From February 2020 to January 2021, Dr. Gruia served as Chief Development Officer at Ichnos Sciences, where she oversaw development activities for several key functions, including Clinical Development and Clinical Operations, Regulatory Sciences, Clinical Pharmacology, Toxicology, and Biostatistics. From August 2004 to February 2020, Dr. Gruia was Senior Vice President and Global Head of Regulatory Affairs for Novartis Oncology, where she led the world class oncology regulatory affairs organization and oversaw all regulatory activities in close partnership with research collaborators, preclinical development, development organization and senior management. While at Novartis, Dr. Gruia spearheaded the worldwide submission and approval of multiple new molecular entities, including Tasigna®, Jakavi®, Afinitor®, Signifor®, Zykadia®, Farydak®, Rydapt®, Odomzo®, Kisqali®, Kymriah®, Adakveo®, and Piqray®. Dr. Gruia serves as a member of the board of directors of TSCAN Therapeutics and Tessa Therapeutics Ltd. Dr. Gruia earned a doctorate in medicine from Bucharest Medical School in Romania and a Masters in Breast Pathology and Mammography from the Rene Huguenin/Curie Institute Cancer Center in Paris, France. She completed training in oncology and hematology at Rene Descartes University in Paris, France. Our Board has concluded that Dr. Gruia should serve as a director of the Company because of her perspective and experience as a board member in the life sciences industry, as well as her strong medical, regulatory and scientific background, specifically in oncology and oncology drug development.

David Hirsch, M.D., Ph.D.

Dr. Hirsch has been a director of the Company since August 2017, effective as of the Merger. Since 2006, Dr. Hirsch has served as a Founder and Venture Partner at Longitude Capital, where he focuses on investments in biotechnology. Dr. Hirsch currently serves as Chief Executive Officer and as a director of Alpha 9 Theranostics, Inc. Dr. Hirsch currently serves on the board of directors of Tricida, Inc. (TCDA), Poseida Therapeutics, Inc. (PSTX) and Rapid Micro Biosystems, Inc. In addition, Dr. Hirsch has previously served on the board of Collegium Pharmaceutical, Inc.

(COLL), Amunix Pharmaceuticals, Inc., and a number of private companies. Dr. Hirsch holds a Ph.D. in Biology from the Massachusetts Institute of Technology, an M.D. from Harvard Medical School and a B.A. in Biology from Johns Hopkins University. Our Board has concluded that Dr. Hirsch should serve as a director of the Company based on Dr. Hirsch's perspective and experience as an investor and board member in the life sciences industry, as well as his strong medical and scientific background.

David R. Hoffmann

Mr. Hoffmann has been a director of the Company since August 2017, effective as of the Merger, and served as a Pre-Merger director of Threshold since April 2007. Since 2002, Mr. Hoffmann has served as the Chief Executive Officer of Hoffmann Associates, a multi-group company specializing in cruise travel and financial and benefit consulting. He serves on the board of directors of DURECT Corporation, serving as Chairman of the Audit Committee and a member of the Compensation Committee. Mr. Hoffmann holds a B.S. in Business Administration from the University of Colorado. Our Board has determined that Mr. Hoffmann qualifies as an "audit committee financial expert" as defined by the rules of the SEC. Our Board has concluded that Mr. Hoffmann should serve as a director of the Company based on Mr. Hoffmann's financial expertise and industry experience.

Kevin Lalande

Mr. Lalande has been a director of the Company since August 2017, effective as of the Merger. Mr. Lalande served on the board of directors of Private Molecular since 2009. Mr. Lalande is the Managing Member of SHV Management Services, LLC, a multi-strategy investment partnership with over $900 million in capital under management. Mr. Lalande currently serves as a director for a number of privately-held companies as well as Lumos Pharma, a publicly-traded biotechnology company, and previously served as a director for LDR Holding Corporation, now Zimmer Biomet, a publicly-traded medical device company. Mr. Lalande holds a B.S. in Electrical and Computer Engineering from Brigham Young University, an M.B.A. with Highest Distinction from the Harvard Business School, and a graduate certificate in Artificial Intelligence from Stanford University. Our Board has concluded that Mr. Lalande should serve as a director of the Company based on his substantial experience as a venture capitalist and as a director of a number of privately-held and public companies.

Jonathan Lanfear

Mr. Lanfear has been a director of the Company since May 2018. Mr. Lanfear is currently Principal at Lanfear Advisors LLC, providing business development, corporate strategy and operational consulting to public and private sector biotech and biopharmaceutical companies. Additionally, Mr. Lanfear presently holds the position of President and Chief Executive Officer at HiberCell, Inc. Prior to assuming these roles, he served as the company's Chief Operating Officer from September 2021 until June 2022. From December 2011 to September 2020, Mr. Lanfear was employed by Takeda Pharmaceuticals where he was Vice President and Global Head of R&D Business Development. Mr. Lanfear holds a B.S. in Chemical Engineering and a Master's degree in Bioengineering, both from the University of Michigan (Ann Arbor), and an M.B.A. from Washington University (St. Louis). Mr. Lanfear previously served on the board of directors of Aquinnah Pharmaceuticals, a privately-held neurodegeneration-focused company and ARTham Therapeutics, Inc., a privately held clinical stage biopharmaceutical company focused on medicines that satisfy significant unmet medical need. Our Board has concluded that Mr. Lanfear should serve as a director of the Company based on Mr. Lanfear's industry perspective and experience developed through his leadership roles with Takeda Pharmaceuticals as well as his industry consulting experience.

Corsee Sanders, Ph.D.

Dr. Sanders has been a director of the Company since December 2019. From November 2019 to February 2020, Dr. Sanders served as a Strategic Advisor to the Global Development Group of Bristol Myers Squibb. Previously, Dr. Sanders served as Strategic Advisor to the Office of the Celgene Chief Medical Officer, since March 2018 to November 2019, ensuring effective integration of Juno Therapeutics' Development Organization into the Celgene Organization, specifically the unique CAR T aspects, advising the label-enabling CAR T legacy Juno program (JCAR017), and advising the Chief Medical Officer and the Chief Medical Officer's leadership team in evolving the clinical development organization. From January 2017 to March 2018, Dr. Sanders was a Member of the Juno Therapeutics Executive Committee as Head of Strategic and Development Operations, with responsibilities for

strategic operations, quantitative sciences, biosample and clinical operations. Dr. Sanders was a Member of the Genentech/Roche Late-Stage Portfolio Committee from 2011 to 2017, and Global Head of the Genentech/Roche Late Stage Clinical Operations from 2012 to 2017, with responsibility for leading nearly 2,500 employees, across 5 strategic and 20 local country sites, in planning and conducting global development and local clinical trials in over 70 countries. Dr. Sanders has directly contributed and/or provided oversight in developing multiple approved pharmaceutical products including Claritin®, Rituxan®, Herceptin®, TNKase®, Cathflo®, Xolair, Avastin®, Tarceva®, Lucentis®, Zelboraf®, Perjeta®, Erivedge®, Gazyva®, Kadcyla®, Alecensa®, Cotellic®, Venclexta®, Tecentriq®, Ocrevus®, Hemlibra®, and JCAR017®, a CAR T cell therapy for NHL. She currently serves as a member of the Board of Trustees as well as the Co-Chair of the Board of Advisors for the Fred Hutchinson Cancer Research Center. Dr. Sanders currently serves as a director for biopharmaceutical companies, such as Ultragenyx Pharmaceuticals, Inc., Beigene, Ltd., AltruBio,r Inc. and Legend Biotech Corporation. Dr. Sanders earned her B.S. and M.S. in statistics, graduating Magna Cum Laude from the University of the Philippines, and her M.A. and Ph.D. in statistics from the Wharton Doctoral Program at the University of Pennsylvania. Our Board has concluded that Dr. Sanders should serve as a director of the Company based on Dr. Sanders's extensive background in pharmaceutical operations as well as her scientific and leadership experience.

