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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2023

OR

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

For the transition period from _______________ to ______________.

Commission File Number: 001-37939

MARKER THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	**45-4497941** (IRS Employer Identification No.)
9350 Kirby Drive, Suite 300 **Houston, Texas** (Address of principal executive offices)	**77054** (Zip code)

(713) 400-6400
(Telephone Number)

4551 Kennedy Commerce Drive, Houston, Texas, 77032
(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	MRKR	The Nasdaq Stock Market LLC

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 of Section 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by checkmark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," accelerated filer", "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 checkmark 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 as of June 30, 2023 (the last day of the registrant's most recently completed second fiscal quarter) based on the closing sale price of $3.10 as reported on the Nasdaq Capital Market as of that date was approximately $23,100,000.

The registrant had 8,902,897 shares of common stock outstanding as of March 18, 2024.

Note Regarding Reverse Stock Splits

On January 26, 2023, we filed an amendment to our Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to effect a reverse split of our authorized, issued and outstanding common stock at a ratio of one for ten. All historical share and per share amounts reflected in this report have been adjusted to reflect the reverse stock split.

Documents Incorporated By Reference

Portions of the registrant's proxy statement relating to registrant's 2024 Annual Meeting of Stockholders (the "Proxy Statement") to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the close of the registrant's fiscal year, are incorporated by reference in Part III of this Annual Report on Form 10-K. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, the Proxy Statement is not deemed to be filed as part of this Annual Report on Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This annual report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1: "Business," Part I, Item 1A: "Risk Factors," and Part 2, Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this annual report. Any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expect", "plan", "intend", "anticipate", "believe", "estimate", "predict", "potential" or "continue", the negative of such terms or other comparable terminology. These statements speak only as of the date of this Annual Report and involve known and unknown risks, uncertainties and other important 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 the forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. Forward-looking statements in this annual report include statements as to:

- our ability to continue as a going concern;
- the timing, progress and results of clinical trials of multi tumor associated antigen ("multiTAA")-specific T cell therapies and our other product candidates, including statements regarding the timing of initiation and completion of preclinical studies or clinical trials or related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing of any submission of filings for regulatory approval of product candidates and our ability to obtain and maintain regulatory approvals for product candidates for any indication;
- our ability to successfully commercialize product candidates;
- our expectations regarding the potential benefits, activity, effectiveness and safety of our product candidates;
- our expectations regarding the size of the patient populations, market acceptance and opportunity for and clinical utility of product candidates, if approved for commercial use;
- our manufacturing capabilities and strategy, including the ease, scalability and commercial viability of our manufacturing methods and processes, as well as our ability to maintain our relationship with Cell Ready LLC;
- our expectations regarding the scope of any approved indications for product candidates;
- the potential benefits of and our ability to maintain our relationships and collaborations with the Baylor College of Medicine ("BCM"), and other potential collaboration or strategic relationships;
- our ability to use the multiTAA-specific T cell platform to develop future product candidates;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional funding;
- our ability to identify, recruit and retain key personnel;
- our ability to protect and enforce our intellectual property position for our product candidates, and the scope of such protection;
- our financial performance;

- our competitive position and the development of and projections relating to our competitors or our industry; and
- the impact of laws and regulations.

You should refer to “Item 1A. Risk Factors” in this annual report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this annual report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this annual report represent our views as of the date of this annual report. We anticipate that subsequent events and developments may cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this annual report.

You should read this annual report and the documents that we reference in this annual report and have filed as exhibits to this annual report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

In this report all references to (i) “Marker” “we,” “us,” “our” or the “Company” mean Marker Therapeutics, Inc. and its wholly-owned subsidiaries, Marker Cell Therapy, Inc. and GeneMax Pharmaceuticals, Inc., which wholly owns GeneMax Pharmaceuticals Canada Inc., unless the context otherwise requires; (ii) “SEC” refers to the Securities and Exchange Commission; (iii) “Securities Act” refers to the United States *Securities Act of 1933*, as amended; (iv) “Exchange Act” refers to the United States *Securities Exchange Act of 1934*, as amended; and (v) all dollar amounts refer to United States dollars unless otherwise indicated.

PART I

ITEM 1. BUSINESS

Overview

We are a clinical-stage immuno-oncology company specializing in the development and commercialization of novel T cell-based immunotherapies for the treatment of hematological malignancies and solid tumor indications. We developed our lead product candidates from our multi tumor associated antigen ("multiTAA")-specific T cell technology, which is based on the manufacture of non-engineered, tumor-specific T cells that recognize multiple tumor-associated antigens, or TAAs. This approach selectively expands tumor-specific T cells from a patient's/donor's blood and is able to recognize multiple tumor targets to produce broad spectrum anti-tumor activity. Targeting multiple antigens simultaneously exploits the natural capacity of T cells to recognize and kill tumor targets via native T cell receptors ("TCR"), while limiting tumor adaptation/escape by antigen-negative selection or antigen down-regulation. When infused into a patient with cancer, the multiTAA-specific T cells are designed to kill cancer cells expressing the TAA and potentially recruit the patient's immune system to participate in the cancer killing process.

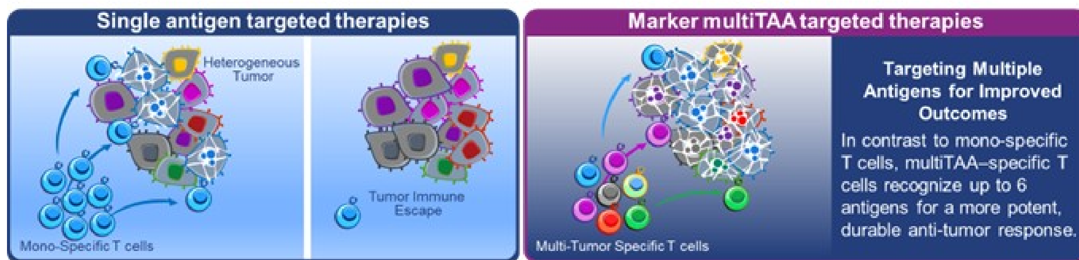
We licensed the underlying technology for multiTAA-specific T cell therapy from Baylor College of Medicine, or BCM, in March 2018. BCM had utilized the therapy in seven exploratory clinical trials. In these studies, BCM treated over 150 patients suffering from a variety of cancers including lymphoma, multiple myeloma, acute myeloid leukemia, or AML, acute lymphoblastic leukemia, or ALL, pancreatic cancer, breast cancer and various sarcomas. In those studies, BCM saw evidence of clinical benefit, expansion of infused cells, and decreased toxicity compared to other cellular therapies.

We are advancing two product candidates for 3 clinical indications as part of our multiTAA-specific T cell program for:

- Autologous multiTAA product for the treatment of lymphoma and pancreatic cancer (MT-601)
- Off-the-Shelf (OTS) product in various indications (e.g., MT-401-OTS)

We do not genetically engineer our multiTAA-specific T cell therapies and we believe that our product candidates are superior to T cells engineered with chimeric antigen receptors, or CAR-T, for several reasons including:

- Multiple targets → enhanced tumoricidal effect→ minimized tumor immune escape
- Clinical safety → no treatment-related side effects, including cytokine release syndrome (CRS) or other severe adverse effects (SAEs), were attributed to the use of multiTAA-specific T cell therapies to date
- Non-genetically engineered T cell products → selective expansion of tumor-specific T cells from a patient's or donor's blood capable of recognizing a broad range of tumor antigens → no risk of mutagenesis and reduced manufacturing complexity → lower cost



For these reasons, we believe our endogenous T cell receptor-based therapies may provide meaningful clinical benefit and safety to patients with both hematological and solid tumors.

We believe that the simplicity of our manufacturing process allows additional modifications to expand multiTAA-specific T cell recognition of cancer targets. For example, we are assessing the potential of combining multiTAA-specific T cell products with other products.

Company-Sponsored Clinical Development of MultiTAA Specific T Cell Therapies

MT-601 for the Treatment of Lymphoma

We developed MT-601, a multiTAA-specific autologous T cell product capable of recognizing multiple target antigens expressed by the tumor, thereby limiting tumor adaptation by negative antigen selection or downregulation.

We are evaluating the safety and efficacy of MT-601 in a Phase 1, multicenter, open-label study (APOLLO) in participants with relapsed or refractory lymphoma who either failed or are ineligible for anti-CD19 CAR T cell therapy. MT - 601 is a multiTAA-specific T cell product that specifically targets six different tumor antigens upregulated in lymphoma cells (Survivin, PRAME, WT1, NY-ESO-1, SSX-2, MAGEA-4). In August 2022, the FDA cleared our IND application for MT-601 for the treatment of patients with relapsed/refractory non-Hodgkin lymphoma who have failed or are ineligible to receive anti-CD19 CAR T cell treatment. The Phase 1 APOLLO trial was initiated in January 2023. In June 2023, we reported first enrollment in the dose escalation stage of the Phase 1 study. The study participant tolerated the treatment well without treatment-related adverse events and achieved a complete metabolic response eight weeks after the second infusion of MT - 601. Six months following the initial treatment with MT-601 the study participant has maintained a complete response to treatment and will continue to be monitored for long-term treatment effects and durability of response. To further validate these observations, additional patients are currently being enrolled in the Phase 1 study.

MT-601 for the Treatment of Pancreatic Cancer

We reported interim data for an ongoing Phase 1/2 clinical trial (TACTOPS) of the multiTAA-specific T cell therapy targeting five TAAs for the treatment of pancreatic adenocarcinoma being conducted by BCM. In this trial, we have observed a clinical benefit with 4 of 13 patients (31%) showing objective responses in front-line unresectable or metastatic pancreatic cancer, which correlated with the post-infusion detection of tumor-reactive T cells in patient peripheral blood and within tumor biopsy samples in patients in the tumor-resection arm of the trial. To date, we have not observed any cytokine release syndrome or neurotoxicity in this trial.

In January 2022, the FDA granted orphan drug designation to MT-601 for the treatment of patients with pancreatic cancer. The FDA cleared our IND application for MT-601 in November 2022 to initiate the PANACEA study, a Phase 1 multicenter clinical trial in locally advanced, unresectable or metastatic pancreatic cancer to assess the safety and efficacy of MT-601 in combination with front-line chemotherapy. The PANACEA trial will include a dose escalation portion followed by a dose expansion portion. Clinical advancement will be pending additional financial support from non-dilutive grant activities.

MT-401 for the Treatment of Patients with AML and MT-401-OTS Program

MT-401 ARTEMIS Study:

We previously announced discontinuation of the Phase 2 ARTEMIS study to prioritize the MT-401-OTS program in patients with Acute Myeloid Leukemia (AML) and Myelodysplastic Syndromes (MDS).

The previous ARTEMIS study was investigating MT-401 (zedenoleucel), in post-allogeneic hematopoietic stem cell transplant (HSCT) patients with AML. The study had three treatment arms, including patients with measurable residual disease (MRD), as well as patients with MRD negative complete remission or active disease. The dose administered in this multicenter trial was up to 200 million cells every two weeks for up to three doses.

- In April 2020, the Orphan Product Development Office of the United States Food and Drug Administration, or the FDA, granted orphan drug designation to MT-401 (zedenoleucel), a multiTAA-specific T cell therapy that targets four TAAs, for the treatment of AML.
- The same multiTAA-specific T cell therapy has been well tolerated in an ongoing Phase 1 clinical trial in AML and myelodysplastic syndrome, or MDS, conducted by our strategic partner Baylor College of Medicine, or BCM.

- As reported in a 2021 publication by Lulla et al., 11 of the 17 patients in the adjuvant disease setting dosed with the multiTAA-specific T cell therapy after receiving an allogeneic HSCT were relapse free [median leukemia-free survival, or LFS, not reached at a median follow-up of 1.9 years], with 11 of 15 patients (two patients were each treated during two different remissions) remaining alive (estimated two-year overall survival of 77%) at a median follow-up of 1.9 years post-infusion, which compares favorably with HSCT outcomes for risk-matched AML/MDS patients post-HSCT [median LFS of nine to 15 months and two-year survival probability of 42%].

- Additionally, eight patients were treated for active disease that was resistant to salvage therapy post-HSCT with a median of five prior lines of therapy (range: four to 10).

    - One of the eight patients crossed over from the adjuvant group, while two patients enrolled twice, but all three patients had active AML that failed another line of salvage therapy after their first multiTAA-specific T cell infusion.

    - Two of the eight patients achieved objective responses, with one complete response and one partial response, with six patients continuing with stable disease.

    - We have observed evidence of a patient's natural immune system participating in cancer killing (epitope spreading) after infusion of our multiTAA-specific T cell therapy.

In 2021, the ARTEMIS trial conducted by Marker has completed the safety lead-in portion, which tested the comparability of MT-401 or zedenoleucel, the multiTAA-specific T cell product manufactured using peptides from two different vendors and enrolled six patients with active disease: one measurable residual disease (MRD) positive patient and five frank relapse patients.

- Consistent with the results of the BCM Phase 1 trial, there were no dose-limiting toxicities, cytokine release syndrome or neurotoxicity observed in this stage of the trial\. Correlative studies showed that the patient saw significant expansion of infused multiTAA-specific T cells. There were no objective responses from the frank relapse patients. By November 2022, all six patients had completed dose-limiting toxicity (DLT) periods with no DLTs reported.

- In the fourth quarter of 2021, the manufacturing of MT-401 for the Phase 2 trial started at the Marker Cell Therapy cGMP manufacturing facility, named MCTF01. We transitioned to treating patients using MT-401 manufactured with Marker's new T cell manufacturing process. The improved manufacturing process greatly reduced the manufacturing time and increased both the antigen specificity and diversity. Specifically, the new process involves an improved T cell manufacturing process for MT-401 that reduces production time to 9 days (compared to the original process of >30 days). This allows a 90% decrease in the number of interventions during production and an improved final T cell product compared to the original product used in previous clinical trials on multiTAA-specific T cells.

- After completing the safety lead-in portion, we initiated the remainder of the Phase 2 trial in July 2021. Group 1 comprised adjuvant (disease-free) patients, with the primary endpoint of relapse-free survival of patients randomized to receive MT-401 versus a control group. Group 2 comprised active disease patients in 2 single arm cohorts (MRD+ only and active disease), with primary endpoints of complete remission and duration of complete remission.

We were previously awarded grants from the FDA Orphan Products Grant program ($2 million), NIH Small Business Innovation Research (SBIR) program ($2 million) and the Cancer Prevention and Research Institute of Texas (CPRIT, $13 million), to support the Phase 2 clinical trial of MT-401. All funding agencies have agreed to continue their financial support and to shift funds to the MT-401-OTS program.

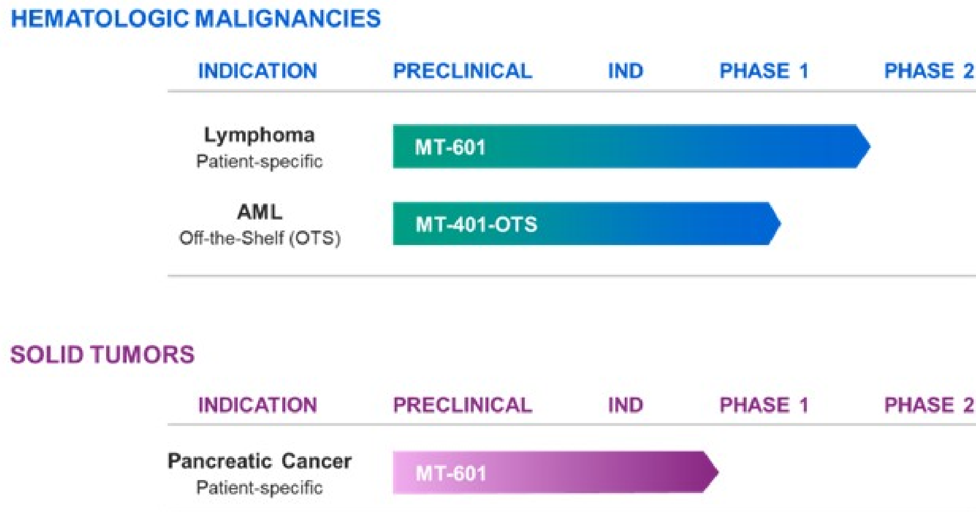
Off-the-Shelf MT-401 (MT-401-OTS) for the Treatment of AML:

Marker previously announced that it intends to focus on the advancement of the MT-401-OTS program in patients with AML. MT - 401-OTS has the potential to provide treatment to patients in as little as 72 hours. Marker believes that this fast turnaround time would be beneficial for treating patients with rapid cancer progression, such as patients with measurable residual disease (MRD) in the AML setting. In the OTS program, we intend to dose patients using "banked" products based on partially human leukocyte antigen (HLA) matching. The U.S. FDA has cleared our clinical protocol to investigate MT-401-OTS as a treatment in patients with AML. We

already established a cellular inventory manufactured from healthy donors, with ongoing efforts to further expand the inventory. At full scale production, we estimate a single donor could provide treatment for approximately 40 patients, and the current stability program indicates that OTS multiTAA-specific T cell products are stable for more than a year in liquid nitrogen, which we expect will permit future on-demand availability for broad-scale implementation. We expect to dose the first patient in the second half of 2024, and, if our OTS program shows promising results in the clinic, we intend to expand the OTS platform to other hematological malignancies and solid tumors.

Pipeline

Our clinical-stage pipeline is set forth below:



Our Strategy

Our multiTAA-specific T cells are designed to enhance the capacity of non-engineered T cells to find and kill cancer by increasing the diversity and quantity of naturally occurring cancer killing T cells within the patient.

Our goal is to be the leader in the development and commercialization of transformative immunotherapies for the treatment of hematological malignancies and solid tumors. We are developing a portfolio of highly differentiated T cell therapies utilizing the multiTAA-specific T cell platform that we believe has the potential to significantly disrupt the current cell therapy landscape, while substantially improving survival and quality of life for patients with cancers.

The key elements of our strategy include:

- ***Expedite clinical development, regulatory approval, and commercialization of our lead product candidates.***

Based on the results of the Phase 1 clinical trials of the multiTAA-specific T cell therapies conducted at BCM and the positive clinical data from the Phase 1 APOLLO study, we plan to prioritize the advancement of MT-601 in patients with lymphoma and to advance the MT-401-OTS program in patients with AML.

We intend to initiate future additional clinical trials in other tumor types based on emerging data. On June 26, 2023, we completed the previously announced transaction with Cell Ready, LLC, or Cell Ready, pursuant to a Purchase Agreement, or the Cell Ready Purchase Agreement, dated May 1, 2023, by and between us and Cell Ready. Following the Closing Date, on February 22, 2024, we and Cell Ready entered into a long-term contract, pursuant to which Cell Ready will perform a wide variety of services for us, including research and development, and manufacturing in support of our clinical trials.

· ***Continue to collaborate with our partners and increase our clinical activities to improve and develop adoptive cell therapy technologies.***

We are contracting with Cell Ready to perform a wide variety of services to ensure the continuation of our research and development efforts and process development to optimize our manufacturing process, product quality and commercial scalability. We previously optimized the multiTAA-specific T cell manufacturing process by closing the system and reducing the total manufacturing time from the original 36 days (BCM) to nine days. The improved manufacturing process has been implemented to supply all of the clinical products used in our current company-sponsored clinical trials. We believe the improved manufacturing process enables products with increased antigen specificity and diversity, both of which have a strong linear correlation to anti-tumor activity and has resulted in a four-fold increase in potency in vitro.

· ***Invest in our platform to maximize the beneficial outcomes for cancer patients.***

We plan to explore new product opportunities by increasing and/or customizing the antigens we target to expand the indications in which the multiTAA-specific T cell products will be efficacious, including solid tumors or other hematologic malignancies. Additionally, our research and development efforts may include the exploration of different doses and/or frequency of dosing and the relationship of these factors with potential therapeutic benefit.

· ***Leverage our relationships with our founding institutions, scientific founders and other scientific advisors.***

Our world-renowned scientific founders and scientific advisors have made seminal contributions to major discoveries in the field of immuno-oncology, and have significant experience in oncology, immunology and cell therapy. We intend to significantly leverage the knowledge, experience and advice of our scientific founders and advisors, as well as the institutional expertise of BCM and our other major institutional partners, to advance our therapies through the clinic and into commercialization.

Background and History of Cancer Immunotherapies

Despite advances in options for treatment, cancer continues to be one of the main causes of death in developed countries. Historically, cancer therapy has been constrained to surgery, radiation, and chemotherapy. More recently, advances in the understanding of the immune system’s role in cancer surveillance have led to immunotherapy becoming an important treatment approach. Cancer immunotherapy began with treatments that nonspecifically activated the immune system and had limited efficacy and/or significant toxicity. In contrast, newer immunotherapy treatments activate specific, potent immune cells, leading to improved safety and efficacy. Within the immunotherapy category, treatments have included vaccines, cytokine therapies, antibody therapies, and adoptive cell therapies.

In 1996, Dr. Dana Leach, Dr. Matthew Krummel and Dr. James Allison reported that monoclonal antibodies, or mAbs, blocking CTLA-4 could treat tumors in animal models. Subsequently, mAbs that targeted CTLA-4 and PD-1 became known as immune checkpoint inhibitors, or ICIs. Immune checkpoints are a means by which cancer cells inhibit or turn down the body’s immune response to cancer. By interfering with these cloaking mechanisms, ICIs have shown an ability to activate T cells, shrink tumors, and improve patient survival. Recent clinical data from checkpoint inhibitors such as ipilimumab, nivolumab and pembrolizumab have confirmed both the validity of this approach and the importance of T cells as promising tools for the treatment of cancer.

Despite these many advances, there persists a significant unmet need in cancer therapeutics. We believe that the use of human cells as a therapeutic modality to re-engage the immune system will be the next significant advancement in the treatment of cancer. These cellular therapies may avoid the long-term side effects associated with current treatments and have the potential to be effective regardless of the type of previous treatments patients have experienced.

T Cell Therapy Overview

The field of adoptive cell transfer is currently comprised primarily of CAR and TCR engineered T cells and has emerged from principles of basic immunology to become a paradigm-shifting clinical immunotherapy. T cell therapy, we believe has evolved as one of the most promising branches of immunotherapy. T cell immunotherapy involves the infusion of T cells into a patient. Immune cells used for immunotherapy treatments can either be collected from the patient (autologous) or harvested from a donor (allogeneic). The cells are retrieved and either genetically modified to express tumor-specific CARs or TCRs or stimulated with specific antigens. The cells are then cultured to proliferate, and the proliferated cells are infused into the patient. Upon infusion, the cells can target and eliminate cancerous cells. Unlike chemotherapy, which is unable to distinguish between healthy and malignant cells, T cells produced for immunotherapy can selectively attack cancer cells that express the target antigen(s). This leads to a more effective treatment platform with fewer side effects. Some of these infused T cells may remain in the body for long periods, providing immunological memory, thus leading to longer and more durable responses.

TCRs and CARs have distinct signaling properties and antigen sensitivities. TCRs recognize peptide fragments from proteins expressed either inside the cell or on the cell surface, which are presented to T cells via major histocompatibility complex molecules. CARs are programmed to recognize a specific cell surface protein. Because CARs are specific for a single antigen, or more precisely a single epitope within the single antigen, they are very narrowly focused and have limitations. When a CAR-T cell product is applied to a specific antigen of a heterogeneous disease, CAR-T cells may leave behind tumor cells that do not express the target antigen, which can lead to tumor relapse due to immune escape.