Certain Corporate Governance Matters

Audit Committee. Our Audit Committee currently has three members, David R. Hoffmann (Chairman), David Hirsch, M.D., Ph.D. and Jonathan Lanfear. All members of the Audit Committee satisfy the current independence standards promulgated by the SEC and by the listing standards of Nasdaq as such standards apply specifically to members of audit committees. The Board has determined that Mr. Hoffmann is an "audit committee financial expert," as the SEC has defined that term in Item 407 of Regulation S-K. Our Audit Committee's role and responsibilities are set forth in the Audit Committee's written charter and include, among others:

- appointing, evaluating, retaining, overseeing, and if need be, terminating the engagement of any independent auditor;
- assessing the qualification, performance and independence of our independent auditor;
- pre-approving all audit and non-audit services to be performed by our independent auditor;
- reviewing our financial statements and related disclosures;
- reviewing the adequacy and effectiveness of our accounting and financial reporting processes, systems of internal control and disclosure controls and procedures;
- reviewing our overall risk management framework;
- overseeing procedures for the treatment of complaints on accounting, internal accounting controls, or audit matters;
- reviewing and discussing with management and the independent auditor the results of our annual audit, reviews of our quarterly financial statements and our publicly filed reports;
- reviewing and approving related person transactions; and
- preparing the audit committee report that the SEC requires in our annual proxy statement.

A copy of the Audit Committee's written charter is publicly available on our website at *www.mtem.com*.

Director Nominations

No material changes have been made to the procedures by which stockholders may recommend nominees to our Board of Directors.

Policy Prohibiting Hedging

We maintain an Insider Trading Policy that prohibits our officers, directors, and employees from, among other things, engaging in speculative transactions in our securities, including by way of the purchase or sale of a put option, a call option or a short sale (including a short sale "against the box"), or engaging in hedging transactions, including prepaid variable forward contracts, equity swaps, collars and exchange funds.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all directors, officers and employees. This code is intended to promote the conduct of all of the Company's business in accordance with high standards of integrity and in compliance with all applicable laws and regulations. It aligns with our Company values, including respect and integrity, and deters wrongdoing. The text of the code of business conduct and ethics is posted on our website at *www.mtem.com* under our "Investors – Governance – Governance Documents" page. Disclosure regarding any amendments to, or waivers from, provisions of the code of business conduct and ethics that apply to our directors, principal executive and financial officers will be included in a Current Report on Form 8-K within four business days following the date of the amendment or waiver, unless website posting or the issuance of a press release of such amendments or waivers is then permitted by the listing standards of Nasdaq.

Delinquent Section 16(A) Reports

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") requires our executive officers, directors, and persons who beneficially own more than 10% of a registered class of our common stock or other equity securities to file with the SEC certain reports of ownership and reports of changes in ownership of our securities. Executive officers, directors, and stockholders who hold more than 10% of our outstanding registered common stock are required by the SEC to furnish us with copies of all required forms filed under Section 16(a). Based solely on a review of this information and written representations from these persons that no other reports were required, we believe that, during the prior fiscal year all of our executive officers, directors, and, to our knowledge, 10% stockholders complied with the filing requirements of Section 16(a) of the Exchange Act, except for the Form 4 filings for each of SHV Management Services, LLC and Kevin M. Lalande, each of whom filed their respective Forms 4 on June 21, 2022 to report the purchase of 100,000 shares of common stock on June 13, 2022, 60,000 shares of common stock on June 14, 2022, and 62,000 shares of common stock on June 15, 2022.

Executive Officers

The following table sets forth certain information regarding our executive officers who are not also directors. We have employment agreements with all of our executive officers, and all of our executive officers are at-will employees.

Name	Age	Position
Jason S. Kim	48	President, Chief Operating Officer, Interim Chief Financial Officer and Treasurer
Roger J. Waltzman, M.D.	55	Chief Medical Officer

Jason S. Kim

Mr. Kim joined Private Molecular in February 2010 and served as its President and Chief Financial Officer until the completion of the Merger. Previously, Mr. Kim served in various corporate development, strategic planning, and commercial roles at OSI Pharmaceuticals, Inc. (now Astellas Pharma US, Inc.) and ImClone Systems, Inc. (now Eli Lilly and Company). Mr. Kim received his B.A. in Neuroscience and Behavior from Wesleyan University and an M.B.A. from the Wharton School, University of Pennsylvania.

Roger J. Waltzman, M.D.

Dr. Waltzman has served as the Chief Medical Officer of the Company since his appointment in February 2019. From April 2017 to January 2019, Dr. Waltzman was the Chief Medical Officer of Rgenix, Inc. (now Inspirna, Inc.), a

privately-held biotech, where he supervised the development of immuno-oncology and metabolic inhibitor assets through Phase 1 a/b clinical trials. From April 2016 to April 2017, Dr. Waltzman was the Chief Scientific Officer of Jaguar Health, Inc., a publicly-traded company, and Napo Pharmaceuticals, Inc. where he led scientific aspects of development and commercialization of Mytesi® (crofelemer) for patients with HIV and diarrhea, as well as development programs in chemotherapy-induced diarrhea. Dr. Waltzman was a director of Jaguar Health, Inc. from April 2016 to April 2017 and was previously a director of Rgenix, Inc. From January 2007 to April 2016, Dr. Waltzman held various positions at Novartis Pharmaceuticals Corporation, including as Executive Director, where he played a leading role in the further development of highly successful branded oncology drugs, Glivec® (imatinib) and Tasigna® (nilotinib) and the NDA of Jakafi® (ruxolitinib). Dr. Waltzman earned an M.B.A. at Columbia Business School, an M.D. from Brown University School of Medicine and a B.A. from Brown University.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table shows the total compensation paid or accrued during the last two fiscal years ended December 31, 2022 and 2021 to (1) our Chief Executive Officer, and (2) our two next most highly compensated executive officers who earned more than $100,000 during the fiscal year ended December 31, 2022.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	All Other Compensation ($)(2)	Total ($)
Eric E. Poma, Ph.D., *Chief Executive Officer and Chief Scientific Officer* (3)	2022	600,000	313,500	624,000	9,840	1,547,340
	2021	576,780	253,800	3,544,680	9,090	4,384,350
Jason S. Kim, *President, Chief Operating Officer, Interim Chief Financial Officer, and Treasurer* (4)	2022	443,200	189,468	260,000	7,178	
	2021	424,644	168,800	1,476,950	6,971	899,8462,077,364
Roger J. Waltzman, M.D., *Chief Medical Officer* (5)	2022	456,000	173,280	260,000	10,440	899,720
	2021	432,576	152,300	1,476,950	9,298	2,071,124

(1) These amounts represent the aggregate grant date fair value of options granted to each officer in 2022 computed in accordance with FASB ASC Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in Note 12 to our Financial Statements, included in our Annual Report on Form 10-K for the year ended December 31, 2022.
(2) This amount represents life insurance premiums paid, discretionary 401k matching contributions paid by the Company and cell phone allowances.
(3) Dr. Poma became Chief Executive Officer of the Company on August 1, 2017, effective as of the effective time of the Merger.
(4) Mr. Kim became President and Chief Operating Officer of the Company on August 1, 2017, effective as of the effective time of the Merger and became interim Chief Financial Officer and Treasurer effective as of January 5, 2023.
(5) Dr. Waltzman commenced employment on February 19, 2019.

Narrative Disclosure to Summary Compensation Table

Eric E. Poma, Ph.D.

Effective as of the effective time of the Merger, the Company's Board appointed Dr. Poma as Chief Executive Officer and Chief Scientific Officer of the Company. Prior to the completion of the Merger, Dr. Poma was Chief Executive Officer and Chief Scientific Officer of Private Molecular. Private Molecular entered into an employment agreement with Dr. Poma on April 22, 2016. The agreement provides for a base salary, which may be modified from time to time at the discretion of the Company's Board, and an annual cash incentive bonus awarded at the discretion of the Company's Board. No changes were made to Dr. Poma's cash incentive bonus target in 2021. On January 29, 2021, the Company awarded a cash bonus of $252,000 to Dr. Poma, which represented 90% of his target bonus of 50% of his base salary and increased his base salary to $576,800 effective as of January 1, 2021. On January 31, 2022, the Company awarded a cash bonus of $253,800 to Dr. Poma, which represented 88% of his target bonus of 50% of his

base salary and increased his base salary to $600,000 effective as of January 1, 2022. In 2022, Dr. Poma's cash incentive bonus target was increased to 55% of his base salary. On January 25, 2023, the Company awarded a cash bonus of $313,500 to Dr. Poma, which represented 95% of his target bonus of 55% of his base salary and increased his base salary to $621,000 effective as of January 1, 2023. No changes were made to Dr. Poma's cash incentive bonus target in 2023. Dr. Poma is also eligible to participate in the employee benefit plans available to the Company's employees, subject to the terms of those plans.

The Company granted an option to purchase 300,000 shares of common stock on February 15, 2021 to Dr. Poma. This grant vests 25% on February 15, 2022, then in equal installments over the 36 following months, fully vesting on February 15, 2025. The Company granted an option to purchase 300,000 shares of common stock on February 15, 2022 to Dr. Poma. This grant vests 25% on February 15, 2023, then in equal installments over the 36 following months, fully vesting on February 15, 2026. The Company granted an option to purchase 400,000 shares of common stock on February 15, 2023 to Dr. Poma. This grant vests 25% on February 15, 2024, then in equal installments over the 36 following months, fully vesting on February 15, 2027.

Dr. Poma is entitled to certain benefits in connection with a termination of his employment or a change of control as discussed below under "Potential Payments upon Termination or Change-In-Control."

Jason S. Kim

Mr. Kim joined Private Molecular in February 2010 and served as its President and Chief Financial Officer until the completion of the Merger. Following the Merger, he became President and Chief Operating Officer of the Company and effective as of January 5, 2023, he became Interim Chief Financial Officer and Treasurer in addition to his roles as President and Chief Operating Officer of the Company. Private Molecular entered into an employment agreement with Mr. Kim on April 22, 2016. The agreement provides for a base salary, which may be modified from time to time at the discretion of the Company's Board, and an annual cash incentive bonus awarded at the discretion of the Company's Board.

No changes were made to Mr. Kim's cash incentive bonus target in 2021, 2022, or 2023. On January 29, 2021, the Company awarded a cash bonus of $167,600 to Mr. Kim, which represented 90% of his target bonus of 45% of his base salary and increased his base salary to $426,200 effective as of January 1, 2021. On January 31, 2022, the Company awarded a cash bonus of $168,800 to Mr. Kim, which represented 88% of his target bonus of 45% of his base salary and increased his base salary to $443,200 effective as of January 1, 2022. On January 25, 2023, the Company awarded a cash bonus of $189,468 to Mr. Kim, which represented 95% of his target bonus of 45% of his base salary and increased his base salary to $458,712 effective as of January 1, 2023. Mr. Kim is also eligible to participate in the employee benefit plans available to the Company's employees, subject to the terms of those plans.

The Company granted an option to purchase 125,000 shares of common stock on February 15, 2021 to Mr. Kim. This grant vests 25% on February 15, 2022, then in equal installments over the 36 following months, fully vesting on February 15, 2025. The Company granted an option to purchase 125,000 shares of common stock on February 15, 2022 to Mr. Kim. This grant vests 25% on February 15, 2023, then in equal installments over the 36 following months, fully vesting on February 15, 2026. The Company granted an option to purchase 170,000 shares of common stock on February 15, 2023 to Mr. Kim. This grant vests 25% on February 15, 2024, then in equal installments over the 36 following months, fully vesting on February 15, 2027.

Mr. Kim is entitled to certain benefits in connection with a termination of his employment or a change of control as discussed below under "Potential Payments upon Termination or Change-In-Control."

Roger J. Waltzman, M.D.

The Company entered into an employment agreement with Dr. Waltzman on January 3, 2019. The agreement provides for an initial base salary of $400,000, and Dr. Waltzman is eligible to receive a target discretionary annual bonus of 40% of his base salary. Dr. Waltzman's cash incentive bonus target remained the same for 2021 and 2022. On January 29, 2021, the Company awarded a cash bonus of $151,200 to Dr. Waltzman, which represented 90% of his target bonus of 40% of his base salary and increased his base salary to $432,600 effective as of January 1, 2021. On January 31, 2022, the Company awarded a cash bonus of $152,300 to Dr. Waltzman, which represented 88% of his target bonus of 40% of his base salary and increased his base salary to $456,000 effective as of January 1, 2022. On

January 25, 2023, the Company awarded a cash bonus of $173,280 to Dr. Waltzman, which represented 95% of his target bonus of 40% of his base salary and increased his base salary to $471,960 effective as of January 1, 2023. Dr. Waltzman is also eligible to participate in the employee benefit plans available to the Company's employees, subject to the terms of those plans.

The Company granted an option to purchase 125,000 shares of common stock on February 15, 2021 to Dr. Waltzman. This grant vests 25% on February 15, 2022, then in equal installments over the 36 following months, fully vesting on February 15, 2025. The Company granted an option to purchase 125,000 shares of common stock on February 15, 2022 to Dr. Waltzman. This grant vests 25% on February 15, 2023, then in equal installments over the 36 following months, fully vesting on February 15, 2026. The Company granted an option to purchase 170,000 shares of common stock on February 15, 2023 to Dr. Waltzman. This grant vests 25% on February 15, 2024, then in equal installments over the 36 following months, fully vesting on February 15, 2027.

Dr. Waltzman is entitled to certain benefits in connection with a termination of his employment or a change of control as discussed below under "Potential Payments upon Termination or Change-In-Control."

Outstanding Equity Awards at 2022 Fiscal Year-End

The following table shows grants of stock options outstanding on the last day of the fiscal year ended December 31, 2022, to each of the executive officers named in the Summary Compensation Table.

Name (a)	Number of Securities Underlying Unexercised Options (#) Exercisable (b)	Number of Securities Underlying Unexercised Options (#) Unexercisable (c)	Option Exercise Price ($) (e)	Option Expiration Date (f)
Eric E. Poma, Ph.D	220,560(1)	—	1.27	11/18/2024
	275,000(2)	—	9.40	10/8/2027
	585,126(3)	—	6.31	5/30/2028
	239,583(6)	10,417	4.66	2/14/2029
	221,354(7)	91,146	14.50	2/13/2030
	137,500(8)	162,500	14.05	2/14/2031
	—(9)	300,000	2.77	2/14/2032
Jason S. Kim	78,069(4)	—	1.27	11/18/2024
	137,500(2)	—	9.40	10/8/2027
	196,161(3)	—	6.31	5/30/2028
	124,583(6)	5,417	4.66	2/14/2029
	106,250(7)	43,750	14.50	2/13/2030
	57,291(8)	67,709	14.05	2/14/2031
	—(9)	125,000	2.77	2/14/2032
Roger J. Waltzman, M.D.	167,708(5)	7,292	4.96	2/27/2029
	85,000(7)	35,000	14.50	2/13/2030
	57,291(8)	67,709	14.05	2/14/2031
	—(9)	125,000	2.77	2/14/2032

(1) On November 19, 2014, Dr. Poma was granted an option to purchase 311,670 shares of common stock of Private Molecular under the 2009 Stock Plan, as amended, at an exercise price of $0.90 per share. In connection with the Merger, this option was converted into an option to purchase 220,560 shares of the Company's common stock at a per share exercise price of $1.27. This award was fully vested on September 19, 2017.