Our approach is to avoid genetic engineering by relying upon the native T cell receptor, which has evolved over millions of years to provide T cells with an exquisite capacity to recognize and kill cancer cells. Use of the native T cell receptor is the bedrock of our versatile immunotherapy, which is intended to provide a cost-effective and non-toxic strategy to target multiple tumor antigens and lead to durable responses. The process entails expanding tumor-specific T cells from patients (autologous), or a patient’s hematopoietic stem cell donor (allogeneic). This is achieved by *in vitro* manipulation consisting of co-culturing a patient’s or donor’s antigen presenting cells with patient (or donor) peripheral blood mononuclear cells, or PBMCs, respectively. As a source of antigen, we use overlapping peptide libraries spanning each of several immunogenic target antigens that are typically associated with certain types of cancer. These peptides are at least 15 amino acids in length, overlapping by approximately 11 amino acids and span the entire length of each of the target antigens. This typical footprint of peptides allows us to induce both $CD4^{+}$ (helper) and $CD8^{+}$ (cytotoxic) T cells. Following manufacture, these cells are frozen and stored for later infusion. Once infused, the natural characteristics of T cells take over and the T cells multiply in quantity, forming an army of T cells that kill the targeted cancer cells.

The MultiTAA-Specific T Cell Therapies

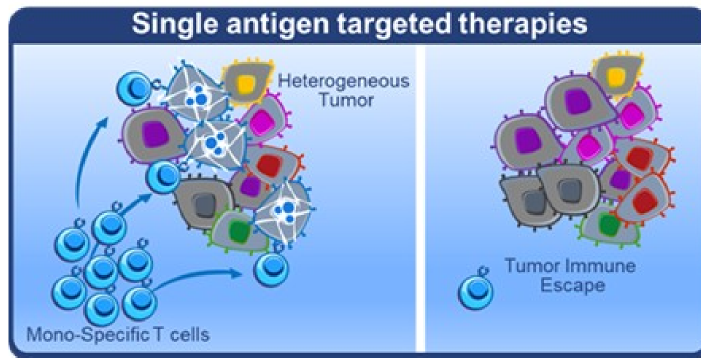
We are advancing two multiTAA-specific T cell therapies through clinical development:

- *Autologous multiTAA-specific T cell therapies* – The autologous product targets the NY-ESO-1, PRAME, MAGE - A4, Survivin, WT1 and SSX2 antigens (MT-601). We recently reported updated clinical data from our Phase 1 clinical trial investigating MT-601 for the treatment of patients with lymphoma who have relapsed after CAR T therapy. In addition, we received an Investigational New Drug (IND) cleared by the U.S. FDA to investigate MT-601 in a Phase 1 trial in patients with pancreatic cancer in combination with first-line chemotherapy.

- *Off-the-Shelf (OTS) multiTAA-specific T cell therapies* – The OTS product targets WT1, NY-ESO-1, PRAME, and Survivin antigens (MT-401-OTS). We plan to enroll patients that will be matched to the pre-manufactured inventory of MT - 401 - OTS products based on their human leukocyte antigen, or HLA. Because the MT-401-OTS product inventory is pre-manufactured, the T cell product is delivered to the patient in a significantly shorter amount of time than a patient-specific T cell product.

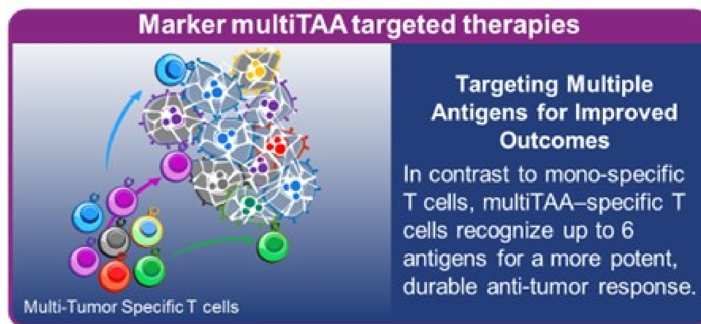
While the blood source and the antigens for stimulation differ between the autologous and OTS therapies, the manufacturing process for each product is identical.

Cancers are heterogeneous in their expression of antigens. Tumors generally consist of individual cancer cells expressing different antigens, and each of those antigens can be present at a different level that can change over time. Therapies targeting only a single antigen are vulnerable to evolutionary escape mechanisms.



While single-antigen specific therapies can eliminate all the tumor cells expressing the targeted antigen, the residual tumor cells that do not express that antigen may survive and expand. In addition, tumor cells may also downregulate or mutate the targeted antigen, thus becoming invisible to the T cell therapy. Both phenomena create a transformed tumor that is impervious to that therapy. This process is referred to as antigen-negative tumor escape.

Our solution to the problem of tumor heterogeneity is the development of T cell products that are intended to simultaneously attack multiple tumor-expressed antigens and thereby enable more complete initial tumor targeting, thus minimizing the subsequent opportunity for the cancer to engage escape mechanisms.



We believe our proprietary multiTAA-specific T cell platform may have meaningful advantages over current CAR and TCR-engineered cell therapy approaches. Compared to current gene-modified T cell therapies, the multiTAA-specific T cell product candidates are characterized by the following:

- **Clinical benefits observed in early-stage clinical trials in multiple cancer indications.**

Based on our observations in clinical trials in AML, pancreatic cancer, lymphoma, ALL and MM, we believe that the multiTAA-specific T cell therapies have the potential to mediate a meaningful anti-tumor effect, as well as significant in vivo expansion of T cells. For example, in BCM's Phase 1 clinical trial in lymphoma, there were complete responses, or CRs, in six of the fifteen evaluable patients with both Hodgkin lymphoma and non-Hodgkin lymphoma with active disease. Significantly, no patient with a CR has subsequently

relapsed with disease, whereas typically 30% or more of patients with CR in reported CAR-T studies relapse within one year. In patient results to date in this trial, observed therapeutic responses appear to be highly durable, with some patients being relapse-free beyond five years. In 2023, Marker treated the first patient in the Phase 1 APOLLO trial investigating the safety and efficacy of MT-601 in patients with lymphoma. Marker recently reported that the first patient treated in this Phase 1 study achieved a complete response 8 weeks after the second dose of MT-601 and that the patient maintained complete response to treatment 6 months after initial infusion with MT - 601.

- **Non-genetically modified T cells.**

Unlike CAR and TCR-based approaches, the multiTAA-specific T cell therapy does not require genetic modification of T cells, a costly and complex process that significantly complicates the manufacturing of a patient product. We believe our multiTAA-specific T cell therapy represent a safe alternative to CAR-T cells and can be manufactured at a fraction of the cost of a gene-modified T cell product, with substantially reduced complexity of manufacturing.

- **Low incidence rate of adverse events.**

As of January 2024, the multiTAA-specific T cell therapy was generally well tolerated by the patients across clinical trials in hematological and solid tumor indications, and no treatment-related adverse events, including CRS or neurotoxicity, were attributed to the use of multiTAA-specific T cell therapies to date. This appears to compare favorably with published CD19 CAR-T studies that have been associated with substantial tolerability concerns, including a Phase 1 trial in which 95% of patients had Grade 3 or higher adverse events during treatment and current investigations by the FDA regarding the risk of CAR-T cell therapies to potentially induce secondary cancers.

- **Capable of addressing a broad repertoire of cancer cells.**

While CAR-T and TCR therapies generally target a single epitope, our manufacturing process selects for T cells that are specific for multiple peptides derived from several targeted antigens. Deep gene sequencing of our products shows that a typical patient dose usually consists of approximately 4,000 unique T cell clonotypes, some of which target up to six different tumor-associated antigens. The six antigen targets can be recognized by a very wide range of T cells, which we believe facilitates robust killing of targeted cancer cells.

Clinical Development of Our multiTAA-Specific T Cell Therapies by BCM

The following clinical trials were conducted by BCM pursuant to our strategic alliance. In each trial, correlative studies showed significant expansion of multiTAA-specific T cells, as well as evidence of epitope spreading against tumor-associated antigens that were not targeted by the multiTAA-specific T cell therapy.

Acute Myeloid Leukemia

To date, available treatments for post-transplant AML patients are limited and include donor lymphocyte infusion, which has an approximately 15% overall response rate but a 30% to 50% risk of severe and debilitating graft-versus-host disease. The five-year mortality rate for patients who receive an allogeneic HSCT exceeds 50%, and patients who relapse after a transplant have a survival expectation of approximately 4.5 months.

BCM recently completed a Phase 1 AML/MDS clinical trial of the multiTAA-specific T cell therapy for the treatment of patients with post-transplant AML. In this trial, patients in remission with high risk for relapse, as well as patients with active disease post-transplant were treated. As reported in a 2021 publication by Lulla et al., 11 of the 17 patients in the adjuvant disease setting dosed with the multiTAA-specific T cell therapy after receiving an allogeneic HSCT did not relapse during the follow-up period of the study [median LFS not reached at a median follow-up of 1.9 years], with 11 of 15 patients (two patients were each treated during two different remissions) remaining alive (estimated two-year overall survival of 77%) at a median follow-up of 1.9 years post-infusion which compares favorably with HSCT outcomes for risk-matched AML/MDS patients post-HSCT [median LFS of nine to 15 months and two-year survival probability of 42%].

Additionally, eight patients were treated for active disease that was resistant to salvage therapy post-HSCT with a median of five prior lines of therapy (range: four to ten). One of the eight patients crossed over from the adjuvant group while two patients enrolled twice, but all three patients had active AML that failed another line of salvage therapy after their first multiTAA-specific T cell infusion. Two of the eight patients achieved objective responses with one complete response and one partial response, with six patients continuing with stable disease.

In this trial, the multiTAA-specific T cell therapy was well tolerated, with no drug-related serious adverse events and no instances of greater than Grade 2 acute graft-versus-host disease or moderate-severe chronic GVHD. The maximum grade treatment-related adverse event was seen in one patient in the adjuvant disease group who had a possibly drug-related Grade 3 elevation of liver enzymes but was treated with prednisone with complete resolution. After discontinuing treatment and receiving decitabine, the patient relapsed and later re-enrolled in the trial in the active disease group and entered CR for 13 months and survived for 2.5 years.

Pancreatic Cancer

In May 2020, we reported interim data from an ongoing Phase 1/2 clinical trial of the multiTAA-specific T cell therapy for the treatment of pancreatic adenocarcinoma being conducted by BCM. In 2020, we reported that in this trial, BCM administered multiTAA-specific T cells to a total of 31 patients with advanced or borderline resectable pancreatic adenocarcinoma in three arms: 13 patients in Arm A, which included patients with unresectable/metastatic disease who were responding to standard first-line chemotherapy; 12 patients in Arm B, which included patients with progressive disease or therapy intolerance; and eight patients in Arm C, which includes patients with surgically resectable disease.

Overall, we have observed a clinical benefit correlated with the detection of tumor-reactive T cells in patient peripheral blood (Arms A, B and C) and within tumor biopsy samples (Arm C) post-infusion. No cytokine release syndrome or neurotoxicity has been observed in any arm of the trial to date.

Arm A was designed to evaluate the safety and potential efficacy of using multiTAA-specific T cell therapy as part of first-line treatment for patients with pancreatic cancer. These patients in the chemo-responsive arm have completed at least three months of standard-of-care chemotherapy (gemcitabine/nab-paclitaxel or FOLFIRINOX), which is the period during which a response to chemotherapy would typically occur, before receiving up to six administrations of multiTAA-specific T cell therapy in conjunction with chemotherapy.

- Out of the 13 evaluable patients (best overall response):
  - four patients experienced objective responses after administration of multiTAA-specific T cells;
  - one patient experienced a radiographic complete response occurring at month nine after starting chemotherapy;
  - three patients experienced partial responses per RECIST occurring at six-nine months after starting chemotherapy;
  - six patients experienced stable disease;
  - one patient experienced a mixed response.
- Patients had durable cancer control with nine of the 13 patients exceeding historical control of overall survival;
- Five patients enrolled in the study were not administered multiTAA-specific T cells, either because of disease progression (four patients) which made them ineligible for treatment, or because insufficient starting material from the patient was available for manufacturing (one patient);
- Evidence of epitope-spreading was observed in all responders, suggesting that the multiTAA-specific T cell therapy triggered the recruitment of a broader endogenous immune system response for improved anti-tumor activity;
- No infusion-related reactions, cytokine release syndrome or neurotoxicity was observed;

In patients responding to therapy, significant expansion of the infused multiTAA-specific T cell therapy was observed.

Lymphoma

BCM evaluated the multiTAA-specific T cell therapy (5 TAA product) in a Phase 1 clinical trial for the treatment of patients with lymphoma. A total of 32 patients received two protocol-specified infusions of multiTAA-specific T cells, 14 with Hodgkin lymphoma, or HL, and 18 with aggressive non-Hodgkin lymphoma, or NHL, [diffuse large B-cell lymphoma, or DLBCL, (n=12), mantle cell lymphoma, or MCL, (n=2), T-cell lymphoma (n=3) and composite lymphoma (HL and DLBCL, n=1)].

As reported in a recent publication by Vasileiou et al., BCM had treated 15 patients with active disease (active lymphoma group), all of whom had completed a follow-up period beyond three months post-infusion. These patients were heavily pre-treated and had failed a median of five prior lines of therapy (range four to eight) for the HL patients and a median of three prior lines of therapy (range three to four) for the NHL patients. As illustrated below, in the active lymphoma group, six patients entered CR and nine patients had experienced stable disease. None of the patients in CR had relapsed, and the range for the duration of CR in these patients was between two and over five years after being infused with the multiTAA-specific T cell therapy with the exception of one patient who died of an unrelated pneumonia while in a CR. Responses in all six patients who entered CR were associated with an expansion of infused T cells, as well as induction of broad-based antigen spreading across many tumor-associated antigens.

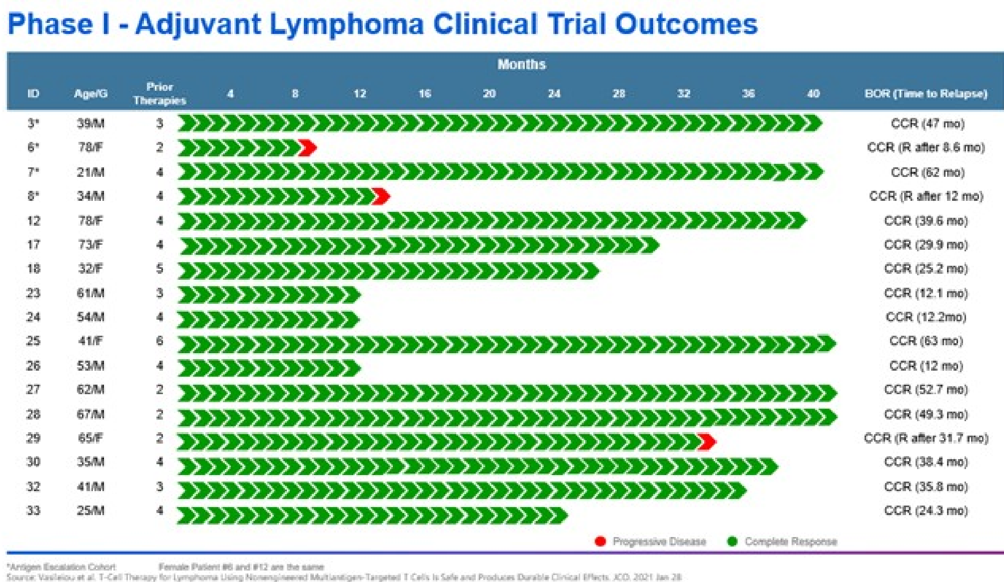
Phase I - Active Lymphoma Clinical Trial Outcomes

ID	Age/G	Prior Therapies	Months: 2 4 6 8 10 12 14 16 18 20 22	BOR (Time to Relapse)
1*	31/F	9		SD (1.4 mo)
2*	55/F	3		CR (3.2mo) Died of unrelated pneumonia
4*	38/M	7		CR (60.8 mo)
5*	44/F	4		SD (2.5 mo)
9	46/M	4		CR (59.4 mo)
10	46/F	3		CR (48.7 mo)
11	31/F	9		SD (9 mo)
13	69/M	3		CR (38.5 mo)
14	54/M	3		SD (6 mo)
15	18/F	5		SD (3.1 mo)
16	48/M	4		CR (30.9 mo)
19	49/M	7		SD (1.4 mo)
20	54/M	4		SD (4.1 mo)
21	64/M	5		SD (1.4 mo)
22	68/M	3		SD (5 mo)

Progressive Disease · Complete Response · Stable Disease · Another line of therapy while in SD

*Antigen Escalation Cohort
Source: Vasileiou et al. T-Cell Therapy for Lymphoma Using Nonengineered Multiantigen-Targeted T Cells Is Safe and Produces Durable Clinical Effects. JCO. 2021 Jan 28.

BCM also treated 17 patients, including one patient who was treated a second time after a relapse, in remission (adjuvant lymphoma group). Like the active lymphoma group, these patients were heavily pre-treated with seven patients with HL treated with a median of 4 prior lines of therapy (range three to five) and 10 patients with NHL with a median of three prior lines of therapy (range one to five). As illustrated below, in the adjuvant lymphoma group, all 17 patients had entered CR, with 14 patients in continued complete remission, or CCR, without relapsing. The duration of response ranged from approximately nine months to over five years.



In both treatment groups, the multiTAA-specific T cell therapy was well tolerated, with no drug-related serious adverse events.

Process Development and Manufacturing of the MultiTAA-Specific T Cell Therapies

In the manufacturing process, blood is drawn from either the individual patient (in the case of the autologous T cells) or from a healthy donors/commercially available leukapheresis material (in the case of the OTS program). Although the T cells that are selected and expanded by our process exist in a patient's circulating blood, these T cells are often present at very low frequencies. Researchers at BCM believe that these T cells are adversely affected by the suppressive tumor microenvironment. It is a well-accepted concept that cancers not only evade immune detection but often actively suppress the function of the human immune system. Our manufacturing and culturing process is intended to (1) identify the T cells specific for the antigens that we intend to target, (2) restore these T cells to functionality with respect to their anti-tumor capability and (3) expand the population of those T cells specific for our targets to achieve the required patient dose.

After blood is drawn, PBMCs are isolated and used to manufacture a patient-specific product. These cells are placed inside a G-Rex manufacturing device and combined with an experimentally optimized mix of GMP-grade cytokines that is used to restore and enhance the functional capability of the cultured T cells. In addition, libraries of overlapping peptides, which we refer to as peptide pools, are added to the cell culture. Each peptide within a peptide pool represents a small segment of a target antigen, which a T cell might recognize. Each library represents the entire protein sequence of a target antigen, with each peptide overlapping significantly with the peptides adjacent to it within the antigen's protein sequence. This overlapping structure allows us to isolate, activate and expand any T cell that is specific for any segment of the antigens that we target in the unique genetic background of every patient.

The G-Rex is a cell culture device manufactured by Wilson Wolf Manufacturing Corporation, or Wilson Wolf, used by many cell therapy developers, both in commercial and academic settings. The device allows a user to introduce cells, medium and other reagents into a cell culture chamber, which has a gas-permeable membrane at its bottom. The cells settle on this gas-permeable membrane through which oxygen and carbon dioxide are exchanged (i.e. the cells can breathe at the base of the device), while nutrients required for cell expansion are obtained from the medium above the cells. This system allows for the highly robust growth of cells in culture, by providing them with superior access to oxygen and nutrients. Cells manufactured in the device grow efficiently without need for agitation by a technician, scientist or automated system.

Inside the G-Rex, PBMCs, including T cells and antigen-presenting cells, are exposed to the stimulating peptide pools. This results in the selective expansion of T cells that specifically recognize the target antigens. At the end of the manufacturing process, the resulting product is a mix of helper (CD4+) and cytotoxic (CD8+) T cells that recognize the targeted antigens.

Once cell manufacturing is complete, the product is tested for identity, sterility, phenotype and functionality before it is released for infusion into a patient. Sampling of product indicates that, on average, approximately 4,000 different T cell clonotypes are present in a typical 5-antigen-specific patient product.

Upon release of the final patient product, the cells are frozen and transported to the site where the cells will be administered. The standard dose for patients with lymphoma ranges from 100 to 400 million cells per adult patient.

Manufacturing

The manufacturing process was originally developed at Baylor College of Medicine, where we also conducted our clinical trials. In 2021, we validated an additional manufacturing site (now Cell Ready) for our multiTAA-specific T cell products.

On June 26, 2023, we completed the transaction with Cell Ready, LLC, or Cell Ready, pursuant to a Purchase Agreement, or the Cell Ready Purchase Agreement, dated May 1, 2023, by and between us and Cell Ready. Pursuant to the Cell Ready Purchase Agreement, effective as of the Closing Date, we (i) assigned to Cell Ready the leases for our two manufacturing facilities in Houston, Texas, or the Manufacturing Facilities, (ii) sold to Cell Ready all of the equipment and leasehold improvements at the Manufacturing Facilities and (iii) assigned to Cell Ready our rights, title and interest in any contracts related to the equipment and Manufacturing Facilities (collectively referred to as the “Purchased Assets”). Cell Ready acquired the Purchased Assets for total consideration of $19.0 million.

On February 22, 2024, we entered into a Master Services Agreement for Product Supply, or MSA, with Cell Ready. Cell Ready, which is owned by one of our directors and shareholders, Mr. John Wilson, is a contract development and manufacturing organization (CDMO). Under the MSA, it is anticipated Cell Ready will perform a wide variety of services for us, including research and development, and manufacturing in support of our clinical trials. Pursuant to the MSA, the Company may contract with Cell Ready for the provision of various products and services from time to time by entering into work orders with Cell Ready. If the services involve the supply of product, Cell Ready is required to supply such product in conformance with the product requirements set forth in the applicable work order(s). Under the MSA, Cell Ready is to use only personnel with sufficient qualifications and experience to supply the services contemplated by the MSA, provide its personnel with adequate training and assume full responsibility for its personnel’s compliance with the MSA. Further, Cell Ready is required to provide the Company with assistance and cooperation in order for the Company to obtain and maintain all necessary regulatory approvals, at the Company’s expense.

Competition

We face competition from numerous pharmaceutical and biotechnology companies, as well as from academic institutions, private and public research institutions, and government agencies. Treatment of relapsed patients with lymphoma remains a challenge with relatively low overall survival rates. To date, there are four CD19-directed CAR T cell therapies (Yescarta, Kymriah, Tecartus, and Bryanzi) approved for patients with relapsed lymphoma. However, up to 60% of CD19 CAR T cell treated patients will relapse, particularly in the third line setting (Chong EA et al, N Engl J Med, 2021). This highlights a significant unmet medical need for alternative and more effective treatments. Our multiTAA-specific T cell drug candidates may compete with product candidates from a number of companies, which are developing various types of immunotherapies to treat cancer, including non-CD19 targeting CAR T cells that target different antigens beyond CD19, multi-targeted CAR T cells as well as NK-CAR therapies. In addition, bispecific antibodies represent promising therapies for patients with lymphoma and provide competition in the oncology space. To date, MT-601 is the only natural T cell product that targets multiple tumor antigens being explored for CAR relapse patients with lymphoma. Therefore, MT-601 fills a void in the market by providing much needed treatment option to the lymphoma patient population.