(2) Dr. Poma and Mr. Kim were granted options to purchase 275,000 and 137,500 shares of common stock, respectively, on October 9, 2017. These awards fully vested on October 9, 2021.

(3) Dr. Poma and Mr. Kim were granted options to purchase 585,126 and 196,161 shares of common stock, respectively, on May 31, 2018. These awards fully vested on May 31, 2022.

(4) On November 19, 2014, Mr. Kim was granted an option to purchase 110,319 shares of common stock of Private Molecular under the 2009 Stock Plan, as amended, at an exercise price of $0.90 per share. In connection with the Merger, this option was converted into an option to purchase 78,069 shares of the Company's common stock at a per share exercise price of $1.27. This award was fully vested on September 19, 2017.

(5) Dr. Waltzman was granted an option to purchase 175,000 shares of common stock on February 28, 2019. These awards vested 25% on February 19, 2020, and 2.1% monthly thereafter through February 19, 2023.

(6) Dr. Poma and Mr. Kim were granted options to purchase 250,000 and 130,000 shares of common stock, respectively, on February 15, 2019. These awards vested 25% on February 15, 2020, and 2.1% monthly thereafter through February 15, 2023.

(7) Dr. Poma, Mr. Kim and Dr. Waltzman were granted options to purchase 312,500, 150,000 and 120,000 shares of common stock, respectively, on February 14, 2020. These awards each vest 25% on February 14, 2021, and 2.1% monthly thereafter through February 14, 2024, provided that at the relevant vesting dates Dr. Poma, Mr. Kim and Dr. Waltzman continue their respective service to the Company.

(8) Dr. Poma, Mr. Kim and Dr. Waltzman were granted options to purchase 300,000, 125,000 and 125,000 shares of common stock, respectively, on February 15, 2021. These awards each vest 25% on February 15, 2022, and 2.1% monthly thereafter through February 15, 2025, provided that at the relevant vesting dates Dr. Poma, Mr. Kim and Dr. Waltzman continue their respective service to the Company.

(9) Dr. Poma, Mr. Kim and Dr. Waltzman were granted options to purchase 300,000, 125,000 and 125,000 shares of common stock, respectively, on February 15, 2022. These awards each vest 25% on February 15, 2023, and 2.1% monthly thereafter through February 15, 2026, provided that at the relevant vesting dates Dr. Poma, Mr. Kim and Dr. Waltzman continue their respective service to the Company.

Potential Payments upon Termination or Change-In-Control

Eric E. Poma, Ph.D.

Pursuant to Dr. Poma's employment agreement, if Dr. Poma's employment is terminated for Cause, death, Disability, or non-renewal or expiration of the employment term, or if Dr. Poma voluntarily resigns without Good Reason, he shall be entitled to: (i) his base salary through the effective date of termination; (ii) the right to continue health care benefits under COBRA, at his cost, to the extent required and available by law; (iii) reimbursement of expenses for which he is entitled to be reimbursed, but for which he has not yet been reimbursed; and (iv) no other severance or benefits of any kind, unless required by law or pursuant to any other Company plans or policies, as then in effect. "Disability" means that Dr. Poma, at the time notice is given, has been unable to substantially perform his duties under the employment agreement for not less than 120 work days within a 12 consecutive month period as a result of his incapacity due to a physical or mental condition and, if reasonable accommodation is required by law, after any reasonable accommodation.

If Dr. Poma is terminated by the Company involuntarily without Cause (excluding any termination due to death or Disability) or if Dr. Poma resigns with Good Reason, then he shall be entitled to receive: (A) his base salary through the date of termination; (B) continuing severance pay at a rate equal to 100% of his base salary, as then in effect (less applicable withholding), for a period of nine months from the date of such termination, to be paid periodically in accordance with the Company's normal payroll practices; (C) reimbursement of all expenses for which he is entitled to be reimbursed, but for which he has not yet been reimbursed; (D) the right to continue health care benefits under COBRA, at his cost, to the extent required and available by law; and (E) no other severance or benefits of any kind, unless required by law or pursuant to any written Company plans or policies, as then in effect.

As defined in Dr. Poma's employment agreement, "Cause" means (i) Dr. Poma's continued failure to substantially perform the duties and obligations under the employment agreement (for reasons other than death or Disability); (ii) the commission by Dr. Poma of (x) an act of dishonesty or act constituting common law fraud, embezzlement or a felony, or (y) any violation of federal or state law, tortious act, unlawful act or malfeasance which causes or reasonably could cause material harm to the Company's standing, condition or reputation; (iii) Dr. Poma's violation of, or a plea of nolo contendere or guilty to, a felony under the laws of the United States or any state; or (iv) Dr. Poma's material breach of the terms of his employment agreement or his proprietary information agreement. With respect to subsection (i) above, before the Company can terminate Dr. Poma for Cause for the continued failure to substantially perform his duties, the Company must provide Dr. Poma with written notice of the grounds for Cause and provide Dr. Poma no less than thirty (30) days from the date of the notice (the "Cure Period") to cure the deficiencies in his performance and avoid termination. If Dr. Poma cures the conditions giving rise to Cause for termination within the Cure Period but the Company terminates Dr. Poma's employment during or at the end of the Cure Period, Dr. Poma will be entitled to the severance payments and/or benefits contemplated by his employment agreement.

As defined in Dr. Poma's employment agreement, "Good Reason" means, without Dr. Poma's written consent: (i) there is a material reduction in his base salary (except where there is a general reduction applicable to the management team generally), (ii) there is a material reduction in his overall responsibilities or authority, title, or scope of duties; (iii) a requirement by the Company that he perform an act or not perform an act that he reasonably believes violates a law, rule or regulation or constitutes fraud or violates a clear mandate of public policy or clear principle of professional ethics or (iv) a material change in the geographic location at which he must perform his services; provided, that in no instance will the relocation of Dr. Poma to a facility or a location of 50 miles or less from his then current office location be deemed material for purposes of the employment agreement.

Jason S. Kim

Pursuant to Mr. Kim's employment agreement, if Mr. Kim's employment is terminated for Cause, death, Disability, or non-renewal or expiration of the employment term, or if Mr. Kim voluntarily resigns without Good Reason, he shall be entitled to: (i) his base salary through the effective date of termination; (ii) the right to continue health care benefits under COBRA, at his cost, to the extent required and available by law; (iii) reimbursement of expenses for which he is entitled to be reimbursed, but for which he has not yet been reimbursed; and (iv) no other severance or benefits of any kind, unless required by law or pursuant to any other Company plans or policies, as then in effect. "Disability" means that Mr. Kim, at the time notice is given, has been unable to substantially perform his duties under the employment agreement for not less than 120 work days within a 12 consecutive month period as a result of his

incapacity due to a physical or mental condition and, if reasonable accommodation is required by law, after any reasonable accommodation.

If Mr. Kim is terminated by the Company involuntarily without Cause (excluding any termination due to death or Disability) or if Mr. Kim resigns with Good Reason, then he shall be entitled to receive: (A) his base salary through the date of termination; (B) continuing severance pay at a rate equal to 100% of his base salary, as then in effect (less applicable withholding), for a period of nine months from the date of such termination, to be paid periodically in accordance with the Company's normal payroll practices; (C) reimbursement of all expenses for which he is entitled to be reimbursed, but for which he has not yet been reimbursed; (D) the right to continue health care benefits under COBRA, at his cost, to the extent required and available by law; and (E) no other severance or benefits of any kind, unless required by law or pursuant to any written Company plans or policies, as then in effect.