We believe that our non-engineered T cell therapy approaches will be synergistic and may improve therapies being developed by potential competitors. Many companies and institutions, either alone or together with their collaborative partners, have substantially greater financial, technical and human resources, and significantly greater experience than we do in the following:

- drug discovery;
- developing products;
- undertaking preclinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of products; and
- manufacturing, marketing, distributing and selling products.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA and other regulatory approval or commercializing products that compete with our drug candidates.

In addition, any drug candidate that we successfully develop may compete with existing therapies that have long histories of safe and effective use. Competition may also arise from:

- other drug development technologies and methods of preventing or reducing the incidence of disease;
- new small molecules; and/ or
- other classes of therapeutic agents.

We face, and will continue to face, competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions and for licenses to drug candidates or proprietary technology. These competitors, either alone or with their collaborative partners, may succeed in developing products that are more effective than ours.

Our ability to compete successfully will depend, in part, on our ability to:

- develop proprietary products;
- develop and maintain products that reach the market first, are technologically superior to and/or are of lower cost than other products in the market;
- attract and retain scientific, product development and sales and marketing personnel;

- obtain patent or other proprietary protection for our products and technologies;
- obtain required regulatory approvals; and
- manufacture, market, distribute and sell any products that we develop.

In a number of countries, including in particular, developing countries, government officials and other groups have suggested that pharmaceutical companies should make drugs available at a low cost. In some cases, governmental authorities have indicated that where pharmaceutical companies do not do so, their patents might not be enforceable to prevent generic competition. Some major pharmaceutical companies have greatly reduced prices for their drugs in certain developing countries. If certain countries do not permit enforcement of any of our patents, sales of our products in those countries, and in other countries could be reduced by generic competition or by parallel importation of our product. Alternatively, governments in those countries could require that we grant compulsory licenses to allow competitors to manufacture and sell their own versions of our products in those countries, thereby reducing our product sales, or we could respond to governmental concerns by reducing prices for our products. In all these situations, our results of operations could be adversely affected.

BCM Exclusive License Agreement

On March 16, 2018, we entered into an exclusive license agreement, or the BCM License Agreement, with BCM, under which we received a worldwide, exclusive license to BCM's rights in and to certain intellectual property rights, including European patent EP 2470644 (estimated expiration date August 24, 2030), to develop and commercialize multiTAA-specific T cell product candidates.

Exclusive License to BCM's Subject Technology:

1. "Generation of CTL Lines with Specificity Against Multiple Tumor Antigens or Multiple Viruses"

2. "Pepmixes to Generate Multiviral CTLs with Broad Specificity"

3. "Immunogenic Antigen Identification from a Pathogen and Correlation to Clinical Efficacy"

4. "T cell performance assay as a prognostic factor for clinical outcome"

In partial consideration for the exclusive rights granted under the BCM License Agreement, Marker Cell Therapy, Inc., an entity that is now our wholly owned subsidiary, issued shares of its common stock to BCM valued at approximately $5.0 million at the time of issuance. Such initial equity issuance was exchanged into merger consideration of 149,081 shares of our common stock and warrants to acquire 54,064 shares of our common stock in connection with the merger we completed in October 2018, each as adjusted to reflect the reverse stock split that we effected in January 2023. Additional consideration includes a royalty paid on net sales by us to BCM according to the royalty schedule in the BCM License Agreement. The royalty fee schedule is based on aggregate net sales in four different ranges: (1) less than $500 million, (2) $500 million to $1.0 billion, (3) $1.0 billion and over, and (4) $2.0 billion and over. The corresponding royalty percentages range from 0.65% to 5.0% - increasing in proportion to the aggregate net sales. The royalty fee may be reduced in the event that we must pay additional royalties with respect to third-party owned patent rights or technology necessary for the use, manufacture or sale of a licensed product. We also agreed to pay BCM up to an aggregate of $64.85 million in milestone payments upon the occurrence of nine particular milestones relating to completion of the first dosing in clinical trials for a first and second distinct product, receipt of approval from the FDA and the achievement of certain net sales goals. We are also responsible for sublicensing fees. In addition, under the BCM License Agreement, we are responsible for reimbursing BCM for patent-related expenses. BCM is responsible for filing, prosecuting and maintaining all patent applications and patents included in the licensed patent rights, and we have agreed to reimburse BCM for all such related legal costs incurred after the date of the BCM License Agreement, except such legal costs shall be reduced on a pro-rata basis on a patent or patent application basis should BCM license such patent or patent application in additional fields of use to any third party.

In addition, upon a liquidity event (as defined in the BCM License Agreement) of the Company, BCM will receive a liquidity incentive payment of 0.5% of the liquidity event proceeds (as defined in the BCM License Agreement).

We have agreed to indemnify BCM and certain persons affiliated with BCM against claims and liabilities directly or indirectly related to or arising out of the design, process, manufacture or use by any third party of the licensed products, even though such claims and liabilities result in whole or in part from the negligence of the BCM indemnified parties or are based upon doctrines of strict liability or product liability, but not claims or liabilities arising from the gross negligence or intentional misconduct of any such BCM indemnified parties.

Unless terminated sooner, the license will expire on a licensed product-by-product basis and country-by-country basis, on the later of (1) the date of expiration of the last valid claim of patent rights to expire that covers the sale of such licensed product in such country, or (2) the first date following the tenth anniversary of the first commercial sale of first licensed product by us in such country. After such expiration, but not termination, the licenses granted to us shall survive and become a perpetual, paid-in-full license in such country with respect to such licensed product.

We have the right in our sole discretion to terminate the BCM License Agreement upon 60 days' written notice to BCM. BCM has the right to terminate the agreement upon material default or failure of us of our overall obligation to perform any of the terms, covenants or provisions of the license agreement, including failure to make timely payment, taken as a whole, and which default or failure remains uncured thirty days after written notice from BCM of such material default or failure to correct such default or failure. Notwithstanding the foregoing, if a material default or failure is not susceptible to cure within the 30-day cure period, BCM's right to terminate shall be suspended if, and for so long as, (1) we have provided BCM with a written plan that is reasonably calculated to effect a cure, (2) such plan is reasonably acceptable to BCM, in its sole but reasonable discretion, and (3) we commit to and do carry out such plan; provided, however, that, unless mutually agreed to by the parties in such plan, such suspension of BCM's right to terminate shall not extend beyond 60 days after the original cure period. In addition, either party's right to terminate the license agreement shall be tolled for so long as dispute resolution procedures are being pursued by the allegedly breaching party in good faith, and if it is finally and conclusively determined that the allegedly breaching party is in material breach, then the breaching party shall have the right to cure within 30 days after such determination. BCM also has the right to terminate the agreement if we shall (1) become involved in insolvency, dissolution, bankruptcy or receivership proceedings affecting the operation of our business, (2) make an assignment of all or substantially all of our assets for the benefit of creditors, or (3) if a receiver or trustee is appointed for us and we, after the expiration of 30 days following any of the enumerated events, are unable to secure a dismissal, stay or other suspension of such proceedings.

In the event of termination of the BCM License Agreement, but not expiration, all rights to the subject technology and patent rights thereunder shall revert to BCM, except to the extent necessary to exercise any surviving right or license thereunder. We may sell any licensed products actually in our possession at the effective date of termination, provided that we continue to pay to BCM royalties on all such sales in accordance with the license agreement, otherwise comply with the terms of the license agreement and sell all such licensed products within six months after the effective date of the termination.

In furtherance of the BCM License Agreement and as contemplated by the terms thereof, we entered into a Sponsored Research Agreement, or the SRA, with BCM, which provides for the conduct of research for us by credentialed personnel at BCM's Center for Cell and Gene Therapy.

We have entered into additional agreements with BCM with respect to a strategic alliance to advance pre-clinical research, early-stage clinical trials, and Phase 2 clinical trials with respect to our product candidates, as well as continued access to our clinical data, and product manufacturing and support, including personnel and space at the institution for the foreseeable future.

Intellectual Property

Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions, improvements, and know-how related to the business; to defend and enforce proprietary rights, including any patents that we may own in the future; to preserve the confidentiality of our trade secrets and other intellectual property; to obtain and maintain licenses to use intellectual property owned by third parties; and to operate without infringing valid and enforceable patents and other proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell, or importing our products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities — for example, the rights obtained under exclusive license arrangements such as those pursuant to our BCM License Agreement. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed in the future, nor can we be sure that any of our existing

patents or any patents that may be granted in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same.

To achieve this objective, a strategic focus for us has been identifying and licensing key patents and patent applications that serve to enhance our intellectual property and technology position. Currently, all of our multiTAA-specific T cell intellectual property rights are licensed from BCM. Our intellectual property portfolio currently includes patent applications having: (1) claims directed to methods of generating multi-antigen specific T cell products; and (2) claims directed to therapeutic uses of such multi-antigen specific T cell products. We believe our patent portfolio, together with our efforts to develop and patent next-generation technologies, provides us with a substantial intellectual property position. However, the area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties.

Patents

Patents and other proprietary rights are vital to our business operations. We protect our technology through various United States and foreign patent filings and maintain trade secrets that we own. Our policy is to seek appropriate patent protection both in the United States and abroad for our proprietary technologies and product candidates. An enforceable patent with appropriate claim coverage can provide an advantage over competitors who may seek to employ similar approaches to develop therapeutics, and so the future commercial success of products, and therefore our future success, will be in part dependent on our intellectual property strategy. We reassess the value of each patent at the time maintenance fees are due, and in cases where maintaining the patent is judged to be of no significant strategic value, we decline to pay the maintenance fee.

There can be no assurance that our patents, and any patents that may be issued, assigned, or licensed to us in the future, will afford protection against competitors with similar technology. In addition, no assurances can be given that any patents issued, assigned, or licensed to us will not be infringed upon or designed around by others or that others will not obtain patents that we would need to license or design around. If existing or future patents held by third parties and containing broad claims over technology used by us were upheld by a court or other authority of competent jurisdiction, the holders of such patents could require us to obtain licenses to use such technology.

Patent coverage may also vary from country to country based on the scope of available patent protection. Moreover, in the United States, patent term may be adjusted to account for delays by the United States Patent and Trademark Office, or USPTO, during prosecution. There are also opportunities to obtain an extension of term for patents covering a product in certain jurisdictions, which adds further complexity to the determination of patent life.

The effect of the issued United States patents is that they provide us with patent protection for the claims covered by the patents. While the expiration of a product patent normally results in a loss of market exclusivity for the covered product or product candidate, commercial benefits may continue to be derived from , for example: (1) later- expiring patents on processes and intermediates related to improved methods of manufacture of the active ingredient of such product; (2) patents relating to the use of such product; (3) patents relating to novel compositions and formulations; and (4) in the United States and certain other countries, other types of market exclusivity that may be available under relevant law. The effect of patent expiration on our product candidates also depends upon many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

Our pending patent applications cover a range of technologies, including specific embodiments and applications for treatment of various medical indications, improved application methods and adjunctive utilization with other therapeutic modalities. The coverage claimed in a patent application can be significantly reduced before the patent is issued. Accordingly, we do not know whether any of the patent applications we own, will acquire, license, or will license will issue as patents, or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because unissued U.S. patent applications are maintained in secrecy for a period of eighteen months and U.S. patent applications filed prior to November 29, 2000 are not disclosed until such patents are issued, and since publication of discoveries/inventions in the scientific or patent literature often lags behind actual discovery/invention, we cannot be certain of the priority of inventions covered by pending patent applications and whether potentially relevant earlier patent filings exist. Moreover, we may have to participate in opposition proceedings in a foreign patent office, or for United States patent applications filed before March 16, 2013, in interference proceedings declared by the USPTO, to determine priority of invention, or in United States inter partes review or post-grant review procedures, any of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued, would be held valid by a court or other authority of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties, or require us to cease using such technology.

We have patents and patent applications in other countries, as well as in the European Patent Office, that we believe provide equivalent or comparable protection for our product candidates in jurisdictions internationally that we consider to be key markets. Because of differences in patent laws and laws concerning proprietary rights, the extent of protection provided by U.S. patents or proprietary rights owned by us may differ from that of their foreign counterparts.

Trade Secrets

We also rely on trade secrets and know-how relating to our proprietary technology and product candidates, continuing innovation, and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of immuno-oncology. However, trade secrets can be difficult to protect. We also plan to rely on regulatory protection afforded through orphan drug designations, data exclusivity, market exclusivity and patent term extensions when available, as well as contractual agreements with our academic and commercial partners.

We require each of our employees, consultants and advisors to execute a confidentiality agreement upon the commencement of any employment, consulting or advisory relationship with us. Each agreement provides that all confidential information developed or made known to the individual during the course of the relationship will be kept confidential and not be disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions conceived by an employee shall be our exclusive property.

Trademarks

We currently have pending with the USPTO applications for registration of the trademarks “Marker Therapeutics.” We also have rights to use other names essential to our business. Federally registered trademarks have a perpetual life if they are maintained and renewed on a timely basis and used properly as trademarks, subject to the rights of third parties to seek cancellation of the trademarks if they claim priority or confusion of usage. We regard our trademarks and other proprietary rights as valuable assets and believe they have significant value to us.

We believe that our patents, the protection of discoveries in connection with our development activities, our proprietary products, technologies, processes and know-how and all our intellectual property are important to our business. There can be no assurance that any of our patents, licenses or other intellectual property rights will afford us any protection from competition.

Government Regulation

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a biologics license application, or BLA, after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial. Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so- called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must 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 product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a 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. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application 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. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and 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. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast-track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast-track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast-track product has opportunities for frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast-track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the 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. The designation includes all of the fast-track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast-track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA’s goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

The regenerative medicine advanced therapy, or RMAT, designation is intended to facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Fast track designation, breakthrough therapy designation, priority review, accelerated approval, and RMAT designation do not change the standards for approval but may expedite the development or approval process.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is 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 available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors 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, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw 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 revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or

- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic 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 biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

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. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program; federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to the federal government, including federal healthcare programs, that are false or fraudulent; the Health Insurance Portability and Accountability Act, or HIPAA, which created additional federal criminal statutes which prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters, and which, as amended by Health Information Technology for Economic and Clinical Health Act, or HITECH, also imposes certain requirements on HIPAA covered entities and their business associates and covered subcontractors relating to the privacy, security and transmission of individually identifiable health information; the U.S. federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the federal government, information related to payments or other transfers of value made to physicians (as defined by the Physician Payments Sunshine Act), other covered physicians and teaching hospitals, as well as ownership and investment interests held by health care professionals and their immediate family members; and U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. In addition, certain states require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and certain states and local jurisdictions require the registration of pharmaceutical sales representatives. If their operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to penalties, including, without limitation, significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Further, 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 the company receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product. No regulatory authority has granted approval for a personalized cancer immunotherapy based on a vaccine approach, and there is no model for reimbursement of this type of product.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

In March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions of particular importance to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, 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, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, the Tax Cuts and Jobs Act was enacted, which, among other things, removed penalties for not complying with ACA's individual mandate to carry health insurance. In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is also unclear how such challenges, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2%, which due to subsequent legislative amendments, including the Infrastructure Investment and Jobs Act, will stay in effect per fiscal year through 2031, except for a temporary suspension from May 1, 2020 through March 32, 2021 due to COVID-19 relief legislation, unless additional Congressional action is taken, and reduced payments to several types of Medicare providers. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Congress is also considering additional health reform measures as part of other reform initiatives. Moreover, there has recently 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. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump Administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020 providing pathways for states to build and submit importation

plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. However, it is unclear whether these or similar policy initiatives will be implemented in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Product Liability and Insurance

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. We have not experienced any product liability claims to date. We currently carry products and clinical trial liability insurance policies. There can be no assurance that liability claims will not exceed such insurance coverage limits, which could have a materially adverse effect on our business, financial condition or results of operations or that such insurance will continue to be available on commercially reasonable terms, if at all.

Human Resources

Employees

As of December 31, 2023, we had 8 full-time employees. There were 6 in clinical and 2 were in administrative support. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Consultants

We have consulting agreements with a number of leading academic scientists, clinicians and regulatory experts. They serve as important contacts for us throughout the broader scientific and clinical communities. They are distinguished individuals with expertise in numerous fields, including cellular biology, molecular biology, oncology, clinical, manufacturing and regulatory.

We retain each consultant according to the terms of a consulting agreement. Under such agreements, we pay them a consulting fee and reimburse them for out-of-pocket expenses incurred in performing their services for us. In addition, some consultants hold options to purchase our common stock, subject to the vesting requirements contained in separate award agreements. Our consultants may be employed by other entities and therefore may have commitments to their employer or may have other consulting or advisory agreements that may limit their availability to us.

Human Capital Resources

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of equity-based compensation awards. We strive to create a diverse environment, and our commitment to diversity, equity and inclusion begins with our leadership team of diverse backgrounds and experiences. 100% of our executive officers are women or self-identify as a member of an underrepresented minority group.

Corporate Information

We were incorporated under the laws of the State of Nevada in 1991 under the name "TapImmune, Inc." and reincorporated in Delaware in October 2018 under the name "Marker Therapeutics, Inc." Our principal executive offices are located at 9350 Kirby Drive, Suite 300, Houston, Texas 77054, and our telephone number is (713) 400-6400. Our common stock is listed for trading on the Nasdaq Capital Market under the symbol "MRKR".

Available Information

Our website is located at *www.markertherapeutics.com*. We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission. Our website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below before making an investment decision in our securities. These risk factors are effective as of the date of this Form 10-K and shall be deemed to be modified or superseded to the extent that a statement contained in our future filings modifies or replaces such statement. All of these risks may impair our business operations. The forward-looking statements in this Form 10-K involve risks and uncertainties and actual results may differ materially from the results we discuss in the forward-looking statements. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected. In that case, the trading price of our stock could decline, and you may lose all or part of your investment.

Risks Associated with Our Business

Our business is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in this "Risk Factors" section and include, among others:

- We are a clinical stage company with a history of operating losses, and we expect losses to continue for the indefinite future. These factors raise substantial doubt regarding our ability to continue as a going concern.
- All of our product candidates are in clinical development. If we are unable to successfully develop, receive regulatory approval for and commercialize our product candidates, or successfully develop any other product candidates, or experience significant delays in doing so, our business will be harmed.
- The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.
- The results of earlier preclinical and clinical trials may not be predictive of future clinical trial results.
- Our preclinical studies and clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.
- We are dependent on third-party vendors to maintain and support our manufacturing and cell processing. If any of our third-party vendors experience disruptions, or otherwise cease or substantially reduce their operations, our business and operations could be adversely affected.
- Our strategic relationship with BCM is dependent, in part, upon our ongoing relationship with key medical and scientific personnel and advisors.

- Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and the medical community.
- The biotechnology and immunotherapy industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises.
- If we are unable to protect our proprietary rights, we may not be able to compete effectively or operate profitably.
- We are subject to extensive regulation, which can be costly, time consuming and can subject us to unanticipated delays. Even if we receive regulatory approval of our product candidates, we will be subject to ongoing quality and regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.
- The price of our stock may be volatile.

Risks Related to our Financial Position and Capital Needs

We are a clinical stage company with a history of operating losses, and we expect losses to continue for the indefinite future. These factors raise substantial doubt regarding our ability to continue as a going concern.

We are a clinical-stage immunotherapy company with a history of losses, and we may always operate at a loss. We expect that we will continue to operate at a loss throughout our development stage, and as a result, we may exhaust our financial resources and be unable to complete the development of our product candidates. We anticipate that our ongoing operational costs will increase significantly, and our deficit will continue to grow, as we continue conducting our clinical development program.

We have no approved products or product candidates pending approval. As a result, we have not derived any revenue from the sales of products and have not yet demonstrated ability to obtain regulatory approval, formulate and manufacture commercial-scale products, or conduct sales and marketing activities necessary for successful product commercialization. We have no sources of significant revenue to provide incoming cash flows to sustain our future operations. Our ability to pursue our planned business activities depends upon our successful efforts to raise additional financing, which may be adversely impacted by potential worsening global economic conditions, including decades-high inflation and concerns of a recession in the United States or other major markets, and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide. Weakness and volatility in the capital markets and the economy in general could also increase our costs of borrowing. Such additional financing may not be available on favorable terms, or at all.

We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future due to the substantial investment in research and development. We expect that our cash and cash equivalents as of December 31, 2023, together with the drawdowns from available grant funds, will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2025. We expect to spend substantial additional sums on the continued administration and research and development of licensed and proprietary product candidates and technologies with no certainty that our approach and associated technologies will become commercially viable or profitable as a result of these expenditures. If we fail to raise a significant amount of capital, we may need to significantly curtail operations, allocate limited financial resources among our product candidates, or cease operations in the near future. If any of our product candidates fail in clinical trials or do not gain regulatory approval, we may never generate revenue. Even if we generate revenue in the future, we may not be able to become profitable or sustain profitability in subsequent periods.

These and other factors raise substantial doubt regarding our ability to continue as a going concern, which may create negative reactions to the price of our common stock. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. Further, the perception that we may be unable to continue as a going concern may impede our ability to pursue strategic opportunities or operate our business due to concerns regarding our ability to discharge our contractual obligations. In addition, if there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, or at all.

Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver.

Although a statement by the U.S. Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day following the date of closure, uncertainty and liquidity concerns in the broader financial services industry remain. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. The U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments. However, widespread demands for customer withdrawals or other needs of financial institutions for immediate liquidity may exceed the capacity of such program. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions in a timely fashion or at all.

Our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws, any of which could have material adverse impacts on our operations and liquidity.

Risks Related to the Development of our Product Candidates

All of our product candidates are in clinical development. If we are unable to successfully develop, receive regulatory approval for and commercialize our product candidates, or successfully develop any other product candidates, or experience significant delays in doing so, our business will be harmed.

We are early in our development efforts and all of our product candidates are still in clinical development. Each of our programs and product candidates will require additional preclinical and/or clinical development, regulatory approval, obtaining manufacturing supply, capacity and expertise, building a commercial organization or successfully outsourcing commercialization, substantial investment and significant marketing efforts before we generate any revenue from product sales. We do not have any products that are approved for commercial sale, and we may never be able to develop or commercialize marketable products.

Our ability to generate revenue from our product candidates, which we do not expect will occur for several years, if ever, will depend heavily on the successful development, regulatory approval and eventual commercialization of our product candidates. The success of our multiTAA product candidates or any other product candidates that we develop or otherwise may acquire will depend on several factors, including:

- timely and successful completion of preclinical studies, including toxicology studies, biodistribution studies and minimally efficacious dose studies in animals, where applicable, and clinical trials;

- effective investigational new drug applications, or INDs, from the FDA or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates;

- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;

- successful enrollment and completion of clinical trials, including under the FDA's current Good Clinical Practices, or GCPs, and current Good Laboratory Practices;
- successful development of, or making arrangements with third-party manufacturers for, our commercial manufacturing processes for any of our product candidates that receive regulatory approval;
- receipt of timely marketing approvals from applicable regulatory authorities;
- launching commercial sales of products, if approved, whether alone or in collaboration with others;
- acceptance of the benefits and use of our products, including method of administration, if approved, by patients, the medical community and third-party payors, for their approved indications;
- the prevalence and severity of adverse events experienced by our product candidates;
- the availability, perceived advantages, cost, safety and efficacy of alternative therapies for any product candidate, and any indications for such product candidate, that we develop;
- our ability to produce any product candidates we develop on a commercial scale;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our product candidates and otherwise protecting our rights in our intellectual property portfolio;
- maintaining compliance with regulatory requirements, including the FDA's current Good Manufacturing Practices, or cGMPs, and complying effectively with other procedures;
- obtaining and maintaining third-party coverage and adequate reimbursement and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement; and
- maintaining a continued acceptable safety, tolerability and efficacy profile of the products following approval.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for any product candidate we develop, we may not be able to continue our operations.

Because we have limited financial and management resources, we must focus on development programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for these product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

Any immunotherapies that we may develop are not likely to be commercially available for at least three years. Any delay in obtaining FDA and/or other necessary regulatory approvals in the United States and in countries outside the United States for any investigational new drug and failure to receive such approvals would have an adverse effect on the investigational new drug's potential commercial success and on our business, prospects, financial condition and results of operations. The time required to obtain approval by the FDA and non-U.S. regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities.

We have not previously submitted a biologics license application, or BLA, to the FDA, or similar approval filings to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of cell therapies for cancer. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained, and the FDA or non-U.S. regulatory authorities may disagree with the design or implementation of our clinical trials or study endpoints.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval by an independent institutional review board, or IRB, at each clinical trial site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a subject by subject basis for use in clinical trials.

Further, the performance of our CROs may also be interrupted by health epidemics or other disruptions, including due to travel or quarantine policies or prioritization of resources toward such health epidemic or disruption. We could also encounter delays if physicians face unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRB for the institutions in which such trials are being conducted, the Data and Safety Monitoring Board or Committee for such trial, or by the FDA or other regulatory authorities due to a number of factors. Those factors could include 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 the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Preclinical studies and clinical trials are expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. Further, we may encounter substantial delays in completing the development of our product candidates.

All of our product candidates are in clinical development and their risk of failure is high. The clinical trials and manufacturing of our product candidates are, and the manufacturing and marketing of our products, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological products,

we will need to demonstrate that they are safe, pure and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates are based on new technologies and manufactured on a patient-by-patient basis for our multiTAA-specific T cell product candidates we expect that they will have substantial manufacturing costs. In addition, the initial estimates of the clinical cost of development may prove to be inadequate, particularly if clinical trial timing or outcome is different than predicted or regulatory agencies require further testing before approval. For example, we previously experienced temporary delays in enrollment due to the COVID-19 pandemic and in satisfying certain FDA requirements for our clinical study of MT-401 for the treatment of post-transplant AML, and any further delay to our planned timelines for our trial may impact our cost estimates for this trial. In addition, costs to treat patients with relapsed/refractory cancer and to treat potential side effects that may result from our product candidates can be significant. Some clinical trial sites may not bill, or obtain coverage from, Medicare, Medicaid, or other third-party payors for some or all of these costs for patients enrolled in our clinical trials, and we may be required by those trial sites to pay such costs. Accordingly, our clinical trial costs may be significantly higher per patient than those of more conventional therapeutic technologies or drug products. In addition, our proposed personalized product candidates involve several complex manufacturing and processing steps, the costs of which will be borne by us. Depending on the number of patients we ultimately enroll in our trials, and the number of trials we may need to conduct, our overall clinical trial costs may be higher than for more conventional treatments. Further, delays and interruptions to ongoing trials related to global pandemics, as experienced with COVID-19, can increase the duration and costs of such trials. We outsource some of the management of our clinical trials to third parties. Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services, place substantial responsibilities on these parties that, if unmet, could result in delays in, or termination of, our clinical trials. If any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, agents. We cannot be certain that we will successfully recruit enough patients to complete our clinical trials nor that we will reach our primary endpoints. Delays in recruitment, lack of clinical benefit or unacceptable side effects would delay our clinical trials.

We, or our regulators, may suspend or terminate our clinical trials for a variety of reasons. For example, in the fourth quarter of 2019 the FDA placed a clinical hold on our IND of MT-401 for the treatment of patients with post-transplant AML and requested certain information regarding quality and technical specifications for two reagents supplied by third-party vendors that are used in our manufacturing process but not present in the final product infused to patients. In January 2021, the FDA lifted the clinical hold, permitting us to initiate a Phase 2 clinical trial for the treatment of post-transplant AML, with a safety lead-in portion. We completed the safety lead-in portion of the trial in June 2021, and we initiated the remainder of the Phase 2 trial in July 2021. We may voluntarily suspend or terminate our clinical trials at any time if we believe they present an unacceptable risk to the patients enrolled in our clinical trials or do not demonstrate clinical benefit. For example, in November 2019 we elected to suspend our Phase 2 clinical trial of TPIV200 for the treatment of platinum-sensitive advanced ovarian cancer based on an unblinded review of interim results conducted by an independent Data and Safety Monitoring Board, or DSMB. Although the DSMB did not express any safety concerns with respect to TPIV200, we elected to suspend the trial because it did not meet the threshold for probability of clinical benefit based upon our pre-specified criteria. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in our clinical trials.

Our clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, and we may be fined, we or our investigators may be precluded from conducting any ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted. The lengthy approval process, as well as the unpredictability of future clinical trial results, may result in us failing to obtain regulatory approval for our product candidates, which would materially harm our business, results of operations and prospects.

The results of earlier preclinical and clinical trials may not be predictive of future clinical trial results.

Failure can occur at any time during the clinical trial process. The results of preclinical testing and early clinical trials of our product candidates may not be predictive of the results of larger, later-stage controlled clinical trials. Product candidates that have shown promising results in early-stage clinical trials may still suffer significant setbacks in subsequent clinical trials. Our clinical trials to date have been conducted on a small number of patients in a single academic clinical site for a limited number of indications. We will have to conduct larger, well-controlled trials in our proposed indications at multiple sites to verify the results obtained to date and to support any regulatory submissions for further clinical development of our product candidates. Our assumptions related to our product candidates, such as with respect to lack of toxicity and manufacturing cost estimates, are based on early limited clinical trials and current manufacturing processes and may prove to be incorrect. Several companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses. We do not know whether any Phase 2, Phase 3, or other clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety with respect to the proposed indication for use sufficient to receive regulatory approval or market our product candidates.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed.

From time to time, we may estimate the timing of the accomplishment of various scientific, clinical, regulatory, manufacturing and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of preclinical studies and clinical trials and the submission of regulatory filings, including IND submissions. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are, and will be, based on a variety of assumptions. The actual timing of these milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control, including with respect to challenges related to enrollment, manufacturing and our reliance on third parties to conduct, supervise or monitor some or all aspects of our clinical trials. We may experience numerous unforeseen events during, or as a result of, any future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates.

We may experience difficulties in patient enrollment in our future clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Accordingly, we cannot guarantee that our clinical trials will progress as planned or as scheduled. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing clinical trial and planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Our preclinical studies and clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and effective for use in each target indication, and failures can occur at any stage of testing. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication.

In addition to side effects caused by the product candidate, the administration process or related procedures also can cause adverse side effects. If any such adverse events occur, our clinical trials could be suspended or terminated. If we cannot demonstrate that any adverse events were not caused by the drug or administration process or related procedures, the FDA, EMA or foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from personalized cell therapy, as with our multiTAA-specific T cell therapy products, are not normally encountered in the general patient population and by medical personnel. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

If our product candidates are associated with side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA or an IRB may also require that we suspend, discontinue, or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the product candidate.

Additionally, if one or more of our product candidates receives marketing approval, and we or others identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the labels;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or other requirements subject to a REMS;
- we could be sued and held liable for harm caused to patients;
- we may not be able to achieve or maintain third-party payor coverage and adequate reimbursement; and
- our reputation and physician or patient acceptance of our products may suffer.

There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or foreign regulatory agency in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We may not obtain or maintain the benefits associated with orphan drug designation, including market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is 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 available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Generally, a product that has orphan drug designation and subsequently receives the first FDA approval for the disease for which it has such designation is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation.

The FDA has granted orphan drug designation for MT-401 for the treatment of AML after receiving an allogeneic stem cell transplant and for MT-601 for the treatment of patients with pancreatic cancer. In 2023, MT-401 was also granted orphan drug designation by the Committee for Orphan Medicinal Products of the European Medicines Agency (EMA) for the treatment of patients with AML. We may seek orphan drug designation for other indications or product candidates. Even if we were to obtain orphan drug designation for a product candidate, we may not obtain orphan exclusivity and that exclusivity may not effectively protect the drug from the competition of different drugs for the same condition, which could be approved during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same indication if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusive marketing rights in the United States also may be lost if the FDA or European Commission (on the basis of the opinion of the European Medicines Agency, or the EMA), later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. The failure to obtain an orphan drug designation for any product candidates we may develop, the inability to maintain that designation for the duration of the applicable period, or the inability to obtain or maintain orphan drug exclusivity could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

Risks Related to Manufacturing

We rely on third-party vendors and contract manufacturing organizations to maintain and support our manufacturing and cell processing operations.

In July 2021, we opened an in-house cGMP manufacturing facility in Houston, Texas, where we manufactured the clinical supply of our product candidates. On June 26, 2023, we completed the previously announced transaction with Cell Ready, LLC (“Cell Ready”), pursuant to a Purchase Agreement (the “Cell Ready Purchase Agreement”), dated May 1, 2023, by and between us and Cell Ready. Pursuant to the Cell Ready Purchase Agreement, we (i) assigned to Cell Ready the leases for our two manufacturing facilities in Houston, Texas, or the Manufacturing Facilities, (ii) sold to Cell Ready all of the equipment and leasehold improvements at our manufacturing facilities and (iii) assigned to Cell Ready our rights, title and interest in any contracts related to the equipment and manufacturing facilities (collectively referred to as the “Purchased Assets”). On February 22, 2024, we entered into a Master Services Agreement for Product Supply (the “MSA”) with Cell Ready. Cell Ready, which is owned by one of our directors and shareholders, Mr. John Wilson, is a contract development and manufacturing organization (CDMO). Under the MSA, it is anticipated Cell Ready will perform a wide variety of services for us, including research and development, and manufacturing in support of our clinical trials.

Although we expect Cell Ready’s cGMP manufacturing facility to be our primary source of multiTAA-specific T cell therapy-based product candidates and for commercial manufacturing of any products, if approved, we intend to evaluate additional potential third-party manufacturing capabilities in order to provide potential multiple sources of clinical and commercial supply. Even if we can secure multiple sources of clinical and commercial supply, third-party manufacturers, such as Cell Ready, may not be able to meet our needs concerning timing, quantity, or quality and/or may cease or substantially reduce their business. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval or the market introduction and subsequent sales of any approved products. Any such delay may lower our revenues and potential profitability. If any

third-party breaches or terminates its agreement with us or fails to conduct its activities in a timely manner, the commercialization of our product candidates could be slowed down or blocked completely. It is possible that third-parties relied upon by us will change their strategic focus, pursue alternative technologies, or develop alternative product candidates, either on their own or in collaboration with others, as a means for developing treatments for the diseases targeted by our collaborative programs, or for other reasons. The effectiveness of these third parties in marketing their own products may also affect our revenues and earnings. Also, if we enter into additional third-party agreements in the future, we may not be able to negotiate such agreements successfully and, even if established, these relationships may not be scientifically or commercially successful. In the event our relationship with a third-party manufacturer is terminated or substantially reduced for any reason, it is possible we will not be able to identify an alternative third-party manufacturer within a reasonable period of time, if ever, which would have an adverse effect our operations.

Additionally, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures, competition with other clients, transportation difficulties and numerous other factors that could prevent us from fully realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our clinical development, commercialization plans and/or general operations. In addition, the manufacturing process for any product candidates that we may develop is subject to the FDA and foreign regulatory authority approval process, and we may need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. If our contract manufacturing organizations, or CMOs, ,including Cell Ready, are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize any approved products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Further, we may be required to establish multiple manufacturing facilities to expand our commercial footprint for any approved products, which may lead to regulatory delays or prove costly. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our clinical development and/or commercialization plans.

Our manufacturing process is reliant upon specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. We, our vendors, and contract manufacturing organizations rely or may rely on sole-source vendors or a limited number of vendors, which could impair the manufacture and supply of our product candidates.

We depend on a limited number of vendors for supply of certain materials and equipment used in the manufacture of our multiTAA-specific T cell therapy-based product candidates. For example, in the past, we purchased equipment and reagents critical for the manufacture of our product candidates from Wilson Wolf (a company controlled by our director John Wilson), Almac and other suppliers. Under the Cell Ready MSA, Cell ready is required to obtain all raw materials and components used in the production of our product candidates, other than as specified in applicable works orders delivered under the MSA. Some of our direct or indirect suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also may not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may not be able to obtain key materials and equipment to support clinical or commercial manufacturing. Further, the FDA may determine that our manufacturing process, or the materials required for the manufacture of our product candidates, are not acceptable, which would require us to find alternative suppliers or processes, which may not be available on favorable terms, if at all.

For some of this equipment and materials, we may rely, and may now and/or in the future rely, on sole-source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial, or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

In the future, we may need to obtain rights to and supplies of specific materials and equipment to be used for the development of our product candidates. For example, our multiTAA-specific T cell manufacturing process is based, in part, upon the G-Rex® cell culture device manufactured by Wilson Wolf, which is used by many cell therapy developers, both in commercial and academic settings. Although we do hold the license to patents from BCM that could be used to prevent third parties from developing similar and competing processes, we do not own any exclusive rights to the G-Rex®. We may not be able to obtain rights to such materials and equipment on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business.

The manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development. If any of our third-party suppliers, including Cell Ready, encounter such difficulties, the supply of our product candidates for clinical trials, or our product candidates for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Our product candidates are biologics, and the process of manufacturing our product candidates is complex, highly regulated and subject to multiple risks. For example, the manufacture of our multiTAA-specific T cell therapy-based product candidates involves complex processes, including drawing blood from patients/donors, manufacturing the clinical product, and ultimately infusing the product into a patient. As a result of the complexities, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Our manufacturing processes will be susceptible to product loss or failure due to any of the following: logistical issues associated with the collection of blood cells, or starting material, from the patient or a donor, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product; manufacturing issues associated with the variability in patients' or donor's starting cells; interruptions in the manufacturing process; contamination; equipment failure; improper installation or operation of equipment, vendor or operator error; inconsistency in cell growth; and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If for any reason we lose a patient's or a donor's cells, or later-developed product at any point in the process, the manufacturing process for that patient will need to be restarted and the resulting delay may adversely affect that patient's outcome and/or the results of clinical trials. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Because our autologous multiTAA-specific T cell therapy-based product candidates, MT-601, is manufactured for each particular patient, we will be required to maintain a chain of identity with respect to the patient's blood cells as it moves from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our product candidates from the market. Further, as product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in order to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

We currently have our clinical supply manufactured at Cell Ready's manufacturing facility, and are working to develop commercially viable processes. Doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale up, process reproducibility, stability issues, lot consistency, and timely availability of raw materials. As a result of these challenges, we may experience delays in our clinical development and/or commercialization plans. We may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

No assurance can be given that we will be able to develop a new, FDA-compliant, more efficient, lower cost manufacturing process upon which our business plan to commercialize multiTAA-based product candidates is dependent.

In cooperation with our current contract manufacturers and suppliers, we developed and have implemented a new nine-day multiTAA-specific T cell manufacturing process for our current as well as future clinical trials using a patient-specific manufacturing approach or using products manufactured from healthy donors ("Off-the-Shelf"). The new manufacturing process marks additional manufacturing

improvements compared to the processes used in the BCM Phase 1 and 2 trials (36-day manufacturing time) and our previous AML trial (20-day manufacturing time). The new nine-day manufacturing process enables increased antigen specificity and diversity, which has exhibited a strong linear correlation to anti-tumor activity in vitro. The new process produces a patient product that is four times more potent, with the potential to greatly improve tumor killing. This new, scaled-up, pharmaceutical manufacturing process is new and subject to uncertainties. We cannot guarantee that we will be able to more efficiently and cost effectively, and in a more automated manner produce, measure and control the physical and/or chemical attributes of our product candidates in a cGMP facility. We also have never manufactured our adoptive T cell therapy product candidate on a commercial scale. As a result, we cannot give any assurance that we will be able to establish a manufacturing process that can produce our product candidates at a cost or in quantities necessary to make them commercially viable. Moreover, we and our third-party manufacturers will have to continually adhere to current cGMP regulations enforced by the FDA through its facilities inspection program. If these facilities cannot pass a pre-approval plant inspection, the FDA premarket approval of our product candidates will not be granted. In complying with cGMP and foreign regulatory requirements, we and any of our third-party manufacturers will be obligated to expend time, money and effort in production, record-keeping and quality control to assure that our product candidates meet applicable specifications and other requirements. If we or any of our third-party manufacturers fail to comply with these requirements, we may be subject to regulatory action. No assurance can be given that we or our partners will be able to establish and operate such a production facility.

Cellular products are not considered to be well characterized products because there are hundreds of markers present on T cells, and even small changes in manufacturing processes could alter the cell subtypes. It is unclear at this time which of those markers are critical for success of T cells to combat cancer, so our ability to predict the outcomes with newer manufacturing processes is limited. The changes that we may make to the existing manufacturing process may require additional testing, which may increase costs and timelines associated with these developments. In addition to developing a multi-antigen T cell-based therapy on existing adoptive T cell therapy technology, we are currently evaluating the desirability of conducting clinical trials of our product candidates in combination with other existing drugs. These combination therapies will require additional testing, and clinical trials will require additional FDA regulatory approval and will increase our future cost of development.

Risks Related to our Reliance on Third Parties

We may not realize the expected benefits from the transaction with Cell Ready.

We may not be able to achieve the full strategic and financial benefits expected to result from the closing of the transaction with Cell Ready, or such benefits may be delayed or not occur at all. In particular, we have made the strategic decision to dispose of our manufacturing facilities and related assets in order to focus on clinical development of the multiTAA-specific T cell therapy-based product candidates in our pipeline. Following the closing of the transaction, we no longer operate our own cGMP manufacturing facility and must rely on Cell Ready and other third parties for the clinical and, if approved, commercial manufacture of our product candidates. Although we entered into an MSA with Cell Ready for manufacturing, among other services, we may not realize the anticipated cost savings associated with contracting out our manufacturing, and research and development requirements. The assumptions we made related to the Cell Ready transaction may prove to be inaccurate, including as to the expected benefits of the transaction and anticipated cost savings. An inability to realize the anticipated benefits of the Cell Ready transaction could have an adverse impact on our business, financial condition and results of operations.

Following the closing of the transaction with Cell Ready, we no longer operate our own cGMP manufacturing facility and instead will rely on third parties, including Cell Ready, for the clinical and, if approved, commercial manufacture of our product candidates. The third-party manufacturing facilities on which we rely may have limited capacity or fail to meet the applicable stringent regulatory requirements.

We do not have any cGMP manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the cGMP manufacture of our product candidates for clinical development and, if approved, commercial supply. We have entered into a long-term agreement with Cell Ready, pursuant to which Cell Ready will perform a wide variety of services for us, including research and development, and manufacturing in support of our clinical trials. There is no guarantee that we will or have properly estimated our required manufacturing capacities or that the third parties we rely on to provide required machinery and materials for the manufacturing process will be able to perform on our proposed timelines or meet our manufacturing demands, if at all. Also, if we must increase production capacity for any reason, we may need to make considerable investments that could lead to significant financing needs or require us to enter into subcontracting agreements in order to outsource part of the production.

If Cell Ready or any other third-party contract manufacturing organization on which we rely ceases or reduces its business or experiences capacity constraints, other disruptions, or delays in manufacturing our multiTAA-specific T cell therapy-based product candidates, our planned clinical trials and necessary manufacturing capabilities will be disrupted or delayed. Third-party manufacturers may not be able to meet our needs concerning timing, quantity, or quality. Additionally, Cell Ready may engage, be engaged by, or otherwise enter into arrangements with our competitors. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval or the market introduction and subsequent sales of any approved products. Any such delay may lower our revenues and potential profitability. If any third-party breaches or terminates its agreement with us or fails to conduct its activities in a timely manner, the commercialization of our product candidates could be slowed down or blocked completely. It is possible that third parties relied upon by us will change their strategic focus, pursue alternative technologies, or develop alternative product candidates, either on their own or in collaboration with others, as a means for developing treatments for the diseases targeted by our collaborative programs, or for other reasons. The effectiveness of these third parties in marketing their own products may also affect our revenues and earnings. We intend to continue to enter into additional third-party agreements in the future. However, we may not be able to negotiate any additional agreements successfully. Even if established, these relationships may not be scientifically or commercially successful.

The facilities used by our contract manufacturers to manufacture our product candidates must be inspected by the FDA. We do not have control over a supplier’s or manufacturer’s compliance with laws, regulations and applicable cGMP standards or similar regulatory requirements and other laws and regulations, such as those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we may be unable to obtain regulatory approval of our marketing applications. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supply of our products.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully, if approved. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed, or we could lose potential revenue.

Our strategic relationship with BCM is dependent, in part, upon our ongoing relationship with key medical and scientific personnel and advisors.

Our multiTAA-specific T cell therapy has been developed through our collaboration with the Center for Cell and Gene Therapy at BCM, founded by Malcolm K. Brenner, M.D., Ph.D., a recognized pioneer in immuno-oncology. Our strategic relationship with BCM is dependent, in part, on our relationship with certain key employees and advisors, some of whom serve on our Scientific Advisory board, and in particular Dr. Vera, our founder, President and Chief Executive Officer and Principal Financial and Accounting Officer. If Dr. Vera discontinues his employment with us, our relationship with BCM may deteriorate, and our business could be harmed. We may also be dependent on BCM facilities and personnel to conduct research and development and manufacturing activities in the future.

Although we have an exclusive license agreement with BCM under which we received a worldwide, exclusive license to BCM's rights in and to three patent families to develop and commercialize the multiTAA-specific T cell product candidates, we will need to enter into additional agreements with BCM with respect to (i) a strategic alliance to advance preclinical research, early stage clinical trials, and clinical trials with respect to our product candidates, as well as continued access to our clinical data, and (ii) support, including personnel and space at the institution for the foreseeable future. Any delays in entering into new strategic agreements with BCM related to our product candidates could delay the development, manufacture, and clinical trials of our product candidates.

An important element of our intellectual property portfolio is to license additional rights and technologies from BCM. Our inability to license the rights and technologies that we have identified, or newly developed multiTAA-specific T cell technology that we may in the future identify, could have a material adverse impact on our ability to complete the development of our product candidates or to develop additional product candidates. No assurance can be given that we will be successful in licensing any additional rights or technologies from BCM and others. Failure to obtain additional rights and licenses may detrimentally affect our planned development of additional product candidates and could increase the cost, and extend the timelines associated with our development of such other product candidates.

We may not be able to establish or maintain the third-party relationships, including strategic collaborations, that are necessary to develop, commercialize and/or market some or all of our product candidates.

We expect to depend on collaborators, partners, licensees, clinical research organizations and other third parties to support our discovery efforts, to formulate product candidates to manufacture our product candidates and to conduct clinical trials for some or all of our product candidates. We cannot guarantee that we will be able to successfully negotiate agreements for or maintain relationships with collaborators, partners, licensees, clinical investigators, vendors and other third parties on favorable terms, if at all. Our ability to successfully negotiate such agreements will depend on, among other things, potential partners' evaluation of the superiority of our technology over competing technologies and the quality of the preclinical and clinical data that it has generated, and the perceived risks specific to developing our product candidates. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidates. Management of any third-party relationships will require significant time and effort from our management team, coordination of our research and development programs with the research and development priorities of our collaborators and effective allocation of our resources to multiple projects.