As defined in Mr. Kim's employment agreement, "Cause" means (i) Mr. Kim's continued failure to substantially perform the duties and obligations under the employment agreement (for reasons other than death or Disability); (ii) the commission by Mr. Kim of (x) an act of dishonesty or act constituting common law fraud, embezzlement or a felony, or (y) any violation of federal or state law, tortious act, unlawful act or malfeasance which causes or reasonably could cause material harm to the Company's standing, condition or reputation; (iii) Mr. Kim's violation of, or a plea of nolo contendere or guilty to, a felony under the laws of the United States or any state; or (iv) Mr. Kim's material breach of the terms of his employment agreement or his proprietary information agreement. With respect to subsection (i) above, before the Company can terminate Mr. Kim for Cause for the continued failure to substantially perform his duties, the Company must provide Mr. Kim with written notice of the grounds for Cause and provide Mr. Kim no less than 30 days from the date of the notice (the "Cure Period") to cure the deficiencies in his performance and avoid termination. If Mr. Kim cures the conditions giving rise to Cause for termination within the Cure Period but the Company terminates Mr. Kim's employment during or at the end of the Cure Period, Mr. Kim will be entitled to the severance payments and/or benefits contemplated by his employment agreement.

As defined in Mr. Kim's employment agreement, "Good Reason" means, without Mr. Kim's written consent: (i) there is a material reduction in his base salary (except where there is a general reduction applicable to the management team generally), (ii) there is a material reduction in his overall responsibilities or authority, title, or scope of duties; (iii) a requirement by the Company that he perform an act or not perform an act that he reasonably believes violates a law, rule or regulation or constitutes fraud or violates a clear mandate of public policy or clear principle of professional ethics or (iv) a material change in the geographic location at which he must perform his services; provided, that in no instance will the relocation of Mr. Kim to a facility or a location of 50 miles or less from his then current office location be deemed material for purposes of the employment agreement.

Roger J. Waltzman, M.D.

Pursuant to Dr. Waltzman's employment agreement, if Dr. Waltzman's employment is terminated by the Company for any reason he will receive (i) 100% of his base salary, as then in effect, through the date of termination, (ii) reimbursement of all expenses for which he is entitled to be reimbursed and (iii) if he participates in the Company's group health plans, the right to continue health care benefits under COBRA, at his cost. If Dr. Waltzman's employment is terminated without "Cause" (as defined in the Company's 2014 Equity Incentive Plan), he will be entitled to receive as severance, 100% of his base salary, as then in effect, for a period of nine months from the date of such termination, to be paid periodically in accordance with the Company's normal payroll practices, provided he delivers to the Company and does not revoke a separation agreement and general release within sixty days following his last day of employment, in addition to the reimbursement of all expenses and right to continue health care benefits under COBRA, described above. In the event that Dr. Waltzman's employment is terminated by the Company without Cause in connection with a Change in Control (as defined in the Company's 2014 Equity Incentive Plan), provided he delivers to the Company and does not revoke a separation agreement and general release within sixty days following his last day of employment, the Company will (i) pay Dr. Waltzman a lump sum amount equal to one times (1x) the sum of his current base salary and his annual target bonus, in lieu of the severance described previously and (ii) accelerate the vesting of Dr. Waltzman's then-held Company time-based equity awards. In the event of such termination without Cause in connection with a Change in Control, all stock options held by Dr. Waltzman will immediately become exercisable in full and any other stock awards held by Dr. Waltzman will become free of restrictions.

As defined in the Company's 2014 Equity Incentive Plan, "Cause" means employment related dishonesty, fraud, misconduct or disclosure or misuse of confidential information, or other employment related conduct that is likely to cause significant injury to the Company, an Affiliate (as defined in the Company's 2014 Equity Incentive Plan), or any of their respective employees, officers or directors (including, without limitation, commission of a felony or similar offense), in each case as determined by the Board. "Cause" shall not require that a civil judgment or criminal conviction have been entered against or guilty plea shall have been made by the Participant (as defined in the Company's 2014 Equity Incentive Plan) regarding any of the matters referred to in the previous sentence. Accordingly, the Board shall be entitled to determine "Cause" based on the Board's good faith belief. If the Participant is criminally charged with a felony or similar offense that shall be a sufficient, but not a necessary, basis for such belief.

As defined in the Company's 2014 Equity Incentive Plan, a "Change in Control" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events: (i) any Exchange Act Person (as defined in the Company's 2014 Equity Incentive Plan) becomes the Owner (as defined in the Company's 2014 Equity Incentive Plan), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities or (B) solely because the level of Ownership (as defined in the Company's 2014 Equity Incentive Plan) held by any Exchange Act Person (the "Subject Person") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner (as defined in the Company's 2014 Equity Incentive Plan) of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned (as defined in the Company's 2014 Equity Incentive Plan) by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur; (ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity (as defined in the Company's 2014 Equity Incentive Plan) in such merger, consolidation or similar transaction or (B) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction; (iii) the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company will otherwise occur, except for a liquidation into a parent corporation; (iv) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries (as defined in the Company's 2014 Equity Incentive Plan), other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity (as defined in the Company's 2014 Equity Incentive Plan), more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or (v) individuals who, on the date this Plan is adopted by the Board, are members of the Board (the "Incumbent Board") cease for any reason to constitute at least a majority of the members of the Board; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Plan, be considered as a member of the Incumbent Board. Notwithstanding the foregoing definition or any other provision of this Plan, the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company.

Director Compensation

The following table shows the total compensation paid or accrued during the fiscal year ended December 31, 2022 to each of non-employee director of the Company. Directors who are employed by us are not compensated for their service on our Board.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)(3)	Total ($)
Harold E. Selick, Ph.D.	79,750	10,736	90,486
Jonathan Lanfear	45,625	10,736	56,361
David Hirsch, M.D., Ph.D.	52,750	10,736	63,486
David R. Hoffmann	55,000	10,736	65,736
Kevin Lalande (2)	52,000	10,736	62,736
Scott Morenstein (4)	23,750	—	23,750
Corsee Sanders, Ph.D.	45,000	10,736	55,736
Gabriela Gruia, M.D. (5)	33,000	54,673	87,673

(1) These amounts represent the aggregate grant date fair value of options granted to each director in 2022 computed in accordance with FASB ASC Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in Note 12 to our Financial Statements, included in our Annual Report on Form 10-K for the year ended December 31, 2022.
(2) Mr. Lalande is a Managing Member of SHVMS, LLC and is obligated to transfer any shares issued to him by the Company, or the economic benefits thereof, to SHVMS, LLC.
(3) As of December 31, 2022, the aggregate number of options held by each of our non-employee directors was as follows (representing both exercisable and unexercisable option awards, none of which have been exercised).
(4) Mr. Morenstein stepped down from our Board in March 2023.
(5) Dr. Gruia became a Board member in March 2022.

Name	Number of Shares Underlying Outstanding Stock Options
Harold E. Selick, Ph.D.	100,000
Jonathan Lanfear	30,000
David Hirsch, M.D., Ph.D.	100,000
David R. Hoffmann	108,635
Kevin Lalande	100,000
Scott Morenstein	85,000
Corsee Sanders, Ph.D.	70,000
Gabriela Gruia, M.D.	40,000

Director Compensation Policy

The following is a description of the standard compensation arrangements under which our non-employee directors are compensated for their service as directors, including as members of the various committees of our Board.

The Company generally provides its non-employee directors with cash and equity compensation for their service on the Board. The Board is responsible for considering and approving the compensation paid to the Company's non-employee directors, upon recommendation from the Compensation Committee. The Compensation Committee reviews the compensation paid to the Company's non-employee directors with input and market data provided by the Compensation Committee's outside compensation consultant. In this regard, in March 2015, the Board of Pre-Merger Threshold approved a non-employee director compensation policy, or the director compensation policy, that set forth the terms of the cash and equity compensation to be paid to the Company's non-employee directors beginning in 2015. In October 2017, May 2018 and December 2019, the Board amended and restated the director compensation policy. Directors who are also our employees, such as Dr. Poma, will not receive additional compensation for their services as directors.