If we continue to enter into research and development collaborations at the early phases of drug development, our success will in part depend on the performance of our corporate collaborators. We will not directly control the amount or timing of resources devoted by our corporate collaborators to activities related to our immunotherapies. Our corporate collaborators may not commit sufficient resources to their research and development programs or the commercialization, marketing or distribution of their immunotherapies. If any corporate collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to this collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestones or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements.

Our strategy includes eventual substantial reliance upon strategic collaborations for marketing and commercialization of our product candidates, and we may rely even more on strategic collaborations for research, development, marketing and commercialization of our other immunotherapies. If we are unsuccessful in securing such strategic collaborations, we may be unable to commercialize any approved products as we have not yet licensed, marketed or sold any of our immunotherapies or entered into successful collaborations for these services in order to ultimately commercialize our immunotherapies. Establishing strategic collaborations is difficult and time-

consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, clinical, regulatory or intellectual property position. If we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our immunotherapies or the generation of sales revenue. To the extent that we enter into co-promotion or other collaborative arrangements, our product revenues are likely to be lower than if we directly marketed and sold any products that we may develop.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed 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, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

Efforts to ensure that our business arrangements comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or in asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to develop our business. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Risks Related to the Commercialization of our Product Candidates

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and the medical community.

Even if we obtain regulatory approval for our product candidates, they may not gain market acceptance among physicians, healthcare payors, patients or the medical community. Market acceptance of our product candidates, if we receive approval, depends on a number of factors, including the:

- efficacy and safety of our product candidates as demonstrated in clinical trials and post-marketing experience;
- clinical indications for which our product candidates may be approved;
- acceptance by physicians and patients of our product candidates as safe and effective;
- potential and perceived advantages of our product candidates over alternative treatments;
- safety of our product candidates seen in a broader patient group, including our use outside the approved indications should physicians choose to prescribe for such uses;

- prevalence and severity of any side effects;
- product labeling, or product insert requirements of the FDA or other regulatory authorities;
- timing of market introduction of our product candidates as well as competitive products;
- cost in relation to alternative treatments;
- pricing and the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration; and
- effectiveness of any sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, healthcare payors and the medical community, we may not be able to generate significant revenues, which would compromise our ability to become profitable.

The market for any products that we successfully develop will also depend on the cost of the product. We do not yet have sufficient information to reliably estimate what it will cost to commercially manufacture our current product candidates, and the actual cost to manufacture these products could materially and adversely affect the commercial viability of these products. Our goal is to reduce the cost of manufacturing our therapies. However, unless we are able to reduce those costs to an acceptable amount, we may never be able to develop a commercially viable product. If we do not successfully develop and commercialize products based upon our approach or find suitable and economical sources for materials used in the production of our products, we will not become profitable.

Even if we are successful in getting market approval, commercial success of any of our product candidates will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations, which may be affected by existing and future health care reform measures designed to reduce the cost of health care. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other health care payors were not to provide adequate coverage and reimbursement levels for any of our products if approved, market acceptance and commercial success would be reduced.

Our multiTAA-specific T cell therapy may be provided to patients in combination with other agents provided by third parties. The cost of such combination therapy may increase the overall cost of multiTAA-specific T cell therapy and may result in issues regarding the allocation of reimbursements between our therapy and the other agents, all of which may adversely affect our ability to obtain reimbursement coverage for the combination therapy from third-party medical insurers.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices

often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Our future success is highly dependent upon our key personnel, and our ability to attract, retain, and motivate additional qualified personnel. We will also be required to establish sales and marketing capabilities or enter into agreements with third parties to market and sell any approved products.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific, and medical personnel. We are highly dependent on our management, scientific, and medical personnel and consultants, including Juan Vera, M.D., our President, Chief Executive Officer, and Principal Financial and Accounting Officer, as well as others. The loss of the services of any of our executive officer, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm to our business. We have a priority to quickly train additional qualified scientific and medical personnel to ensure the ability to maintain business continuity. Any delays in training such personnel could delay the development, manufacture, and clinical trials of our product candidates.

Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other biotechnology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than us. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, or integrating them into our operations, our business, prospects, financial condition and results of operations will be materially adversely affected. In such circumstances, we may be unable to conduct certain research and development programs, unable to adequately manage our clinical trials and development of our product candidates, and unable to adequately address our management needs.

We do not currently have an organization for the sale, marketing and distribution of any approved products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products approved by the FDA or comparable foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third - party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

The biotechnology and immunotherapy industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed immunotherapies could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

Potential competitors in the market for treating hematological malignancies include numerous pharmaceutical and biotechnology companies, as well as academic institutions, private and public research institutions, and government agencies. Treatment of relapsed patients with lymphoma remains a challenge with relatively low overall survival rates. To date, there are four CD19-directed CAR T cell therapies (Yescarta, Kymriah, Tecartus, and Bryanzi) approved for patients with relapsed lymphoma. However, up to 60% of CD19 CAR T cell treated patients will relapse, particularly in the third line setting (Chong EA et al, N Engl J Med, 2021). This highlights a significant unmet medical need for alternative and more effective treatments. Our multiTAA-specific T cell drug candidates may compete with product candidates from a number of companies, which are developing various types of immunotherapies to treat cancer, including non-CD19 targeting CAR T cells that target different antigens beyond CD19, multi-targeted CAR T cells as well as NK-CAR therapies. In addition, bispecific antibodies represent promising therapies for patients with lymphoma and provide competition in the oncology space. To date, MT-601 is the only natural T cell product that targets multiple tumor antigens being explored for CAR relapse patients with lymphoma. Therefore, MT-601 fills a void in the market by providing much needed treatment to patient population. Current and potential competitors may have substantially greater research and development capabilities and financial, scientific, regulatory, manufacturing, marketing, sales, human resources, and experience than we do. Many of our competitors have several therapeutic products that have already been developed, approved and successfully commercialized, or are in the process of obtaining regulatory approval for their therapeutic products in the United States and internationally. While these universities and public and private research institutions primarily have educational objectives, they may develop proprietary technologies that lead to other FDA approved therapies or that secure patent protection that we may need for the development of our technologies and product candidates.

Even if we obtain regulatory approval for our lead product candidate, the availability and price of competitors' products could limit the demand and the price we will be able to charge for our therapy. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from other methods of treatment to our product, or if physicians switch to other new therapies, drugs or biologic products or choose to reserve our product candidates for use in limited circumstances. We are aware of certain investigational new drugs under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that have the potential to directly compete with our immunotherapies even though their approach may be different. The competition comes from both biotechnology firms and from major pharmaceutical companies. Many of these companies have substantially greater financial, marketing, and human resources than us. We also experience competition in the development of our immunotherapies from universities, other research institutions and others in acquiring technology from such universities and institutions.

In addition, certain of our immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

The FDA often approves new oncology therapies initially only for use in patients with relapsed or refractory metastatic disease. We expect to initially seek approval of our product candidates in this setting. Subsequently, for those product candidates that prove to be sufficiently beneficial, if any, we would expect to seek approval in earlier lines of treatment and potentially as a first line therapy. There is no guarantee, however, that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive second or third-line therapy, and who have the potential to benefit from treatment with our product candidates, are based on our research and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research by third parties, and may prove to be incorrect. We do not have verifiable internal marketing data regarding the potential size of the commercial market for our product candidates, nor have we obtained independent marketing surveys to verify the potential size of the commercial markets for our current product candidates or any future product candidates. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of treatable patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates and may also be limited by the cost of our treatments and the reimbursement of those treatment costs by third-party payors. For instance, we expect our lead product candidate to initially target patients with lymphoma that relapsed after anti-CD19 CAR T cell therapy. Even if we obtain significant market share for our product candidates, because the potential target populations might be small, we may not achieve profitability without obtaining regulatory approval for additional indications, and we may spend large amounts of money trying to obtain approval for product candidates that have an uncertain commercial market.

New regulatory pathways for biosimilar competition could reduce the duration of market exclusivity for our products.

Under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, there is an abbreviated path in the United States for regulatory approval of products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-approved biological product. The ACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to (but not generic copies of) innovative drugs on the basis of less extensive data than is required by a full BLA. Under this regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. However, the term of regulatory exclusivity may not remain at 12 years in the United States and could be shortened. A number of jurisdictions outside of the United States have also established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier versions of biological products. For example, the European Union has had an established regulatory pathway for biosimilars since 2005.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if one of our late-stage product candidates or other clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent to the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection laws. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize any product candidate.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could inhibit or prevent the commercialization of products we develop, alone or with collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no insurance coverage. While we obtained clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

The multiple roles of Dr. Vera, our President, Chief Executive Officer, and Principal Financial and Accounting Officer, could limit his time and availability to us, and create, or appear to create, conflicts of interest.

Dr. Vera is a co-founder and director of Allovir Inc., or Allovir. Allovir has technology which is being developed under a license agreement with BCM by the same research group at BCM. Allovir is a clinical-stage biopharmaceutical company that is investigating and developing virus-specific T cell therapy technology for the prevention and/or treatment of viral infections.

Further, Dr. Vera has certain fiduciary or other obligations to us and certain fiduciary or other obligations to Allovir and BCM. Such multiple obligations may in the future result in a conflict of interest with respect to presenting other potential business opportunities to us or to Allovir. A conflict of interest also may arise concerning the timing and scope of the parties' planned and ongoing clinical trials, investigational new drug application filings and the parties' opportunities for marketing their respective product candidates, as well as

our intellectual property rights with those of Allovir. In addition, he may be faced with decisions that could have different implications for us than for Allovir.

Risks Related to Our Intellectual Property

If we are unable to protect our proprietary rights, we may not be able to compete effectively or operate profitably.

Our commercial success is dependent in part on our ability to obtain, maintain, and enforce the patents and other proprietary rights that we have licensed and may develop, and on our ability to avoid infringing the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims are directed to the technology. There can be no assurance that our patent applications or those of our licensor will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with relevant employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of the premises and physical and electronic security of the 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, trade secrets may otherwise become known or be independently discovered by competitors. To the extent that the consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Although we have patents and patent applications in other countries, we cannot be certain that the claims in other pending U.S. or European patent applications, international patent applications, and patent applications in certain other foreign territories directed to methods of generating multi-antigen specific T cell product candidates, or our other product candidates, will be considered patentable by the USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued licensed European patent will not be found invalid or unenforceable if challenged.

Most of our intellectual property rights are currently licensed from BCM, so that the preparation and prosecution of these patents and patent applications was not performed by us or under our control. Furthermore, patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and, consequently, patent positions in our industry may not be as strong as in other more well-established fields. The patent positions of biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- patent applications may not result in any patents being issued;

- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than us, and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also 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 or in all jurisdictions where protection may be commercially advantageous. 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 patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license from third parties. We may also require the cooperation of our licensor in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensor have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and it is uncertain how much protection, if any, will be given to the patents we have licensed from a licensor if either the licensor or we attempt to enforce the patents and/or if they are challenged in court or in other proceedings, such as oppositions, invalidations, or like proceedings, which may be brought in foreign jurisdictions to challenge the validity of a patent. A third - party may challenge our patents, if issued, or the patent rights that we license from others in the courts or patent offices in the United States and abroad. It is possible that a competitor may successfully challenge our patents or that a challenge will result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our products and product candidates. Moreover, the cost of litigation to defend the validity of patents and to prevent or remedy infringement can be substantial. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to us. Moreover, it is possible that competitors may infringe our patents or successfully avoid them through design innovation. To stop violation of our patent rights, we may need to file a lawsuit. These lawsuits are expensive and would consume time and other resources, even if we were successful in stopping or remedying the violation of our patent rights. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of our patents was upheld, a court would refuse to stop the other party on the ground that its activities are not covered by, that is, do not infringe, our patents.

Should third parties file patent applications, or be issued patents claiming technology also used or claimed by our licensor(s) or by us in any future patent application, we may be required to participate in interference proceedings in the USPTO to determine priority of invention for those patents or patent applications that are subject to the first-to-invent law in the United States, or may be required to participate in derivation proceedings in the USPTO for those patents or patent applications that are subject to the “first-inventor-to-file” law in the United States. We may be required to participate in such interference or derivation proceedings involving our issued patents and pending applications. We may be required to cease using the technology or to license rights from prevailing third parties as a result of an unfavorable outcome in an interference proceeding or derivation proceeding. A prevailing party in that case may not offer us a license on commercially acceptable terms or on any terms.

If we, our licensing partners, or any potential future collaborator initiates legal proceedings against a third - party to enforce a patent directed to one of our product candidates, the defendant could counterclaim that the patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, non-obviousness or enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they are no longer directed to our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensor invalid or could prevent a patent from issuing from one or more of our pending patent applications. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Furthermore, even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection could have a material adverse impact on our business development.

The use of our technologies could potentially conflict with the rights of others.

Our potential competitors or other entities may have or acquire patent or proprietary rights that they could enforce against our licensor. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexaminations, *inter partes* review proceedings and post-grant review, or PGR, proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Such potential third-party patents or patent applications could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position by requiring us to alter our product candidates, pay licensing fees or cease activities.

As the biotechnology industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that later issue as patents that our product candidates may infringe. If our product candidates conflict with patent rights of others, third parties could bring legal actions against us or our collaborators, licensees, suppliers or customers, claiming damages and seeking to enjoin manufacturing and marketing of the affected product candidates. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected product candidates. We may not prevail in any legal action and a required license under the patent may not be available on acceptable terms or at all.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or

enforced in our patents or in third-party patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO and may become involved in post-grant proceedings including post grant review, derivation, reexamination, *inter-partes* review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. In addition, recent U.S. Supreme Court rulings on several patent cases have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain 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. While we do not believe that any of the patents owned or licensed by us will be found invalid based on these decisions, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing its inventions in all countries outside the United States, or from selling or importing products made using its inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and 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 certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical 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 could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

As is common in the biotechnology and pharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. We have received confidential and proprietary information from third parties. We employ individuals or engage consultants who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

If we fail to comply with any obligations under our existing license agreements or any future license agreements, or disputes arise with respect to those agreements, it could have a negative impact on our business and our intellectual property rights.

We are a party to license agreements with BCM that impose, and we may enter into additional licensing arrangements with third parties that may impose, diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Our rights to use the licensed intellectual property are subject to the continuation of and our compliance with the terms of these agreements. Disputes may arise regarding our rights to intellectual property licensed to us from a third - party, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the creation or use of intellectual property by us, alone or with our licensors and collaborators;
- the scope and duration of our payment obligations;
- our rights upon termination of such agreement; and
- the scope and duration of exclusivity obligations of each party to the agreement.

If disputes over intellectual property and other rights that we have licensed or acquired from third parties prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we fail to comply with our obligations under current or future licensing agreements, these agreements may be terminated or the scope of our rights under them may be reduced and we might be unable to develop, manufacture or market any product that is licensed under these agreements.

Under our license agreement with BCM for our multiTAA-specific T cell therapy technologies, we are currently required to pay both substantial milestone payments and royalties to BCM based on our revenues from sales of any approved products utilizing the licensed technologies, and these payments could adversely affect the overall profitability for us of any products that we may seek to commercialize. In order to maintain our license rights under the BCM license agreement, we will need to meet certain specified milestones, subject to certain cure provisions, in the development of our product candidates.

In addition, upon a liquidity event (as defined in our BCM license agreement with BCM) of the licensee under the BCM license agreement (which, the licensee shall be the Company), BCM will receive a liquidity incentive payment of 0.5% of the liquidity event

proceeds (as defined in the BCM license agreement) received by such licensee or its stockholders in the liquidity event, thereby diluting the amount of proceeds available to the licensee or its stockholders in a liquidity event.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be subject to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide sufficient rights to exclude others from commercializing products similar or identical to our product candidates.

Certain of our technologies are in-licensed from third parties, and the protection of those technologies is not entirely within our control.

We have a world-wide exclusive license from BCM of the rights in and to three patent families to develop and commercialize multiTAA-specific T cell product candidates in the field of oncology. As a result of these in-licenses, we could lose the right to develop each of the technologies if:

- the owner (s) of the patent rights underlying the technologies that we license do not properly maintain or enforce the patents and intellectual property underlying those properties,
- BCM seeks to terminate our license in contravention of the license agreements;
- we fail to make all payments due and owing under any of the licenses; or
- we fail to obtain on commercially reasonable terms, if at all, in-licenses from BCM or others for other rights that are necessary to develop the technology that we have already in-licensed.

If any of the above occurs, we could lose the right to use the in-licensed intellectual property, which would adversely affect our ability to commercialize our technologies, products or services. The loss of any current or future licenses from BCM, or the exclusivity rights provided by such license agreements, could materially harm our financial condition and operating results.

We rely upon patents and licensed technologies to protect our technology. We may be unable to protect our intellectual property rights, and we may be liable for infringing the intellectual property rights of others.

Our ability to compete effectively depends on our ability to maintain the proprietary nature of our technologies and the proprietary technology of others with whom we have entered into collaboration and licensing agreements. We own or hold licenses to a number of issued patents and U.S. pending patent applications, as well as foreign patents and foreign counterparts. Our success depends in part on our ability to obtain patent protection both in the United States and abroad for our product candidates, as well as the methods for treating patients in the product indications using these product candidates. Such patent protection is costly to obtain and maintain, and sufficient funds might not be available. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if our product candidates, as well as methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Accordingly, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes.

In addition, we cannot guarantee that any patents will be issued from any pending or future patent applications owned by or licensed to us. Even if patents have been issued or will be issued, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries offer different degrees of protection against use of the patented invention by others. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

The patent positions of biotechnology and pharmaceutical companies, including our patent positions, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated, or circumvented. Our patents can be challenged by our competitors who can argue that our patents are invalid and/or unenforceable, or that the patent claims should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without infringing our patents. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our technologies, methods of treatment, product candidates, and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets and we have the funds to enforce our rights, if necessary.

The expiration of our owned or licensed patents before completing the research and development of our product candidates and receiving all required approvals in order to sell and distribute the products on a commercial scale can adversely affect our business and results of operations.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensor, which could be expensive, time-consuming and unsuccessful.

We may face legal claims involving stockholders, consumers, competitors, entities from whom we license technology, entities with whom we collaborate, persons claiming that we are infringing on their intellectual property and others. The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. Competitors may infringe our intellectual property rights or those of our licensor. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that one or more of the patents which we own or in-license is not valid or is unenforceable, and/or is not infringed. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In addition, litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patent and/or pending patent applications will be due to the USPTO and foreign patent agencies in several stages over the lifetime of our patents and/or applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance 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. Noncompliance 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. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business development.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensor. Should third parties file patent applications or be issued patents claiming technology also used or claimed by us, we may be required to participate in interference or derivation proceedings in the USPTO to determine priority of invention. We may be required to participate in interference or derivation proceedings involving our issued patents and pending applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially acceptable terms.

The costs of litigation or any proceeding relating to our intellectual property or contractual rights could be substantial even if resolved in our favor. Some of our competitors or financial funding sources have far greater resources than we do and may be better able to afford the costs of complex legal procedures. Also, in a lawsuit for infringement or contractual breaches, even if frivolous, we will require considerable time commitments on the part of management, our attorneys and consultants. Defending these types of proceedings or legal actions involve considerable expense and could negatively affect our financial results.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

If we are unable to obtain licenses needed for the development of our product candidates, or if we breach any of the agreements under which we license rights to patents or other intellectual property from third parties, we could lose license rights that are important to our business.

If we are unable to maintain and/or obtain licenses needed for the development of our product candidates in the future, we may have to develop alternatives to avoid infringing on the patents of others, potentially causing increased costs and delays in product development and introduction or precluding the development, manufacture, or sale of planned product candidates. Some of our licenses provide for limited periods of exclusivity that require minimum license fees and payments and/or may be extended only with the consent of the licensor. We might not meet these minimum license fees in the future, or these third parties might not grant extensions on any or all such licenses. This same restriction may be contained in licenses obtained in the future.

Additionally, the patents underlying the licenses might not be valid and enforceable. To the extent any product candidates developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such product candidates uneconomical. In addition, the loss of any current or future licenses or the exclusivity rights provided therein could materially harm our business financial condition and our operations.

Risks Related to Government Regulation

We are subject to extensive regulation, which can be costly, time consuming and can subject us to unanticipated delays. Even if we receive regulatory approval of our product candidates, we will be subject to ongoing quality and regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

All of our current and future product candidates, cell processing and manufacturing activities, are subject to comprehensive regulation by the FDA in the United States and by comparable authorities in other countries. The process of obtaining FDA and other required regulatory approvals, including foreign approvals, is expensive and often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. In addition, regulatory agencies may lack experience with our technologies and product candidates, which may lengthen the regulatory review process, increase our development costs and delay or prevent their commercialization.

No adoptive T cell therapy using multiTAA-specific T cells has been approved for marketing in the U.S. by the FDA. Consequently, there is no precedent for the successful commercialization of products based on our technologies. In addition, we have had only limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain timely FDA approvals, if at all. We have not yet sought FDA approval for any adoptive T cell therapy product. We will not be able to commercialize any of our potential product candidates until we obtain FDA approval, and so any delay in obtaining, or inability to obtain, FDA approval would harm our proposed business.

If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be fined, forced to remove a product from the market and experience other adverse consequences including delay, which could materially harm our business development. Additionally, we may not be able to obtain the labeling claims necessary or desirable for the promotion of our products. We may also be required to undertake post-marketing trials. Prescription drugs may be promoted only for the approved indications in accordance with the approved label. 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 may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatment but the FDA does restrict manufacturer’s communications on the subject of off-label use of their products. In addition, if we or others identify side effects after any of our adoptive T cell therapy products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn, and reformulation of our products may be required.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

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 product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of any approved product candidates will be harmed.

Any relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors in connection with our current and future business activities are and will continue to be subject, directly or indirectly, to federal and state healthcare laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

Our business operations and activities may be directly, or indirectly, subject to various federal and state healthcare laws, including without limitation, fraud and abuse laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. These laws may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as current and future sales, marketing, patient co-payment assistance and education programs.

Such laws include:

- the federal Anti-Kickback Statute which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing 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, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for, among other things, 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;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals)(such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and

- analogous state, local, and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third - party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; state and local "drug takeback" laws and regulations; and state and foreign laws governing 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.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. While our interactions with healthcare professionals have been structured to comply with these laws and related guidance, it is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws. If our operations or activities 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, without limitation, significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

In addition, any sales of our product once commercialized outside the U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Recently enacted and future legislation in the United States and other countries may affect the prices we may obtain for our product candidates and increase the difficulty and cost to commercialize our product candidates.

In the United States and many other countries, rising healthcare costs have been a concern for governments, patients and the health insurance sector, which has resulted in a number of changes to laws and regulations, and may result in further legislative and regulatory action regarding the healthcare and health insurance systems that could affect our ability to profitably sell any product candidates for which we have obtained marketing approval.

For example, the ACA was enacted in the United States in March 2010, with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare, and includes measures to change health care delivery, increase the number of individuals with insurance, ensure access to certain basic health care services, and contain the rising cost of care. There have been judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is also unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other federal health reform measures have been proposed and adopted in the United States. For example, as a result of the Budget Control Act of 2011 and subsequent legislative amendments thereto, including the Infrastructure Investment and Jobs Act, providers are subject to Medicare payment reductions of 2% per fiscal year until 2031, unless additional Congressional action is taken. Under current legislation the actual reduction in Medicare Payments will vary from 1% in 2022 to up to 3% in the fiscal year of this sequester. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and also introduced a quality payment program, or the Quality Payment Program, under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. This Quality Payment Program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. It is still unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent 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 products. At the federal level, for example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but it is likely to have a significant impact on the pharmaceutical industry. In addition, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries.