On December 19, 2019, our director compensation policy was amended to clarify the annual cash retainers as 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, as applicable, with such fees to 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

Pursuant to our current director compensation policy, in each year of a non-employee director's tenure, the director is granted a nonstatutory stock option to purchase 15,000 shares of our common stock on the date of our annual meeting of stockholders, provided that such individual has served as a non-employee director for at least six months prior to the date of such annual meeting. Upon the initial election or appointment to the Board, new non-employee directors are granted a nonstatutory stock option to purchase 25,000 shares of our common stock. Each annual option grant will vest and become exercisable on the first anniversary of the date of grant, subject to the non-employee director's continuous service through such dates. Each initial option grant will vest and become exercisable as to 50% of the shares of common stock subject to the option on each of the first and second anniversaries of the date of grant, subject to the non-employee director's continuous service (as defined in our director compensation policy) through such dates. All annual and initial stock option grants to our non-employee directors under the director compensation policy fully vest immediately prior to a fundamental transaction or change in control, as such terms are defined in our director compensation policy.

Each non-employee director is entitled to reimbursement from the Company for all reasonable out-of-pocket expenses incurred by the non-employee director in connection with his or her attendance at Board and Committee meetings.

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

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of April 19, 2023 for:

- the executive officers named in the Summary Compensation Table in Item 11 of this Amendment,
- each of our directors and director nominees,
- all of our current directors and executive officers as a group, and
- each stockholder known by us to own beneficially more than 5% of our common stock.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. We deem shares of common stock that may be acquired by an individual or group within 60 days of April 19, 2023 pursuant to the conversion of our Series A Preferred Stock and exercise of options or warrants, each to the extent applicable, to be outstanding for the purpose of computing the percentage ownership of such individual or group but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Each share of our common stock is entitled to one vote on each matter considered at the annual meeting and shares of our Series A Preferred Stock do not have any voting rights, unless converted into common stock. Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them based on information provided to us by these stockholders. Percentage of ownership is based 56,351,647 shares of common stock outstanding on April 19, 2023.

Name and Address of Beneficial Owner**	Shares Beneficially Owned	
	Number	Percent
Five Percent Stockholders:		
Biotech Target N.V. (1) Ara Hill Top Building Unit A-5 Pletterijwg Oost 1, Curacao	11,192,003	19.9%
Entities affiliated with SHV Management Services LLC (2) c/o Santé Ventures 201 West 5th Street, Suite 1500 Austin, Texas 78701	7,258,100	12.9%
Longitude Venture Partners III, L.P. (3) 2740 Sand Hill Road, 2nd Floor Menlo Park, CA 94025	4,647,302	8.0%
BVF Partners, L.P. (4) 44 Montgomery St., 40th Floor San Francisco, CA 94104	5,246,565	9.3%
Named Executive Officers and Directors:		
Eric E. Poma, Ph.D. (5)	2,143,717	3.7%
Jason S. Kim (6)	876,805	1.5%
Roger J. Waltzman (7)	389,582	*
David Hirsch, M.D. Ph.D. (8)	100,000	*
David R. Hoffmann (9)	106,817	*
Kevin Lalande (10)	7,358,100	13.0%
Jonathan Lanfear (11)	30,000	*
Corsee Sanders, Ph.D. (12)	70,000	*
Harold E. Selick, Ph.D. (13)	140,806	*
Gabriela Gruia, M.D.	27,500	*
All directors and current executive officers as a group (10 persons) (14)	11,243,327	18.8%

* Represents beneficial ownership of less than 1% of the outstanding shares of our common stock.

** Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Molecular Templates, Inc., 9301 Amberglen Blvd., Suite 100, Austin TX 78729.

(1) This information is based solely on a Schedule 13G filed with the SEC on February 14, 2023. Consists of 11,192,003 shares of common stock held by Biotech Target N.V. BB Biotech AG is the sole stockholder of Biotech Target N.V. and may be deemed to share voting and investment power over our securities held by Biotech Target N.V. BB Biotech AG disclaims beneficial ownership of these securities except to the extent of its pecuniary interest therein.

(2) This information is based solely on a Form 4 filed with the SEC on June 21, 2022. Consists of (i) 864,665 shares of common stock held by Santé Health Ventures I Annex Fund, L.P., (ii) 4,827 shares of common stock issuable upon exercise of warrants held by Santé Health Ventures I Annex Fund, L.P., (iii) 6,097,298 shares of common stock held by Santé Health Ventures I, L.P., (iv) 19,310 shares of common stock issuable upon exercise of warrants held by Santé Health Ventures I, L.P, (v) 50,000 shares of common stock held by SHV Management Services, L.P. and (vi) 222,000 shares of common stock held by SHVMS, LLC. The securities held by Santé Health Ventures I Annex Fund, L.P., Santé Health Ventures I, L.P. and SHVMS, LLC may be deemed to be beneficially owned by Kevin Lalande, a member of our Board, Joe Cunningham, M.D. and Douglas D. French, who are managing directors (the "SHV Directors") of SHV Management Services, LLC ("SHV Management"). SHV Management is the general partner of SHV Annex Services, LP, which is the general partner of Santé Health Ventures I Annex Fund, L.P. SHV Management is also the general partner of SHV Management Services, LP, which is the general partner of Santé Health Ventures I, L.P. Each of the SHV Directors, SHV Management, SHV Annex Services, LP and SHV Management Services, LP disclaims beneficial ownership of these securities except to the extent of its or his pecuniary interest therein.

(3) This information is based solely on a Schedule 13D/A filed with SEC on February 14, 2023. Consists of (i) 3,199,035 shares of common stock held by Longitude Venture Partners III, L.P. ("Longitude Venture III") and (ii) 1,448,267 shares of common stock issuable upon exercise of warrants held by Longitude Venture III. Such securities are held by Longitude Venture III and may be deemed to be beneficially

owned by Longitude Capital Partners III, LLC ("Longitude Capital III"), Patrick G. Enright, and Juliet Tammenoms Bakker. Longitude Capital III is the general partner of Longitude Venture III and may be deemed to share voting and investment power over our securities held by Longitude Venture III. Mr. Enright and Ms. Bakker are members of Longitude Capital III and Mr. Enright and Ms. Bakker are the managing members of Longitude Capital III, and all of them may be deemed to share voting and investment power over our securities held by Longitude Venture III. Each of Longitude Capital III, Mr. Enright and Ms. Bakker disclaims beneficial ownership of these securities except to the extent of its, his or her pecuniary interest therein.

(4) This information is based solely on a Schedule 13G filed with the SEC on February 14, 2023. Consists of (i) 2,832,414 shares of common stock beneficially owned by Biotechnology Value Fund, L.P. ("BVF"), including 128,000 shares of common stock issuable upon conversion of 128 shares of Series A Convertible Preferred Stock ("Series A Preferred Stock") held by BVF, (ii) 2,085,580 shares of common stock beneficially owned by Biotechnology Value Fund II, L.P. ("BVF2"), including 104,000 shares of common stock issuable upon conversion of 104 shares of Series A Preferred Stock held by BVF2, and (iii) 250,575 shares of common stock beneficially owned by Biotechnology Value Trading Fund OS LP ("Trading Fund OS"), including 18,000 shares of common stock issuable upon conversion of 18 shares of Series A Preferred Stock held by Trading Funds OS, and (iv) 77,996 shares of common stock held through certain Partners managed accounts (the "Partners Managed Accounts"). BVF Partners OS Ltd. ("Partners OS"), as the general partner of Trading Fund OS, may be deemed to beneficially own the shares of common stock beneficially owned by Trading Fund OS. BVF Partners, L.P. ("Partners") as the general partner of BVF, BVF2, the investment manager of Trading Fund OS, and the sole member of Partners OS, may be deemed to beneficially own the shares of common stock beneficially owned in the aggregate by BVF, BVF2, Trading Fund OS, and the Partners Managed Accounts. BVF Inc., as the general partner of Partners, may be deemed to beneficially own the shares of Common Stock owned by Partners. Mark N. Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the shares of Common Stock beneficially owned by BVF Inc. The foregoing excludes (i) 168,508 shares of common stock issuable upon the exercise of warrants held by BVF, (ii) 108,536 shares of common stock issuable upon the exercise of warrants held by BVF2, and (iii) 30,190 shares of common stock issuable upon the exercise of warrants held by Trading Funds OS, and (iv) 54,830 additional shares of common stock issuable upon the exercise of warrants held by the Partners Managed Accounts, due to a beneficial ownership limitation. The shares of Series A Preferred Stock are only convertible to the extent that the holder, together with its affiliates and any other person or entity acting as a group, would not beneficially own more than 9.99% of the outstanding shares of common stock after giving effect to such conversion, as such percentage ownership is determined in accordance with the terms and provisions of the Company's Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock. The warrants referenced above have an exercise price of $6.8423 per share and expire on August 1, 2024, but are only exercisable to the extent that the holder, together with its affiliates and any other person or entity acting as a group, would not beneficially own more than 4.99% of the outstanding shares of common stock after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the warrants. Partners OS disclaims beneficial ownership of the shares of common stock beneficially owned by Trading Fund OS. Each of Partners, BVF Inc. and Mr. Lampert disclaims beneficial ownership of the shares of common stock beneficially owned by BVF, BVF2, Trading Fund OS, and the Partners Managed Accounts.