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, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

The combination of healthcare cost containment measures, increased health insurance costs, reduction of the number of people with health insurance coverage, as well as future legislation and regulations focused on reducing healthcare costs by reducing the cost of, or reimbursement and access to, pharmaceutical products, may limit or delay our ability to commercialize our products, generate revenue or attain profitability.

As described above, the ACA and potential regulations thereunder easing the entry of competing follow-on biologics into the marketplace, other new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

We expect that additional state and federal healthcare reform measures will continue to be adopted in the future. While it is not possible to predict whether and when any such changes will occur, changes in the laws, regulations, and policies governing the development and approval of our product candidates and the commercialization, importation, and reimbursement of our product candidates could adversely affect our business.

We are subject to stringent and changing laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of our business, we may collect, receive, store, process, generate, use, transmit, disclose, make accessible, protect, secure, dispose of, share (collectively, processing) personal data and other sensitive data, including proprietary and confidential business data, intellectual property, trade secrets, data regarding clinical trial subjects, and sensitive third-party data. We may rely on third parties (such as service providers) for our data processing-related activities. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Additionally, the California Consumer Privacy Act of 2018, or CCPA, applies to personal data of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, California Privacy Rights Act of 2020, or CPRA, expands the CCPA’s requirements, including by adding a new right for individuals to correct their personal data and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties upon whom we rely. Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union’s General Data Protection Regulation (“EU GDPR”), the United Kingdom’s GDPR (“UK GDPR”), Brazil’s General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or “LGPD”) (Law No. 13,709/2018), and China’s Personal Information Protection Law (“PIPL”) impose strict requirements for processing personal data. For example, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions, fines of up to 20 million euros or 4% of annual global revenue, whichever is greater, or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Risks Related to our Securities

The price of our stock may be volatile.

The listing of our common stock on Nasdaq does not assure that a meaningful, consistent and liquid trading market currently exists or will exist in the future. The trading price of our common stock may fluctuate substantially. The price of our common stock that will prevail in the market may be higher or lower than the price at which our shares of common stock, depending on many factors, some of which are beyond our control and may not be related to our company or our operating performance. These fluctuations could cause you to lose part or all of your investment in our common stock. Those factors that could cause fluctuations include, but are not limited to, the following:

- price and volume of fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- the thinly traded nature of our common stock;
- actual or anticipated changes in our net loss or fluctuations in our operating results or in the expectations of securities analysts;
- results of our preclinical studies and clinical trials or delays in anticipated timing;
- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock , or sales of large blocks of our stock and sales by insiders and our institutional investors;
- announcements of new collaboration agreements with strategic partners or developments by our existing collaboration partners;
- announcements of acquisitions, mergers or business combinations;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- general economic conditions and trends, including changes in interest rates, and other national and global conditions, including pandemics and related global economic uncertainty;
- major catastrophic events;
- departures of key personnel;
- events affecting BCM, Cell Ready or any future collaborators;
- announcements of new product candidates or technologies, commercial relationships or other events , including the results of clinical trials, or variations in our quarterly operating results;
- regulatory developments in the United States and other countries , including changes in the structure of healthcare payment systems, or other positive and negative events relating to healthcare and the overall pharmaceutical and biotechnology sectors;
- failure of our common stock to maintain listing requirements on Nasdaq;
- the outcome of any litigation to which we are a party;
- changes in accounting principles; and

- discussion of our company or our stock price by the financial and scientific press and in online investor communities.

The stock market in general, and the Nasdaq Capital Market, or Nasdaq, and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors, including potentially worsening economic conditions, may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Due to the potential volatility of our stock price, we may therefore be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

We completed a reverse stock split of our shares of common stock, which may reduce and may limit the market trading liquidity of the shares due to the reduced number of shares outstanding and may potentially have an anti-takeover effect.

We completed a reverse stock split, or the Reverse Stock Split, of our common stock by a ratio of one-for-ten (1:10) effective January 26, 2023. The liquidity of our common stock may be adversely affected by the Reverse Stock Split as a result of the reduced number of shares outstanding following the Reverse Stock Split. In addition, the Reverse Stock Split may increase the number of stockholders who own odd lots of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty affecting such sales. Reducing the number of outstanding shares of our common stock through the Reverse Stock Split is intended, absent other factors, to increase the per share market price of our common stock. However, other factors, such as our financial results, market conditions and the market perception of our business may adversely affect the market price of our common stock. As a result, there can be no assurance that the Reverse Stock Split will result in the intended benefits, that the market price of our common stock will remain higher following the Reverse Stock Split or that the market price of our common stock will not decrease in the future.

Sales of additional equity securities may adversely affect the market price of our common stock and your rights may be reduced. Our stockholders may experience dilution in the future and it may adversely affect the market price of our securities.

We expect to continue to incur drug development and sale, general and administrative costs. Until such time, if ever, as we can generate substantial product revenue, we expect to fund our cash requirements through a combination of equity offerings, debt financings and potential collaboration, license and development agreements. We do not currently have a committed external source of funds, but have entered into the ATM agreement under which we may sell shares. To the extent that we sell equity securities or convertible debt securities, including under the ATM agreement, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. The sale or the proposed sale of substantial amounts of our common stock or other equity securities in the public markets may adversely affect the market price of our common stock. Debt financing and preferred 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.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to 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 drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

As of December 31, 2023, we had 8.9 million shares of our common stock issued and outstanding (as adjusted for the Reverse Stock Split). Those outstanding shares represent a minority of our authorized shares, meaning that the ownership position of the current stockholders could be diluted significantly were we to issue a large number of additional shares. In addition, as of December 31, 2023, there were outstanding options for an aggregate of approximately 0.7 million shares of common stock at a weighted average exercise price of $25.42 per share (each as adjusted for the Reverse Stock Split). We have registered the resale of the shares issuable upon exercise of our outstanding warrants, and as a result the shares issued upon exercise will be tradable by the exercising party. Upon such registration, the holders may sell these shares in the public markets from time to time, without limitations on the timing, amount, or method of sale. If our stock price rises, the holders may exercise their warrants and options and sell a large number of shares. This could cause the market price of our common stock to decline and cause existing stockholders to experience significant further dilution.

We do not intend to pay cash dividends.

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. Any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and depends on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

General Risk Factors

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, or are perceived to have been compromised, we could experience adverse consequences, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely, may collect, receive, store, use, transmit, disclose, transfer, disclose, make accessible, protect, secure, dispose of, transmit, share, or otherwise process proprietary, confidential, and sensitive data, including personal data (such as health-related data regarding clinical trial subjects), intellectual property, and trade secrets.

Cyberattacks, malicious internet-based activity, and online and offline fraud and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely may be subject to a variety of threats, including, but not limited to, malicious code (such as viruses and worms), social engineering attacks (including through phishing attacks), malware (including as a result of advanced persistent threat intrusions), denial of service attacks (such as credential stuffing), credential harvesting, software bugs, server malfunctions, software or hardware failures, unauthorized access, natural disasters, fire, terrorism, successful breaches, personnel misconduct or error, or human or technological error, war and telecommunication and electrical failures.

In particular, severe ransomware attacks are becoming increasingly prevalent and severe, and can lead to significant interruptions in our operations, loss of sensitive data, reputational harm, and diversion of funds. Extortion payments may alleviate some of the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Additionally, future pandemics could pose increased risks to our information technology systems and data if our employees are required to work from home, utilizing network connections outside our premises. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third parties (such as service providers and technologies) to process sensitive information in a variety of contexts, including without limitation third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised. Any of the previously identified or similar threats could cause a security incident or other incident during which our information technology systems or data could be compromised, which could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure

of, or access to our data; it could also disrupt our ability (and that of third parties upon which we rely) to operate our business, including conducting our clinical trials. For example, if a compromise were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. Similarly, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against the compromise of our information technology systems and data. Further, certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and data. While we have implemented security measures designed to prevent our information technology systems and data from being compromised, there can be no assurance that these measures will be effective. We may be unable to detect vulnerabilities in our information technology systems because the threats against these systems change frequently, are often sophisticated, and may not be detected until after a compromise has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any identified vulnerabilities.

If we (or a third - party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, including: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing data (including personal data); litigation (including class actions); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Additionally, applicable data privacy and security obligations may require us to notify relevant stakeholders; such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from claims related to our data privacy and security obligations. We have cybersecurity insurance for a breach event covering expenses for notification, credit monitoring, investigation, crisis management, public relations and legal advice. We also maintain property and casualty insurance that may cover restoration of data, certain physical damage or third-party injuries caused by potential cybersecurity incidents. However, damage and claims arising from such incidents may not be covered or may exceed the amount of any insurance available. Additionally, we cannot be sure that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

As a result of being a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting, and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. We are also required to disclose significant changes made in our internal control procedures on a quarterly basis.

To comply with Section 404, we have engaged in the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. Our compliance with Section 404 requires that we incur substantial professional fees and expend significant management efforts, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common

stock could decline, and we could be subject to sanctions or investigations by the Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our ability to use net operating losses and certain other tax attributes to offset future taxable income may be subject to limitation.

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Our federal NOLs generated in tax years beginning before January 1, 2018, are permitted to be carried forward for only 20 years under applicable U.S. tax law. Our federal NOLs generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax law.

In addition, under Section 382 and Section 383 of the Internal Revenue Code of 1986, as amended, or, the Code, if a corporation undergoes an "ownership change," its ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points (by value) over their lowest ownership percentage over a rolling three-year period. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership (some of which are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations.

Catastrophic events may disrupt our business.

In the event of a major hurricane or other serious weather event or catastrophic event such as fire, power loss, cyberattack, war, terrorist attack or epidemic or pandemic that impacts the facilities of any third parties on which we may rely, we may be unable to continue our operations and may experience delays in our manufacturing process and shipment of clinical supply to trial sites or interruptions in our clinical trials and research activities, all of which could delay our development plans and materially harm our business, results of operations and prospects.

Our business and operations could be adversely affected by the effects of health epidemics, including pandemics.

Our business and operations could be adversely affected by the effects of health epidemics, as was recently experienced in connection with the COVID-19 virus, which was declared by the World Health Organization as a global pandemic.

Remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the pandemics or other health epidemics may negatively impact productivity. For instance, the COVID-19 pandemic disrupted our ongoing research and development activities and delayed certain of our clinical programs and timelines. In addition, although our employees are accustomed to working remotely, changes in internal controls due to remote work arrangements may result in control deficiencies in the preparation of our financial reports, which could be material. Such orders may also impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities.

Health epidemics may also affect the conduct of our clinical trials. Although we are enrolling patients and initiating clinical sites in our Phase 2 trial of MT-401 (zedenoleucel) for post-transplant AML, we previously experienced temporary delays in enrollment due to the COVID-19 pandemic and in satisfying certain FDA requirements to move forward with the trial, which together resulted in a delay in our overall timelines for this trial. Our ongoing and future clinical trials may be also affected by future pandemics. Patient enrollment and clinical site initiation, while ongoing, may be delayed due to prioritization of hospital resources toward pandemics or other health emergencies, if they arise. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement

or interrupt healthcare services. Similarly, we may be unable to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to health epidemics, which would adversely impact clinical trial operations.

The extent to which future pandemics impact our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the continued geographic spread of the disease, the duration and effect of any future business disruptions in the United States and other countries to contain and treat patients with the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects and may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section.

Unfavorable global political or economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, in recent years the COVID-19 pandemic, decades-high inflation and concerns about an economic recession in the United States or other major markets resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. The Federal Reserve recently raised interest rates multiple times in response to concerns about inflation and is expected to continue to raise rates. Higher interest rates, coupled with reduced government spending and volatility in financial markets, including with respect to foreign exchange, may increase economic uncertainty. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. In addition, military conflicts such as between Russia and Ukraine could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely, although we have not experienced any such disruption to date. Related sanctions, export controls or other actions have been or may in the future be initiated by nations including the United States, the European Union or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.), which could adversely affect our business and/or our supply chain, our CROs, CMOs and other third parties with whom we conduct business. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. Any significant increases in inflation and related increase in interest rates could have a material adverse effect on our business, results of operations and financial condition.

Changes in tax laws or regulations could materially adversely affect our company.

New tax laws or regulations could be enacted at any time, and existing tax laws or regulations could be interpreted, modified or applied in a manner that is adverse to us, which could adversely affect our business and financial condition. For instance, the United States recently passed the Inflation Reduction Act, which provides for a minimum tax equal to 15% of the adjusted financial statement income of certain large corporations, as well as a 1% excise tax on certain share buybacks by public corporations that would be imposed on such corporations. In addition, it is uncertain if and to what extent various states will conform to federal tax legislation. The impact of such changes or future legislation could increase our U.S. tax expense and could have a material adverse impact on our business and financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We operate in the biotechnology sector, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees or customers; violation of privacy laws and other litigation and legal risk; and reputational risk. We have implemented a risk-based approach to identify and assess the cybersecurity threats that could affect our business and information systems. Our cybersecurity program is aligned with industry standards and best practices, such as the National Institute of Standards and Technology (“NIST”) Cybersecurity Framework. We expect the third-party vendors that provide our IT services to use various tools and methodologies to manage cybersecurity risk and to monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. We expect to require third-party service providers with access to personal, confidential or proprietary information to implement and maintain cybersecurity practices consistent with applicable legal standards and industry best practices.

Our business depends on the availability, reliability, and security of our information systems, networks, data, and intellectual property. Any disruption, compromise, or breach of our systems or data due to a cybersecurity threat or incident could adversely affect our operations, customer service, product development, and competitive position. They may also result in a breach of our contractual obligations or legal duties to protect the privacy and confidentiality of our stakeholders. Such a breach could expose us to business interruption, lost revenue, ransom payments, remediation costs, liabilities to affected parties, cybersecurity protection costs, lost assets, litigation, regulatory scrutiny and actions, reputational harm, customer dissatisfaction, harm to our vendor relationships, or loss of market share.

Cybersecurity Governance and Oversight

Our board of directors addresses our cybersecurity risk management as part of its general oversight function.
Our cybersecurity risk assessment and management processes are implemented and maintained by various members of our management team, third party service providers and other employees, who we believe have a combination of relevant expertise, experience, education and training.

Certain members of our management team are responsible for hiring appropriate personnel and third-party IT service providers, helping to integrate cybersecurity risk considerations into our overall risk management strategy, communicating key priorities to relevant personnel, approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including in some cases to our executive team. Our cybersecurity incident management team, and other individuals as needed, work to help us mitigate and remediate cybersecurity incidents of which we are notified. In addition, our incident response processes include a procedure for reporting certain cybersecurity incidents to the board of directors.

The board of directors receives regular reports from management concerning our cybersecurity risk management program. The board also receives various summaries and/or presentations related to cybersecurity threats, risks and mitigation.

ITEM 2. PROPERTIES

We do not own any real estate or other properties. We do not directly lease any property but utilize office space through our service agreements with Cell Ready at 9350 Kirby Drive, Suite 300, Houston, Texas 77054, which is also our principal business office.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Other than as described below, we are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

ITEM 4. MINE SAFETY DISCLOSURE

Not Applicable

PART II

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

Market Information

Our common stock is listed for trading on the Nasdaq Capital Market under the symbol "MRKR". As of March 18, 2024, we had 36 stockholders of record, whom are holding shares. The price of our common stock on March 18, 2024 was $4.43 per share.

Dividend Policy

No dividends have been declared or paid on our common stock. We have incurred recurring losses and do not currently intend to pay any cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

We did not record any issuances of unregistered securities during the fourth quarter of 2023.

Issuer Repurchase Of Equity Securities

We did not repurchase any equity securities.

ITEM 6. [RESERVED]

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

The following discussion of our financial condition, changes in financial condition, plan of operations and results of operations should be read in conjunction with (i) our audited consolidated financial statements as of December 31, 2023 and December 31, 2022 and (ii) the section entitled "Business", included in this annual report. The discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors.

Company Overview

We are a clinical-stage immuno-oncology company specializing in the development and commercialization of novel T cell-based immunotherapies for the treatment of hematological malignancies and solid tumor indications. We developed our lead product candidates from our multiTAA-specific T cell technology, which is based on the manufacture of non-engineered, tumor-specific T cells that recognize multiple tumor-associated antigens, or TAAs. MultiTAA-specific T cells are able to recognize multiple tumor targets to produce broad spectrum anti-tumor activity. When infused into a patient with cancer, the multiTAA-specific T cells are designed to kill cancer cells expressing the TAA and potentially recruit the patient's immune system to participate in the cancer killing process.

We licensed the underlying technology for multiTAA-specific T cell therapy from Baylor College of Medicine, or BCM, in March 2018. BCM had utilized the therapy in seven exploratory clinical trials. In these studies, BCM treated over 150 patients suffering from a variety of cancers including lymphoma, multiple myeloma, acute myeloid leukemia, or AML, acute lymphoblastic leukemia, or ALL, pancreatic cancer, breast cancer and various sarcomas. In those studies, BCM saw evidence of clinical benefit, expansion of infused cells, and decreased toxicity compared to other cellular therapies.

We are advancing two product candidates for 3 clinical indications as part of our multiTAA-specific T cell program for:

- Autologous multiTAA product for the treatment of lymphoma and pancreatic cancer (MT-601)
- Off-the-Shelf (OTS) product in various indications (e.g., MT-401-OTS)

We do not genetically engineer our multiTAA-specific T cell therapies and we believe that our product candidates are superior to T cells engineered with chimeric antigen receptors, or CAR-T, for several reasons including:

- Multiple targets → enhanced tumoricidal effect→ minimized tumor immune escape
- Clinical safety → no treatment-related side effects, including cytokine release syndrome (CRS) or other severe adverse effects (SAEs), were attributed to the use of multiTAA-specific T cell therapies to date
- Non-genetically engineered T cell products → no risk of mutagenesis and reduced manufacturing complexity → lower cost

For these reasons, we believe our endogenous T cell receptor-based therapies may provide meaningful clinical benefit and safety to patients with both hematological and solid tumors.

We believe that the simplicity of our manufacturing process allows additional modifications to expand multiTAA-specific T cell recognition of cancer targets. For example, we are assessing the potential of combining multiTAA-specific T cell products with other products.

Reverse Stock Split

On January 24, 2023, our board of directors approved the filing of a certificate of amendment to our amended and restated certificate of incorporation (the "Amendment") with the Secretary of State of the State of Delaware to effect the one-for-ten (1:10) Reverse Stock Split of our outstanding common stock and a reduction in the total number of authorized shares of our common stock from 300,000,000 to 30,000,000 (the "Shares Reduction"). The Amendment became effective at 5:00 p.m. Eastern Time on January 26, 2023.

Pursuant to the Amendment, at the effective time of the Amendment, every ten (10) shares of our issued and outstanding common stock was automatically combined into one (1) issued and outstanding share of common stock and the authorized shares of our common stock was reduced from 300,000,000 to 30,000,000, without any change in par value per share. The Reverse Stock Split affected all shares of our common stock outstanding immediately prior to the effective time of the Amendment. No fractional shares were issued as a result of the Reverse Stock Split. Stockholders of record who would otherwise be entitled to receive a fractional share received a cash payment in lieu thereof. As a result of the Reverse Stock Split, proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options and warrants issued by us and outstanding immediately prior to the effective time of the Amendment, which resulted in a proportionate decrease in the number of shares of our common stock reserved for issuance upon exercise or vesting of such stock options and warrants and a proportionate increase in the exercise price of all such stock options and warrants. In addition, the number of shares reserved for issuance under our equity compensation plans immediately prior to the effective time of the Amendment were reduced proportionately. All share and per share amounts of common stock presented in this Annual Report on Form 10-K have been retroactively adjusted to reflect the one-for-10 (1:10) Reverse Stock Split.

Financial Overview

Research and Development Expenses

Our research and development expenses are primarily costs associated with our clinical trials, including compensation, share-based compensation expense and benefits for employees and selected consultants, manufacturing expenses and fees paid to third parties.

Clinical costs are expensed as incurred. Costs and timing of clinical trials and development of our product candidates will depend on a variety of factors that include, but are not limited to, the following:

- per patient clinical trial costs;
- the number of patients that participate in the clinical trials;
- the number of sites included in the clinical trials;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the efficacy and safety profile of the product candidates; and
- the ability to successfully manufacture patient doses.

In addition, the potential for success of each product candidate will depend on numerous factors, including clinical trial outcomes, acceptance by regulatory authorities, competition, manufacturing capability and commercial viability. We determine which programs to pursue and how much to fund each program in response to ongoing scientific assessments, competitive developments, clinical trial results, as well as an assessment of each product candidate’s commercial potential. We anticipate our clinical trial costs will continue to increase over the next several years due to increased spending on the clinical development and manufacturing of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, including share-based compensation, legal fees relating to patent and corporate matters, insurance costs, consulting and professional fees, audit and investor relations.

Income Taxes

We recognized $4,000 in state tax expense for the year ended December 31, 2023 and none for the year ended December 31, 2022.

Other Income (Expense)

Other income (expense), net consists of interest income and arbitration settlement expenses.

Results of Operations For the Years Ended December 31, 2023 and 2022

The following table summarizes the results of our continuing operations (rounded to the thousand except for per share amounts) for the years ended December 31, 2023 and 2022, together with the changes to those items:

	For the Years Ended December 31,			
	2023	2022	Change	
Revenues:				
Grant income	$ 3,311,000	$ 3,514,000	$ (203,000)	(6)%
Total revenues	3,311,000	3,514,000	(203,000)	(6)%
Operating expenses:				
Research and development	10,417,000	11,968,000	(1,551,000)	(13)%
General and administrative	7,476,000	11,336,000	(3,860,000)	(34)%
Total operating expenses	17,893,000	23,304,000	(5,411,000)	(23)%
Loss from operations	(14,582,000)	(19,790,000)	5,208,000	(26)%
Other income (expenses):				
Arbitration settlement	—	(233,000)	233,000	(100)%
Interest income	539,000	248,000	291,000	117 %
Loss from continuing operations before income taxes	**(14,042,000)**	**(19,775,000)**	**5,733,000**	**(29)%**

Revenue

We did not generate any revenue during the years ended December 31, 2023 and 2022, respectively, from the sales or licensing of our product candidates.

In August 2021, we received notice of a Product Development Research award totaling approximately $13.1 million from the Cancer Prevention and Research Institute of Texas, or CPRIT, to support our Phase 2 clinical trial of MT-401. During the years ended December 31, 2023 and 2022, respectively, we recognized $2.7 million and $3.4 million of revenue associated with the CPRIT grant.

On September 13, 2022, we received notice from the FDA that we had been awarded a $2.0 million grant from the FDA's Orphan Products Grant program to support our Phase 2 clinical trial of MT-401 for the treatment of post-transplant AML. During the years ended December 31, 2023 and 2022, we recognized $0.4 million and $0.1 million of revenue associated with the FDA grant, respectively.

In May 2023, we received notice of a $2.0 million grant from the National Institutes of Health Small Business Innovation Research ("SBIR") program to support the development and investigation of MT-401 for the treatment of AML patients following standard-of-care therapy with hypomethylating agents. During the year ended December 31, 2023, we recognized $0.2 million of revenue associated with the SBIR grant.

All funding agencies have agreed to continue their financial support and to shift funds to the MT-401-OTS program.

Operating Expenses

Operating expenses incurred during the fiscal year ended December 31, 2023 were $17.9 million compared to $23.3 million in the prior year. Significant changes and expenditures in operating expenses are outlined as follows:

Research and Development Expense

Research and development expenses or clinical trial costs decreased by 13% to $10.4 million for the year ended December 31, 2023, compared to $12.0 million for the year ended December 31, 2022, mainly as a result of the Cell Ready transaction.

The decrease of $1.6 million in 2023 was primarily attributable to the following:

- decrease of $2.1 million in process development expenses,
- decrease of $0.8 million in AML Phase 2 clinical trial expenses, offset by
- increase of $1.3 million in Cell Ready (outsourced) clinical manufacturing costs and process development expenses.

General and Administrative Expenses

General and administrative expenses decreased by 34% to $7.5 million for the year ended December 31, 2023 from $11.3 million during the prior period.

The decrease in general and administrative expenses of $3.8 million mainly comprised the following:

- decrease of $3.2 million in headcount-related expenses, including stock-based compensation expense and net of severance expense,
- decrease of $0.6 million in rent and utilities expense, primarily as a result of the Cell Ready transaction, including its assumption of facility leases,
- decrease of $0.6 million in legal and professional fees,
- decrease of $0.2 million in insurance expense, offset by
- increase of $0.8 million in consulting expenses.

In 2023, the Company implemented changes to its organizational structure due to the transaction with Cell Ready and to reduce operational costs. In connection with these changes, the Company reduced headcount, including the separation of its former Chief Executive Officer, Peter Hoang, in May 2023 and its former Chief Accounting Officer, Michael Loiacono, in June 2023. During the second quarter of 2023, the Company recorded $0.9 million of severance and termination-related costs. The payments of these costs were completed in July of 2023. Effective May 1, 2023, the Company's board of directors appointed Dr. Juan Vera as the Company's President and Chief Executive Officer.

Effective June 30, 2023, the board of directors appointed Eliot M. Lurier as the Company's Interim Chief Financial Officer, whereby Mr. Lurier provided consulting services to the Company pursuant to a consulting between the Company and Danforth Advisors, LLC ("Danforth") and received no compensation directly from the Company. On November 17, 2023, the Company terminated the consulting agreement between the Company and Danforth, effective January 16, 2024.

On November 17, 2023, Mr. Lurier ceased serving as the Company's Interim Chief Financial Officer and Dr. Vera was appointed as the Company's Principal Financial and Accounting Officer.

Other Income /(Expense)

Arbitration settlement

An arbitration proceeding was brought against us before the Financial Industry Regulatory Authority, Inc., or FINRA by a broker seeking to be paid compensation for two financing transactions that occurred in 2018, a warrant conversion and a private placement, each brokered by another broker. The broker's claims were based on a placement agent agreement for a private placement it brokered in 2017, under which it alleged it was entitled to compensation for the 2018 transactions. The FINRA panel found in favor of the broker and awarded the broker $2.4 million for compensation, interest and attorney fees. As of December 31, 2021, we recorded an accrual of $2.4 million in accrued liabilities on our consolidated balance sheet and a $2.4 million charge to other expenses. On September 17, 2021, the broker filed a petition to confirm the FINRA arbitration award in the Supreme Court of New York for the County of New York. We removed the case to the United States District Court for the Southern District of New York on September 27, 2021. On October 22, 2021, we filed a motion in federal court to vacate the award. On March 9, 2022, we were notified that our motion to vacate the award was denied and the broker was awarded an additional $0.1 million in interest. Post judgment interest accrued at 1.02% until the judgment was paid. We paid the $2.5 million judgment on March 24, 2022. On January 4, 2023, we were notified that the broker was awarded an additional $0.1 million in attorneys' fees, which we recorded to other expenses during fiscal year ending December 31, 2022. We paid the $0.1 million on January 9, 2023.

Interest Income

Interest income was $0.5 million and $0.2 million for the years ended December 31, 2023 and 2022, respectively, and was attributable to interest income relating to funds that are held in U.S. Treasury notes and U.S. government agency-backed securities.

Net Loss from continuing operations

The decrease in our net loss from continuing operations during the year ended December 31, 2023 compared to the year ended December 31, 2022 was due to higher grant income and related party service revenue, cost reductions in our research and development activities and moderate stabilization of our clinical trial activities. We anticipate that we will continue to incur net losses in the future as we continue to invest in research and development activities, including clinical development of our multiTAA T cell product candidates.

Liquidity and Capital Resources

We have not generated any revenues from the sales or licensing of our product candidates since inception and only have limited revenue associated with grants to fund research. We have financed our operations primarily through public and private offerings of our stock and debt including warrants and the exercise thereof, grants, and more recently through the cash proceeds received from the Cell Ready transaction and additional grants to fund research.

The following table sets forth our cash and cash equivalents and working capital as of December 31, 2023 and 2022:

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 15,111,000	$ 11,782,000
Working capital	$ 14,053,000	$ 8,837,000

Cash Flows

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

	For the Years Ended December 31,	
	2023	2022
Continuing operations:		
Net cash used in operating activities	$ (10,341,000)	$ (21,513,000)
Net cash provided by financing activities	1,105,000	202,000
Discontinued operations		
Net cash used in operating activities	(6,099,000)	(5,459,000)
Net cash provided by (used in) investing activities	$ 18,664,000	$ (4,945,000)
Net increase (decrease) in cash and cash equivalents	$ 3,329,000	$ (31,715,000)

Continuing Operations

Operating Activities

Net cash used in operating activities from continuing operations during the year ended December 31, 2023 was $10.3 million. The use of cash primarily related to our net loss from continuing operations of $14.0 million, partially offset by a $2.8 million increase from changes in assets and liabilities and $0.9 million of stock-based compensation.

Net cash used in operating activities from continuing operations during the year ended December 31, 2022 was $21.5 million. The use of cash primarily related to our net loss from continuing operations of $19.8 million and a $4.7 million decrease from changes in assets and liabilities. This decrease was partially offset by $3.3 million of stock-based compensation.

Financing Activities

Net cash provided by financing activities was $1.1 million and $0.2 million during the years ended December 31, 2023 and 2022, respectively, primarily due to the net proceeds received from sale of common stock through the ATM Agreement as well as the exercise of stock options.

Discontinued Operations

Operating Activities

Net cash used in operating activities from discontinued operations during the year ended December 31, 2023 was $6.1 million, which primarily related to our net loss from discontinued operations of $3.0 million, which is net of $2.5 million in revenue for which cash had been received in the prior period.

Net cash used in operating activities from discontinued operations during the year ended December 31, 2022 was $5.5 million, which primarily related to our net loss from discontinued operations of $10.2 million, partially offset by cash received in advance of related party revenue recorded.

Investing Activities

Net cash provided by investing activities from discontinued operations for the year ended December 31, 2023 was $18.7 million primarily due to the proceeds from the Cell Ready transaction, net of transaction costs.

Net cash used in investing activities from discontinued operations was $4.9 million for the year ended December 31, 2022. $1.3 million in purchases of property and equipment for the year ended December 31, 2022 were comprised of laboratory equipment along with $0.1 million of computers, software and equipment and $0.1 million of furniture and fixtures. $3.5 million of purchases in construction in progress related to a second modular cleanroom and the continued buildout of our former manufacturing facility.

Future Capital Requirements

To date, we have not generated any revenues from the commercial sale of approved drug products, and we do not expect to generate substantial revenue for at least the next several years. If we fail to complete the development of our product candidates in a timely manner or fail to obtain their regulatory approval, our ability to generate future revenue will be compromised. We do not know when, or if, we will generate any revenue from our product candidates, and we do not expect to generate significant revenue unless and until we obtain regulatory approval of, and commercialize, our product candidates. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of and seek marketing approval for our product candidates. In addition, if we obtain approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

In August 2021, the Company received notice of a Product Development Research award totaling approximately $13.1 million from the CPRIT to support the Company’s Phase 2 clinical trial of MT-401. The CPRIT award is intended to support the adjuvant arm of the Company’s Phase 2 clinical trial evaluating MT-401 when given as an adjuvant therapy to patients with acute myeloid leukemia following a hematopoietic stem cell transplant. The primary objectives of the adjuvant arm of the trial are to evaluate relapse-free survival after MT-401 treatment when compared with a randomized control group. Through the date of this filing, the Company has received $6.8 million of funds from the CPRIT grant. The Company recorded $2.7 million of grant income related to the CPRIT grant as revenue for the year ended December 31, 2023 and at December 31, 2023, the Company recorded $0.5 million of grant income receivable.

On September 13, 2022, the Company received notice from the FDA that it had awarded the Company a $2.0 million grant from the FDA’s Orphan Products Grant program to support the Company’s Phase 2 clinical trial of MT-401 for the treatment of post-transplant AML. The Company recorded $0.4 million of grant income related to the FDA grant as revenue for the year ended December 31, 2023 and at December 31, 2023, the Company recorded $0.3 million of grant income receivable. In February 2024, the Company received $0.3 million of funds from the FDA grant.

In May 2023, the Company announced that it had received a $2.0 million grant from the National Institutes of Health Small Business Innovation Research (“SBIR”) program to support the development and investigation of MT-401 for the treatment of AML patients following standard-of-care therapy with hypomethylating agents. The Company recorded $0.2 million of grant income related to the SBIR grant as revenue for the year ended December 31, 2023 and at December 31, 2023, the Company recorded $0.2 million of grant income receivable. In February 2024, the Company received $0.2 million of funds from the SBIR grant.

All funding agencies have agreed to continue their financial support and to shift funds to the MT-401-OTS program.

As of December 31, 2023, we had working capital of $14.1 million, compared to working capital of $8.8 million as of December 31, 2022. Operating expenses incurred during the fiscal year ended December 31, 2023 were $17.9 million compared to $23.3 million in the prior year. Based on our clinical plans and our timing expectations related to the progress of our programs, we expect that, together with drawdowns of available grant funds, our cash and cash equivalents as of December 31, 2023 will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2025. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Furthermore, our operating plan may change, and we may need additional funds sooner than planned in order to meet operational needs and capital requirements for

product development and commercialization. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, as we:

- initiate or continue clinical trials of our product candidates;
- continue the research and development of our product candidates and seek to discover additional product candidates; seek regulatory approvals for our product candidates if they successfully complete clinical trials;
- continue development of our manufacturing capabilities and our manufacturing facility;
- establish sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any product candidates that may receive regulatory approval;
- evaluate strategic transactions we may undertake; and
- enhance operational, financial and information management systems and hire additional personnel, including personnel to support development of our product candidates and, if a product candidate is approved, our commercialization efforts.

Because all of our product candidates are in the early stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of product candidates or whether, or when, we may achieve profitability. Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity or debt financings and collaboration arrangements.

We plan to continue to fund our operations and capital funding needs through equity and/or debt financing. We may also consider new collaborations or selectively partner our technology. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our existing stockholders' common stock. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us. We may also be required to pay damages or have liabilities associated with litigation or other legal proceedings involving our company.

In addition to the foregoing, based on our current assessment, we do not expect any material impact on our long-term liquidity due to the COVID-19 pandemic. However, we will continue to assess the effect of the pandemic on our operations. Further, the COVID-19 pandemic, decades-high inflation and concerns about an economic recession in the United States or other major markets has resulted in, among other things, volatility in the capital markets that may have the effect of reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction due to these factors could materially affect our business and the value of our common stock.

ATM Agreement

In August 2021, we entered into a Controlled Equity Offering[SM] Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co. and RBC Capital Markets, LLC, or the Sales Agents, pursuant to which we can offer and sell, from time to time at our sole discretion through the Sales Agents, shares of our common stock having an aggregate offering price of up to $75.0 million. Any shares of our common stock sold will be issued pursuant to our shelf registration statement on Form S-3 (File No. 333-258687), which the SEC declared effective on August 19, 2021. However, our use of the shelf registration statement on Form S-3 will be limited for so long as we are subject to General Instruction I.B.6 of Form S-3, which limits the amounts that we may sell under the registration statement and in accordance with the ATM agreement. The Sales Agents will be entitled to compensation under the Sales Agreement at a commission

rate equal to 3.0% of the gross sales price per share sold under the ATM Agreement, and we have provided each of the Sales Agents with indemnification and contribution rights. During the year ended December 31, 2023, we sold 265,334 shares of our common stock under the ATM Agreement for proceeds of $1.0 million. During the year ended December 31, 2022, we sold 60,651 shares of our common stock under the ATM agreement for proceeds of $202,100.

Stock Purchase Agreement

On December 12, 2022, we entered into a purchase agreement, or the Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, which provides that, upon the terms and subject to the conditions of the agreement, we have the right, but not the obligation, to sell to Lincoln Park up to $25,000,000 of shares of our common stock, or the Purchase Shares, from time to time over a 24-month term, at a variable price with certain market-based terms as defined in the agreement. The purchase agreement does not exhibit any of the characteristics for liability classification under ASC Topic 480, Distinguishing Liabilities from Equity. During the year ended December 31, 2023, we sold 12,500 shares of our stock under the Purchase Agreement. In January 2023, Lincoln Park was issued 180,410 shares of stock as a commitment fee at a value of $0.5 million. On February 29, 2024, we terminated the Purchase Agreement with Lincoln Park effective March 1, 2024.

Going Concern

We have no sources of revenue to provide incoming cash flows to sustain our future operations. Prior to the Cell Ready transaction, there was substantial doubt regarding the Company’s ability to continue as a going concern, which was alleviated by the proceeds from the transaction. As outlined above, we expect that our cash and cash equivalents including drawdowns from available grant funds will enable us to fund our operations into the fourth quarter of 2025. However, our ability to pursue our longer term planned business activities is dependent upon our successful efforts to raise additional capital and obtain grant funding.

Our consolidated financial statements have been prepared on a going concern basis, which implies that we will continue to realize our assets and discharge our liabilities in the normal course of business. Our financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Critical Accounting Policies and Estimates

The consolidated financial statements are prepared in conformity with U.S. GAAP, which require the use of estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of expenses in the periods presented.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of expenses that are not readily apparent from other sources. Actual results could differ from those estimates.

Discontinued Operations

The Purchased Assets sold to Cell Ready pursuant to the Cell Ready Purchase Agreement constituted a significant disposition and as such, the Company concluded that the disposition of its Purchased Assets represented a strategic shift that had a major effect on its operations and financial results. Therefore, the Purchased Assets, related party revenue, service revenue and related expenses are classified as discontinued operations for all periods presented herein. See Note 6 to the accompanying financial statements for further information.

Property and Equipment

Leasehold improvements, furniture, equipment and software are recorded at cost and are depreciated using the straight-line method over the estimated useful lives of the related assets, which range from three to five years. Leasehold improvements are amortized over the shorter of the estimated useful life or the remaining lease term.

Stock-Based Compensation

The Company incurs stock-based compensation expense related to the issuance of common stock and stock options. The Company estimates the fair value of stock options granted using the Black-Scholes option pricing model. The Black-Scholes option pricing model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility and expected option life:

Expected Term — The expected life of stock options was estimated using the "simplified method," as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant.

Expected Volatility — The Company computes stock price volatility over expected terms based on its historical common stock trading prices.

Risk-Free Interest Rate — The Company bases the risk-free interest rate on the implied yield available on U. S. Treasury zero-coupon issues with an equivalent remaining term.

Expected Dividend — The Company has never declared or paid any cash dividends on its common shares and does not plan to pay cash dividends in the foreseeable future, and, therefore, uses an expected dividend yield of zero in its valuation models.

The Company amortizes the fair value of the awards expected to vest on a straight-line basis over the requisite service period of the awards. The Company recognizes fair value of stock options granted to nonemployees as stock-based compensation expense over the period in which the related services are received as if the Company had paid cash for those services. Forfeitures are accounted for as incurred.

Grant Income

Grant Income represents funding under cost reimbursement programs from government agencies and non-profit foundations for qualified research and development activities performed by the Company. In applying the provisions of ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"), we determined that grants and awards are out of the scope of ASC 606 because the funding entities do not meet the definition of a "customer", as defined by ASC 606, as there is not considered to be a transfer of control of goods or services. With respect to each grant or award, the Company determines if it has a collaboration in accordance with ASC Topic 808, Collaborative Arrangements ("ASC 808"). To the extent the grant or award is within the scope of ASC 808, the Company recognizes the award upon achievement of certain milestones as credits to research and development expenses. For grant and awards outside the scope of ASC 808, the Company applies ASC 606 by analogy, and revenue is recognized when the Company incurs expenses related to the grants for the amount the Company is entitled to under the provisions of the contract.

In August 2021, we received notice of a Product Development Research award totaling approximately $13.1 million from CPRIT to support our Phase 2 clinical trial of MT-401.

The Company determined that the CPRIT Contract is not in the scope of ASC 808 or ASC 606. In accordance with ASC 730-20-25-8, the financial risk associated with the research and development has been transferred to CPRIT, because repayment of the grant depends solely on the results of research and development having future economic benefit. The Company accounts for this arrangement as a contract to perform research and development for others and applies ASC 606 by analogy.

The Company recognizes grant income when amounts eligible for reimbursement are determinable and have been incurred, the applicable conditions under the grant arrangements have been met, and collectability of amounts due is reasonably assured or already received. The classification of costs incurred related to grants is based on the nature of the activities performed by the Company. Grant Income is recognized when the related costs are incurred. Restricted cash received from grants in advance of incurring qualifying costs is recorded as deferred revenue and recognized as revenue when qualifying costs are incurred. Qualifying grant income earned in advance of cash received from grants is recognized as revenue and recorded as other receivable.

In September 2022, the Company received notice from the FDA that it had awarded the Company a $2.0 million grant from the FDA's Orphan Products Grant program to support the Company's Phase 2 clinical trial of MT-401 for the treatment of post-transplant AML.

In May 2023, the Company announced that it had received a $2.0 million grant from the National Institutes of Health Small Business Innovation Research ("SBIR") program to support the development and investigation of MT-401 for the treatment of AML patients following standard-of-care therapy with hypomethylating agents.

All funding agencies have agreed to continue their financial support and to shift funds to the MT-401-OTS program.

New Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed, the Company does not believe that the impact of recently issued standards that are not yet effective will have a material impact on its financial position or results of operations upon adoption.

Recently Issued Accounting Standards Not Yet Adopted

Improvements to Reportable Segment Disclosures

In November 2023, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. The ASU requires disclosures to include significant segment expenses that are regularly provided to the chief operating decision maker, among other provisions. The ASU is effective for fiscal year periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted and the ASU requires retrospective application to all prior periods presented in the financial statements. The Company is currently evaluating the standard to determine the impact of adoption to its consolidated financial statements and disclosures.

Improvements to Income Tax Disclosures

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (ASU 2023-09), which improves the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. This guidance will be effective for the annual periods beginning the year ended December 31, 2025. Early adoption is permitted. Upon adoption, the guidance can be applied prospectively or retrospectively. We do not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues, expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Tax Loss and Credit Carryforwards

As of December 31, 2023, we have approximately $131.8 million of federal and $38.4 million of state net operating loss carryforwards that may be available to offset future taxable income, if any. The federal net operating loss carryforwards of $38.0 million, if not utilized, will expire between 2030 and 2037. The federal net operating loss carryforwards of $93.8 million generated in 2018 and thereafter are subject to an 80% limitation on taxable income, do not expire and will carry forward indefinitely. The state net operating loss carryforwards of $21.7 million, if not utilized, will begin to expire in 2035. The state net operating loss carryforwards of $16.6 million generated in 2018 and thereafter are subject to an 80% limitation on taxable income, do not expire and will carry forward indefinitely. Any change in ownership greater than 50% under Section 382 of the Internal Revenue Code places significant annual limitations on the use of such net operating loss carryforwards.

At December 31, 2023 and 2022, we recorded a 100% valuation allowance against our deferred tax assets of approximately $39.7 million and $41.3 million, respectively, as our management believes it is uncertain that they will be fully realized. For the year ended December 31, 2023, we realized $3.6 million of federal net operating losses and $0.1 million of state net operating losses as a result of the gain on sale of assets and capitalization for Section 174 R&E expenditures. If we determine in the future that we will be able to realize all or a portion of our net operating loss carryforwards, an adjustment to valuation allowance against our deferred tax assets would increase net income in the period in which we make such a determination.

Inflation

Inflation affects the cost of raw materials, goods and services that we use. In recent years, inflation has been modest. However, fluctuations in energy costs and commodity prices can affect the cost of all raw materials and components. The competitive environment somewhat limits our ability to recover higher costs resulting from inflation by raising prices. Although we cannot precisely determine the effects of inflation on our business, it is management's belief that the effects on future revenues and operating results will not be significant. We do not believe that inflation has had a material impact on our results of operations for the periods presented, except with respect to payroll-related costs and other costs arising from or related to government-imposed regulations.

Recent Developments

On February 22, 2024, we entered into a Master Services Agreement for Product Supply (the "MSA") with Cell Ready LLC ("Cell Ready") to provide services previously performed by the company until the disposition of its contract development and manufacturing operations. Cell Ready, which is owned by one of our directors and shareholders, Mr. John Wilson, is a contract development and manufacturing organization (CDMO).

Pursuant to the MSA, the Company may contract with Cell Ready for the provision of various products and services from time to time by entering into work orders with Cell Ready. If the services involve the supply of product, Cell Ready is required to supply such product in conformance with the product requirements set forth in the applicable work order(s). The MSA contains customary representations, warranties and indemnification provision. The initial term of the MSA is three years and may be extended upon the mutual written agreement of the parties. Either party may terminate the MSA (a) for material breach by the other party if such breach has not been cured within 30 days following notice of termination or (b) if the other party is the subject of an insolvency event.

Under the MSA, Cell Ready is to use only personnel with sufficient qualifications and experience to supply the services contemplated by the MSA, provide its personnel with adequate training and assume full responsibility for its personnel's compliance with the MSA. Further, Cell Ready is required to provide the Company with assistance and cooperation in order for the Company to obtain and maintain all necessary regulatory approvals, at the Company's expense.

With regard to intellectual property, the MSA provides that each party will solely and exclusively own all right, title and interest in and to their Background IP and all inventions derived from such background IP (such invention being referred to as Foreground IP).

Background IP means all intellectual property either (a) owned or controlled by a party prior to the effective date of the MSA or (b) developed or acquired by a party independently from performance under the MSA without the use of, reliance on, or access to the other parties confidential information. Furthermore, pursuant to the MSA, Cell Ready grants to the Company a non-exclusive, perpetual, irrevocable, transferable, assignable, fully-paid up, royalty-free, worldwide license to and under any of Cell Ready's Background IP and Foreground IP to the extent they are incorporated or embedded in any deliverables provided to the Company or in the process of generating or manufacturing such deliverables and reasonably necessary or useful for the Company to make, have made, manufacture, have manufactured, use, have used, offer for sale, sell, import, and otherwise exploit such deliverables. The Company grants to Cell Ready until the termination or expiry of any applicable Work Order and for a period not exceeding the term of the MSA, a non-exclusive, fully paid-up, non-transferable, non-sublicensable limited license under and to the Company's Background IP made available to Cell Ready pursuant to a Work Order solely to the extent required for Cell Ready to provide the services under such Work Order.

Also on February 22, 2024, the Company entered into Work Order #1 under the MSA, pursuant to which Cell Ready will provide the Company with GMP drug product for Marker MT-401 and/or MT-601. The services include the delivery of final drug product and quality control testing. The Company also requested Cell Ready to provide general support services in connection therewith. The total projected sum (inclusive of taxes) for the services under Work Order #1 are not anticipated to exceed $750,000. The services will cover the anticipated manufacturing costs for the first quarter of 2024. Additional Work Orders are expected to be generated for the remainder of 2024.