(5) Consists of (i) 277,615 shares of common stock held by Dr. Poma and (ii) 1,866,102 shares of our common stock issuable upon the exercise of options to purchase common stock held by Dr. Poma exercisable within 60 days of April 19, 2023.

(6) Consists of (i) 95,493 shares of our common stock and (ii) 781,312 shares of our common stock issuable upon the exercise of options to purchase common stock held by Mr. Kim exercisable within 60 days of April 19, 2023.

(7) Consists of 389,582 shares of common stock issuable upon exercise of options to purchase common stock held by Dr. Waltzman exercisable within 60 days of April 19, 2023.

(8) Consists of 100,000 shares of our common stock issuable upon the exercise of options to purchase common stock held by Dr. Hirsch exercisable within 60 days of April 19, 2023.

(9) Consists of 106,817 shares of our common stock issuable upon the exercise of options to purchase common stock held by Mr. Hoffmann exercisable within 60 days of April 19, 2023.

(10) Shares reported as beneficially owned by Mr. Lalande include (i) 864,665 shares of common stock held by Santé Health Ventures I Annex Fund, L.P., (ii) 4,827 shares of common stock issuable upon exercise of warrants held by Santé Health Ventures I Annex Fund, L.P., (iii) 6,097,298 shares of common stock held by Santé Health Ventures I, L.P., (iv) 19,310 shares of common stock issuable upon exercise of warrants held by Santé Health Ventures I, L.P., (v) 50,000 shares of common stock held by SHV Management Services, L.P, (vi) 222,000 shares of common stock held by SHVMS, LLC. and (vii) 100,000 shares of our common stock issuable upon the exercise of options to purchase common stock held by Mr. Lalande exercisable within 60 days of April 19, 2023. The securities held by Santé Health Ventures I, L.P., Santé Health Ventures I Annex Fund, L.P. and SHVMS, LLC may be deemed to be beneficially owned by Mr. Lalande, who is a managing director of SHV Management Services, LLC, which is the general partner of SHV Management Services, LP, which is the general partner of Santé Health Ventures I, L.P., and SHV Annex Services, LP, which is the general partner of Santé Health Ventures I Annex Fund, L.P. As a managing director of SHV Management Services, LLC, Mr. Lalande may be deemed to share voting and investment power over these securities held by Santé Health Ventures I, L.P. and Santé Health Ventures I Annex Fund, L.P. Mr. Lalande disclaims beneficial ownership of these securities except to the extent of his pecuniary interest therein.

(11) Consists of 30,000 shares of our common stock issuable upon the exercise of options to purchase common stock held by Mr. Lanfear exercisable within 60 days of April 19, 2023.

(12) Consists of 70,000 shares of our common stock issuable upon the exercise of options to purchase common stock held by Dr. Sanders exercisable within 60 days of April 19, 2023.

(13) Consists of (i) 40,806 shares of our common stock held by Dr. Selick and (ii) 100,000 shares of our common stock issuable upon the exercise of options to purchase common stock within 60 days of April 19, 2023.

(14) See footnotes (6) through (13) above.

Equity Compensation Plan Information

The following table provides certain aggregate information with respect to all of the Company's equity compensation plans in effect as of December 31, 2022.

	(a)	(b)	(c)
Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders (1)	8,144,101	$7.94	2,814,408
Equity compensation plans not approved by security holders (2)	302,362	$1.28	—
Total	8,446,463	$7.70	2,814,408

(1) These plans consist of the 2018 Equity Incentive Plan, the 2014 Equity Incentive Plan, as amended; the 2004 Amended and Restated Equity Incentive Plan; and the Amended and Restated 2004 Employee Stock Purchase Plan. As of May 31, 2018, the 2014 Equity Incentive Plan; and the 2004 Equity Incentive Plan were terminated, and no further shares will be granted from those plans.

(2) In August 2017, the Company assumed the Private Molecular 2009 Stock Plan as part of the Merger. The 2009 Stock Plan permits the granting to full or part-time officers, employees, directors, consultants and other key persons as selected from time to time by the administrator in its discretion of (i) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and (ii) options that do not so qualify. The option exercise price of each option is determined by the administrator but may not be less than 100% of the fair market value of the common stock on the date of grant. The term of each option is fixed by the administrator and may not exceed 10 years from the date of grant. The administrator determines at what time or times each option may be exercised. In addition, the 2009 Stock Plan permits the granting of restricted stock. As of May 31, 2018, the Private Molecular 2009 Stock Plan was terminated, and no further shares will be granted from this plan.

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

Certain Relationships and Related Person Transactions

The following describes transactions since January 1, 2021 to which we have been a party and in which:

- the amounts involved exceeded or will exceed the lesser of $120,000 or 1% of the average of the Company's total assets at year-end for fiscal year 2022 and 2021; and
- any of our directors, executive officers, or beneficial holders of more than 5% of our voting securities, or their affiliates or immediate family members, had or will have a direct or indirect material interest.

We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, from unrelated third parties. Compensation arrangements for our directors and named executive officers are described in "Director Compensation" and "Executive Compensation."

Indemnification Arrangements

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by Delaware law. Further, we have entered into separate indemnification agreements with each of our directors and executive officers. Such agreements require us, among other things, to indemnify our directors and officers, other than for liabilities arising from willful misconduct of a culpable nature, and to advance their expenses incurred as a result of any proceedings against them as to which they could be indemnified.

Policies and Procedures for Related Party Transactions

We have adopted a written policy that requires all future transactions between us and any director, executive officer, holder of 5% or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of them, or any other related persons, as defined in Item 404 of Regulation S-K, or their affiliates, in which the amount involved is equal to or greater than $120,000, be approved in advance by our Audit Committee. Any request for such a transaction must first be presented to our Audit Committee for review, consideration and approval. In approving or rejecting any such proposal, our Audit Committee is to consider the relevant facts and circumstances available and deemed relevant to the Audit Committee, including, but not limited to, the extent of the related party's interest in the transaction, and whether the transaction is on terms no less favorable to us than terms we could have generally obtained from an unaffiliated third party under the same or similar circumstances.

Our Audit Committee reviews and approves in advance all related-party transactions.

Director Independence

Rule 5605 of the Nasdaq Listing Rules requires a majority of a listed company's board of directors to be comprised of independent directors. In addition, the Nasdaq Listing Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and corporate governance committees be independent under the Exchange Act. Under Rule 5605(a)(2), a director will only qualify as an "independent director" if, in the opinion of our Board of Directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries.

Compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. In order to be considered independent for purposes of Rule 10C-1, a board must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director; and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

Our Board has reviewed the composition of our Board and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board of Directors has determined that each of our directors, with the exception of Eric E. Poma, Ph.D., is an "independent director" as defined under Rule 5606(a)(2) of the Nasdaq Listing Rules. As such, our Board of Directors determined that each of David Hirsch, M.D., Ph.D., David R. Hoffmann, Kevin Lalande, Gabriela Gruia, M.D., Jonathan Lanfear, Harold E. "Barry" Selick, Ph.D., and Corsee Sanders, Ph.D. are independent. Our Board of Directors determined that David R. Hoffmann, David Hirsch, M.D., Ph.D., and Jonathan Lanfear, who comprise our Audit Committee, Harold E. "Barry" Selick, Ph.D., Gabriela Gruia, M.D., and David Hirsch, M.D., Ph.D. who comprise our Nominating and Corporate Governance Committee and Kevin Lalande, Corsee Sanders, Ph.D., and Harold E. "Barry" Selick, Ph.D., who comprise our Compensation Committee, satisfy the independence standards for such committees established by the SEC and the Nasdaq Listing Rules, as applicable. In making such determinations, our Board of Directors considered the relationships that each such non-employee director has with our Company and all other facts and circumstances our Board of Directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table presents fees for professional audit services rendered by Ernst & Young LLP for the audit of the Company's annual financial statements for the years ended December 31, 2022, and December 31, 2021, and fees billed for other services rendered by Ernst & Young LLP during those periods.

	2022	2021
Audit fees:(1)	579,500	465,000
Audit related fees:(2)	—	—
Tax fees:(3)	—	—
All other fees:(4)	—	—
Total	579,500	465,000

(1) Audit fees consisted of audit services of the annual consolidated financial statements included in our Form 10-K, the quarterly reviews of financial statements included in our Form 10-Q filings, fees associated with SEC registration statements, and accounting consultations related to audit services.
(2) Audit related fees consisted principally of fees related to the annual audit and the quarterly reviews, but outside the scope of the Audit Committee approved audit and agreed upon procedure.
(3) Tax fees consist principally of assistance with matters related to tax compliance and reporting, tax advice, and tax planning.
(4) All other fees consist principally of all other permissible work performed by Ernst & Young LLP that does not meet the above category descriptions.

The percentage of services set forth above in the categories that were approved by the Audit Committee pursuant to Rule 2-01(c)(7)(i)(C) (relating to the approval of a *de minimis* amount of non-audit services after the fact but before completion of the audit), was 100%.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-audit Services of Independent Public Accountant

Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm.

Prior to engagement of an independent registered public accounting firm for the next year's audit, management will submit an aggregate of services expected to be rendered during that year for each of four categories of services to the Audit Committee for approval.

1. ***Audit*** services include audit services traditionally performed by an independent registered accounting firm of the annual consolidated financial statements included in our Form 10-K, the quarterly reviews of financial statements included in our Form 10-Q filings, fees associated with SEC registration statements, assistance in responding to SEC comment letters and accounting consultations related to audit services.

2. ***Audit-Related*** services are for assurance and related services that are traditionally performed by an independent registered public accounting firm, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.

3. ***Tax*** services include all services performed by an independent registered public accounting firm's tax personnel except those services specifically related to the audit of the financial statements, and includes fees in the areas of tax compliance, tax planning, and tax advice.

4. ***Other Fees*** are those associated with services not captured in the other categories.

Prior to engagement, the Audit Committee pre-approves these services by category of service. The fees are budgeted and the Audit Committee requires our independent registered public accounting firm and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage our independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval before engaging our independent registered public accounting firm.

The Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(1) Consolidated Financial Statements

No financial statements are filed with this Amendment No. 1 to our Annual Report on Form 10-K. See Index to Consolidated Financial Statements at Item 8 of the Original 10-K.

(2) Financial Statement Schedules

No financial statement schedules are filed with this Amendment No. 1 to our Annual Report on Form 10-K.

(3) Exhibits

The following is a list of exhibits filed as part of this Amendment No. 1 to our Annual Report on Form 10-K.

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 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).
3.5	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	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).
4.2	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).
4.3	Form of Warrant issued to Wedbush Securities, dated December 1, 2017 (incorporated by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 30, 2018).
4.4	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).
4.5	Form of Senior Indenture (incorporated by reference to Exhibit 4.7 to the Company's registration statement on Form S-3 (File No. 333-228975) filed on December 21, 2018).
4.6	Form of Subordinated Indenture (incorporated by reference to Exhibit 4.8 to the Company's registration statement on Form S-3 (File No. 333-228975) filed on December 21, 2018).
10.1+	2004 Amended and Restated Equity Incentive Plan of the Company, as amended (incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 15, 2012).
10.2+	Amended and Restated 2004 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8 (File No. 333-164865) filed on February 11, 2010).
10.3	Amended and Restated Non-Employee Director Compensation Policy, adopted by the Board of Directors of the Company on October 9, 2017, amended as of May 31, 2018 and further amended as of December 19, 2019 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on December 19, 2019).

10.4	2014 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on October 13, 2017).
10.5+	Form of Indemnification Agreement between the Company and each of its directors and executive officers (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-32979) filed on August 7, 2017).
10.6+	Form of Notice of Grant of Stock Options and Option Agreement under the 2004 Equity Incentive Plan (incorporated by reference to Exhibit 10.25 to the Company's Current Report on Form 8-K (File No. 000-51136) filed on March 17, 2006).
10.7+	Form of Stock Option Grant Notice and Option Agreement for employees under the 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 30, 2018).
10.8+	Form of Stock Option Grant Notice and Option Agreement for non-employee directors under the 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 30, 2018).
10.9+	Amended and Restated Executive Employment Agreement, dated April 22, 2016, between Molecular Templates OpCo, Inc. and Eric E. Poma, Ph.D. (incorporated by reference to Exhibit 10.43 to the Company's Registration Statement on Form S-4 (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 May 15, 2017).
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).
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†	Cancer Research Grant Contract, dated as of November 7, 2012, by and between the Cancer Prevention & Research Institute of Texas and Molecular Templates OpCo, Inc. (incorporated by reference to Exhibit 10.33 to the Company's Current Report on Form 8-K (File No. 001-32979), filed on June 22, 2018).
10.21+	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).
10.22+	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).
10.23+	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).
10.24†	Cancer Research Grant Contract, dated September 18, 2018, by and between The Company and the Cancer Prevention and Research Institute of Texas (incorporated by reference to Exhibit 10.3 to the Company Quarterly Report on Form 10-Q/A (File No. 001-32979) filed on February 13, 2019).
10.25	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).
10.26	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).
10.27	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).
10.28+	Executive Employment Agreement, dated January 3, 2019, by and between Roget J. Waltzman, M.D. and the Company (incorporated by reference to Exhibit 10.48 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 13, 2020).

10.29	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).
10.30	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).
10.31	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).
10.32††	Collaboration Agreement, dated February 10, 2021, by and between the Company and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-32979) filed on May 14, 2021).
10.33††*	Amendment No. 1 to Collaboration Agreement, dated December 2, 2021, by and between the Company and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.54 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 29, 2022.
21.1	Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 30, 2023.
23.1	Consent of Ernst & Young LLP (incorporated by reference to Exhibit 23.1 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 30, 2023.
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 (incorporated by reference to Exhibit 32.1 to the Company's Annual Report on Form 10-K (File No. 001-32979) filed on March 30, 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)

^ 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.

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

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

+ Indicates a management contract or compensatory plan or arrangement.

ITEM 16. 10-K SUMMARY

Not applicable.

SIGNATURES

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

MOLECULAR TEMPLATES, INC.

April 28, 2023 By: /s/ ERIC E. POMA, PH.D.

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