The above description of the MSA and Work Order #1 do not purport to be complete and are qualified in their entirety by reference to the full text of the MSA and Work Oder #1, copies of which are attached hereto as Exhibits 10.8 and 10.9 and are incorporated herein by reference. The MSA has been filed as an exhibit to this Annual Report on Form 10-K to provide investors with information regarding the terms of the MSA and is not intended to modify or supplement any factual disclosures about the Company in its public reports filed with the SEC. In particular, the MSA is not intended to be, and should not be relied upon as, disclosure regarding any facts and circumstances relating to the Company. The representations, warranties, and covenants contained in the MSA have been made solely for the purposes of the MSA and as of specific dates; were solely for the benefit of the parties to the MSA; are not intended as statements of fact to be relied upon by the parties' shareholders; may no longer be true as of a given date; and may apply standards of materiality in a way that is different from what may be viewed as material by shareholders. Security holders are not third-party beneficiaries under the MSA and should not rely on the representations, warranties, and covenants or any descriptions thereof as characterizations of any actual state of facts or of the condition of the Company.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

The Financial Statements are incorporated herein by reference to pages beginning on page F-1 at the end of this report and the supplementary data is not applicable.

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

We have had no changes in, or disagreements with our principal independent accountants.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We have established disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934. Under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2023 to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 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 us in the reports that we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure. Our management, with participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2023 to provide reasonable assurance that the information required to be disclosed by us in this Annual Report was (a) reported within the time periods specified by SEC rules and regulations and (b) communicated to our management, including our Chief Executive Officer and Principal Financial Officer, to allow timely decisions regarding any required disclosure.

Management’s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2023 based on the framework in Internal Control—Integrated Framework 2013 issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

Cybersecurity

We utilize information technology for internal and external communications with vendors, clinical sites, banks, investors and shareholders. Loss, disruption or compromise of these systems could significantly impact operations and results.

We are not aware of any material cybersecurity violation or occurrence. We believe our efforts toward prevention of such violation or occurrence, including system design and controls, processes and procedures, training and monitoring of system access, limit, but may not prevent unauthorized access to our systems.

Other than temporary disruption to operations that may be caused by a cybersecurity breach, we consider cash transactions to be the primary risk for potential loss. We and our financial institution take steps to minimize the risk by requiring multiple levels of authorization and other controls.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the fiscal quarter ended December 31, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Internal Controls

In designing and evaluating the disclosure controls and procedures, management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Our management, including our Chief Executive Officer and Principal Financial and Accounting Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud.

ITEM 9B. OTHER INFORMATION

Rule 10b5–1 trading arrangement. During the fourth quarter of 2023, no director or Section 16 officer adopted or terminated any Rule 10b5-1 plan or non-Rule 10b5-1 trading arrangements.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item and not set forth below will be set forth in the sections headed "Election of Directors," "Executive Officers" and "Delinquent Section 16(a) Reports" in our definitive proxy statement for our 2023 Annual Meeting of Stockholders, or our Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023 and is incorporated herein by reference.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial and accounting officer or controller, or persons performing similar functions, known as the Code of Ethics and Business Conduct. The Code of Ethics and Business Conduct is available on our website at www.markertherapeutics.com under the Corporate Governance section of our Investors page. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be set forth in the section headed "Executive Compensation" in our Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth in the section headed "Securities Authorized for Issuance Under Equity Compensation Plans" and "Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement and is incorporated herein by reference.

The information required by Item 201(d) of Regulation S-K will be set forth in the section headed "Executive Compensation" and "Information Regarding the Board of Directors and Corporate Governance" in our Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item will be set forth in the section headed "Transactions with Related Persons and Indemnification" and "Information Regarding the Board of Directors and Corporate Governance" in our Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item will be set forth in the section headed "Principal Accountant Fees and Services" in our Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The documents filed as part of this report are as follows:

1. The financial statements and accompanying report of independent registered public accounting firm are set forth immediately following the signature page of this report beginning on page F-1.

2. All financial statement schedules are omitted because they are inapplicable, not required or the information is included elsewhere in the financial statements or the notes thereto.

3. The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

EXHIBIT INDEX

		Incorporated by Reference				
Exhibit number	**Exhibit description**	**Form**	**File no.**	**Exhibit**	**Filing date**	**Filed herewith**
3.1	Certificate of Incorporation	8-K	001-37939	3.4	10/17/18	
3.2	Certificate of Amendment to Certificate of Incorporation of Marker Therapeutics, Inc.	8-K	001-37939	3.1	5/27/22	
3.3	Certificate of Amendment to Certificate of Incorporation of Marker Therapeutics, Inc.	8-K	001-37939	3.1	1/26/23	
3.4	Bylaws of Marker Therapeutics, Inc.	8-K	001-37939	3.6	10/17/18	
4.0	Form of Common Stock Certificate of Marker Therapeutics, Inc.					X
4.1	Description of Securities of Marker Therapeutics, Inc.					X
10.1	Exclusive License Agreement between Baylor College of Medicine and Marker Therapeutics, Inc. dated March 16, 2018***	10-K	001-37939	10.21	3/15/19	
10.2	Sponsored Research Contract between Baylor College of Medicine and Marker Therapeutics, Inc. dated November 16, 2018***	10-K	001-37939	10.22	3/15/19	
10.3	Consulting Agreement between Dr. Juan Vera and Marker Therapeutics, Inc. dated October 19, 2018*	8-K	001-37939	10.1	10/23/18	
10.4	Form of Director and Officer Indemnification Agreement*	10-K	001-37939	10.39	3/15/19	
10.5	Marker Therapeutics, Inc. 2020 Equity Incentive Plan	S-8	333-239136	99.1	6/12/20	
10.6	Form of Stock Option Grant Notice and Stock Option Agreement under the Marker Therapeutics, Inc. 2020 Equity Incentive Plan.	10-Q	001-37939	10.1	11/9/20	
10.7	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the Marker Therapeutics, Inc. 2020 Equity Incentive Plan.	10-Q	001-37939	10.2	11/9/20	

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
10.8	Master Services Agreement for Product Supply between Marker Therapeutics, Inc. and Cell Ready LLC dated February 22, 2024**					X
10.9	Work Order #1 between Marker Therapeutics, Inc. and Cell Ready LLC dated February 22, 2024**					X
10.10	Controlled Equity Offering Sales Agreement, dated as of August 10, 2021, by and among Marker Therapeutics, Inc. and Cantor Fitzgerald & Co. and RBC Capital Markets, LLC	S-3	333-258687	1.2	8/10/21	
21.1	List of Subsidiaries					X
23.1	Consent of Marcum LLP, an independent public accounting firm.					X
24.1	Powers of Attorney (included on signature page)					X
31.1	Certification of Chief Executive Officer pursuant to Securities Exchange Act of 1934 Rule 13a-14(a) or 15d-14a					X
31.2	Certification of Chief Financial Officer pursuant to Securities Exchange Act of 1934 Rule 13a-14(a) or 15d-14a					X
32.1	Certification of Chief Executive Officer pursuant to 18 U. S. C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002#					X
32.2	Certification of Chief Financial Officer pursuant to 18 U. S. C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002#					X
97	Incentive Compensation Recoupment Policy					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101 filed herewith)					

* Executive management contract or compensatory plan or arrangement.

** Confidential treatment has been granted as to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended, or Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

*** Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for conditional treatment and this exhibit has been submitted separately with the SEC.

These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350 and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 and 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.

Dated: March 25, 2024

Marker Therapeutics, Inc.

By: /s/ Juan Vera
Juan Vera
Chief Executive Officer and Treasurer (Principal Executive Officer and Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each of the undersigned officers and directors of Marker Therapeutics, Inc., hereby constitutes and appoints Juan Vera their true and lawful attorney-in-fact and agent, for them and in their name, place and stead, in any and all capacities, to sign their name to any and all amendments to this Report on Form 10-K, and other related documents, and to cause the same to be filed with the Securities and Exchange Commission, granting unto said attorneys, full power and authority to do and perform any act and thing necessary and proper to be done in the premises, as fully to all intents and purposes as the undersigned could do if personally present, and the undersigned for himself hereby ratifies and confirms all that said attorney shall lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on March 25, 2024 on behalf of the registrant and in the capacities indicated.

Signature	Title	Date
/s/ Juan Vera Juan Vera	President, Chief Executive Officer and Treasurer, Director (Principal Executive Officer and Principal Financial and Accounting Officer)	March 25, 2024
/s/ N. David Eansor N. David Eansor	Chairman	March 25, 2024
/s/ John Wilson John Wilson	Director	March 25, 2024
/s/ Katharine Knobil Katharine Knobil	Director	March 25, 2024
/s/ Steve Elms Steve Elms	Director	March 25, 2024

MARKER THERAPEUTICS, INC.
CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2023 AND DECEMBER 31, 2022

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Marker Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Marker Therapeutics, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

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 audits 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 Description

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Discontinued Operations – Recognition and deconsolidation of assets sold to a related party.

Critical Audit Matter Description

The Company evaluates the classification of assets and liabilities in connection with any disposition of significant assets to determine the appropriate financial statement recognition. We identified the sale of a significant portion of the Company's operations comprising a majority of its net assets in a sale to a related party as a critical audit matter due to the related party nature of the transaction and the significance of the disposition resulting in a strategic shift in the Company's business activities. The accounting for the disposition of net assets included in consolidated net assets requires auditor judgment when performing audit procedures to evaluate whether management appropriately recognized the classification of net assets sold and revenues and costs associated with discontinued operations and the calculation of gain or loss on sale to a related party.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the evaluation of the sale of certain operations to a related party, Cell Ready, LLC, included the following, among others:

- We evaluated management's assessment of the transaction:
  - As the sale of an asset or business;
  - To determine gain or loss recognition;
  - To determine classification of items between continuing and discontinued operations;
  - To determine accounting for transaction costs; and
  - Testing of completeness and accuracy of deconsolidation of net assets.
- We inspected Board of Director's minutes for authorization of the transaction.
- We evaluated management's assessment of the business purpose of the transaction in connection with our review of related party transactions.
- We examined the transaction documents to ensure the Company recognized and disclosed all significant transaction terms.
- We examined key employee agreements, including modifications to employee stock options, in connection with the sale for recognition and disclosure.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2014.

Houston, TX
March 25, 2024

MARKER THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,111,450	$ 11,782,172
Prepaid expenses and deposits	988,126	1,849,239
Other receivables	1,027,815	2,402,004
Current assets of discontinued operations	—	585,840
Total current assets	17,127,391	16,619,255
Non-current assets of discontinued operations	—	17,802,929
Total assets	**$ 17,127,391**	**$ 34,422,184**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 1,745,193	$ 2,521,193
Related party payable	1,329,655	—
Current liabilities of discontinued operations	—	5,260,616
Total current liabilities	3,074,848	7,781,809
Non-current liabilities of discontinued operations	—	7,039,338
Total liabilities	3,074,848	14,821,147
Stockholders' equity:		
Preferred stock, $0.001 par value, 5 million shares authorized, 0 shares issued and outstanding at December 31, 2023 and 2022, respectively	—	—
Common stock, $0.001 par value, 30 million shares authorized, 8.9 million and 8.4 million shares issued and outstanding as of December 31, 2023 and 2022, respectively (see Note 10)	8,891	8,406
Additional paid-in capital	450,329,515	447,641,680
Accumulated deficit	(436,285,863)	(428,049,049)
Total stockholders' equity	14,052,543	19,601,037
Total liabilities and stockholders' equity	**$ 17,127,391**	**$ 34,422,184**

On January 26, 2023, the Company effected a one-for-ten (1-for-10) reverse stock split of its common stock and a corresponding reduction in the total number of authorized shares of its common stock from 300,000,000 to 30,000,000. All historical share and per share amounts reflected in this report have been adjusted to reflect the reverse stock split.

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

MARKER THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2023	2022
Revenues:		
Grant income	$ 3,311,133	$ 3,513,544
Total revenues	3,311,133	3,513,544
Operating expenses:		
Research and development	10,416,789	11,968,428
General and administrative	7,475,722	11,336,120
Total operating expenses	17,892,511	23,304,548
Loss from operations	(14,581,378)	(19,791,004)
Other income (expenses):		
Arbitration settlement	—	(232,974)
Interest income	539,158	248,063
Loss from continuing operations before income taxes	(14,042,220)	(19,775,915)
Income tax expense	3,675	—
Net loss from continuing operations	**(14,045,895)**	**(19,775,915)**
Discontinued operations:		
Loss from discontinued operations	(2,922,406)	(10,154,779)
Gain on disposal of discontinued operations, net of $63,000 in tax	8,731,487	—
Income (loss) from discontinued operations	5,809,081	(10,154,779)
Net loss	**$ (8,236,814)**	**$ (29,930,694)**
Net earnings (loss) per share:		
Loss from continuing operations, basic and diluted	$ (1.59)	$ (2.37)
Income (loss) from discontinued operations, basic and diluted	$ 0.66	$ (1.22)
Net loss per share, basic and diluted	$ (0.94)	$ (3.58)
Weighted average number of common shares outstanding:		
Basic	8,809,382	8,351,003
Diluted	8,809,382	8,351,003

On January 26, 2023, the Company effected a one-for-ten (1-for-10) reverse stock split of its common stock. All historical share and per share amounts reflected in this report have been adjusted to reflect the reverse stock split.

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

MARKER THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par value			
Balance at January 1, 2022	**8,307,868**	**$ 8,308**	**$ 442,095,642**	**$ (398,118,355)**	**$ 43,985,595**
Issuance of common shares for cash, net	60,651	61	202,069	—	202,130
Stock-based compensation	37,252	37	5,343,969	—	5,344,006
Net loss	—	—	—	(29,930,694)	(29,930,694)
Balance at December 31, 2022	**8,405,771**	**8,406**	**447,641,680**	**(428,049,049)**	**19,601,037**
Shares issued pursuant to ATM and Lincoln Park agreements	277,834	277	1,014,363	—	1,014,640
Issuance of common stock as commitment fee	180,410	180	(180)	—	—
Issuance of common stock from exercise of stock options	27,518	28	90,450	—	90,478
Stock-based compensation	—	—	1,583,202	—	1,583,202
Net loss	—	—	—	(8,236,814)	(8,236,814)
Fractional shares adjustment due to reverse split	(113)	—	—	—	—
Balance at December 31, 2023	**8,891,420**	**8,891**	**450,329,515**	**(436,285,863)**	**14,052,543**

On January 26, 2023, the Company effected a one-for-ten (1-for-10) reverse stock split of its common stock. All historical share and per share amounts reflected in this report have been adjusted to reflect the reverse stock split.

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

MARKER THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2023	2022
Cash Flows from Operating Activities:		
Net loss	$ (8,236,814)	$ (29,930,694)
Less: gain (loss) from discontinued operations, net of $63,000 in tax	5,809,081	(10,154,779)
Net loss from continuing operations	(14,045,895)	(19,775,915)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation	858,269	3,304,634
Gain on lease termination	—	(278,681)
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	861,113	104,147
Other receivables	1,374,189	(2,401,767)
Accounts payable and accrued expenses	611,262	(1,319,710)
Deferred revenue	—	(1,146,186)
Net cash used in operating activities - continuing operations	(10,341,062)	(21,513,478)
Net cash used in operating activities - discontinued operations	(6,098,899)	(5,458,675)
Net cash used in operating activities	(16,439,961)	(26,972,153)
Cash Flows from Investing Activities:		
Net cash provided by (used in) investing activities - discontinued operations	18,664,122	(4,945,136)
Net cash provided by (used in) investing activities	18,664,122	(4,945,136)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	1,014,640	202,130
Proceeds from stock options exercise	90,477	—
Net cash provided by financing activities	1,105,117	202,130
Net increase (decrease) in cash and cash equivalents	3,329,278	(31,715,159)
Cash and cash equivalents at beginning of the year	11,782,172	43,497,331
Cash and cash equivalents at end of the year	$ 15,111,450	$ 11,782,172

	For the Years Ended December 31,	
	2023	2022
Supplemental schedule of non-cash financing and investing activities:		
Capital expenditures in accounts payable	$ —	$ 57,607
Issuance of common stock as commitment fee for future financing	$ 180	$ —
Changes to right of use assets and lease liability due to close out of operating lease	$ —	$ 3,459,332

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

MARKER THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
FOR THE FISCAL YEARS DECEMBER 31, 2023 AND 2022

NOTE 1: NATURE OF OPERATIONS

Marker Therapeutics, Inc., a Delaware corporation (the “Company” or “we”), is a clinical-stage immuno-oncology company specializing in the development and commercialization of novel T cell-based immunotherapies for the treatment of hematological malignancies and solid tumor indications. The Company’s multiTAA-specific T cell technology is based on the selective expansion of non-engineered, tumor-specific T cells that recognize tumor associated antigens, which are tumor targets, and kill tumor cells expressing those targets. These T cells are designed to recognize multiple tumor targets to produce broad spectrum anti-tumor activity. The Company was incorporated in Nevada in 1992 and reincorporated in Delaware in October 2018.

Purchase Agreement with Cell Ready

On June 26, 2023, the Company completed the previously announced transaction with Cell Ready, LLC (“Cell Ready”) pursuant to a Purchase Agreement (the “Cell Ready Purchase Agreement), dated May 1, 2023, by and between the Company and Cell Ready. Mr. John Wilson is a member of the Company’s board of directors and is serving as the CEO of Cell Ready, therefore Cell Ready is a related party. Pursuant to the Cell Ready Purchase Agreement, effective as of the Closing Date, the Company (i) assigned to Cell Ready the leases for the Company’s two manufacturing facilities in Houston, Texas (the “Manufacturing Facilities”), (ii) sold to Cell Ready all of the equipment and leasehold improvements at the Manufacturing Facilities and (iii) assigned to Cell Ready its rights, title and interest in the Company’s Master Services Agreement for Product Supply (the “MSA”), dated April 7, 2023, by and between the Company, Cell Ready and Indapta Therapeutics, Inc., as well as its rights, title and interest in any contracts related to the equipment and Manufacturing Facilities (collectively, the “Purchased Assets”). Cell Ready acquired the Purchased Assets for total consideration of $19.0 million. In connection with the purchase of the Manufacturing Facilities, Cell Ready also extended offers of employment to approximately 50 of the Company’s former employees in its manufacturing, development, quality, and regulatory affairs functions.

The Purchased Assets constituted a significant disposition. Based upon the magnitude of the disposition and because the Company is exiting certain manufacturing operations, the disposition represents a significant strategic shift that will have a material effect on the Company’s operations and financial results. Accordingly, the assets sold meet the definition of a discontinued operation, as defined by Accounting Standards Codification (“ASC”) 205-20 - Discontinued Operations, and prior comparative periods have been retroactively adjusted to reflect the current presentation. See additional discussion at Note 6.

On February 22, 2024, we entered into a Master Services Agreement for Product Supply (the “MSA”) with Cell Ready to provide outsourced services previously performed by the Company prior to its asset sale to Cell Ready. Cell Ready, which is owned by one of our directors and shareholders, Mr. John Wilson, is a contract development and manufacturing organization (CDMO). Under the MSA, it is anticipated Cell Ready will perform a wide variety of services for us, including research and development, and manufacturing in support of our clinical trials. Pursuant to the MSA, the Company may contract with Cell Ready for the provision of various products and services from time to time by entering into work orders with Cell Ready. If the services involve the supply of product, Cell Ready is required to supply such product in conformance with the product requirements set forth in the applicable work order(s). Under the MSA, Cell Ready is to use only personnel with sufficient qualifications and experience to supply the services contemplated by the MSA, provide its personnel with adequate training and assume full responsibility for its personnel’s compliance with the MSA. Further, Cell Ready is required to provide the Company with assistance and cooperation in order for the Company to obtain and maintain all necessary regulatory approvals, at the Company’s expense.

Organizational Changes

In 2023, the Company implemented changes to its organizational structure due to the transaction with Cell Ready and to reduce operational costs. In connection with these changes, the Company reduced headcount, including the separation of its former Chief Executive Officer, Peter Hoang, in May 2023 and its former Chief Accounting Officer, Michael Loiacono, in June 2023. During the second quarter of 2023, the Company recorded $0.9 million of severance and termination-related costs. The payments of these costs were completed in July of 2023. Effective May 1, 2023, the Company's board of directors appointed Dr. Juan Vera as the Company's President and Chief Executive Officer.

Effective June 30, 2023, the board of directors appointed Eliot M. Lurier as the Company's Interim Chief Financial Officer, whereby Mr. Lurier provided consulting services to the Company pursuant to a consulting between the Company and Danforth Advisors, LLC ("Danforth") and received no compensation directly from the Company. On November 17, 2023, the Company terminated the consulting agreement between the Company and Danforth, effective January 16, 2024.

On November 17, 2023, Mr. Lurier ceased serving as the Company's Interim Chief Financial Officer and Dr. Vera was appointed as the Company's Principal Financial and Accounting Officer.

Reverse Stock Split

On January 26, 2023, the Company effected a one-for-ten (1-for-10) reverse stock split of its common stock (the "Reverse Stock Split") and a corresponding reduction in the total number of authorized shares of its common stock from 300,000,000 to 30,000,000. The Reverse Stock Split, which was approved by stockholders at an annual stockholder meeting on May 24, 2022, was consummated pursuant to a Certificate of Amendment filed with the Secretary of State of Delaware on January 26, 2023. The Reverse Stock Split was effective on January 26, 2023. All references to common stock, warrants to purchase common stock, options to purchase common stock, share data, per share data and related information contained in the consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

NOTE 2: FINANCIAL CONDITION, GOING CONCERN AND MANAGEMENT PLANS

As of December 31, 2023, the Company had cash and cash equivalents of approximately $15.1 million. The Company's activities since inception have consisted principally of acquiring product and technology rights, raising capital, and performing research and development. Successful completion of the Company's development programs and, ultimately, the attainment of profitable operations are dependent on future events, including, among other things, its ability to access potential markets; secure financing; successfully progress its product candidates through preclinical and clinical development; obtain regulatory approval of one or more of its product candidates; maintain and enforce intellectual property rights; develop a customer base; attract, retain and motivate qualified personnel; and develop strategic alliances and collaborations. From inception, the Company has been funded by a combination of equity, debt financings and grants.

In August 2021, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "ATM Agreement") with Cantor Fitzgerald & Co. and RBC Capital Markets, LLC (the "Sales Agents"), pursuant to which the Company can offer and sell, from time to time at its sole discretion through the Sales Agents, shares of its common stock having an aggregate offering price of up to $75.0 million. Any shares of its common stock sold will be issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-258687), which the SEC declared effective on August 19, 2021, however, our use of the shelf registration statement on Form S-3 will be limited for so long as we are subject to General Instruction I.B.6 of Form S-3, which limits the amounts that we may sell under the registration statement and in accordance with the ATM agreement. The Sales Agents will be entitled to compensation under the Sales Agreement at a commission rate equal to 3.0% of the gross sales price per share sold under the ATM Agreement, and we have provided each of the Sales Agents with indemnification and contribution rights. During the year ended December 31, 2023, the Company sold 265,334 shares of its common stock under the ATM Agreement for proceeds of $1.0 million.

In August 2021, the Company received notice of a Product Development Research award totaling approximately $13.1 million from the Cancer Prevention and Research Institute of Texas ("CPRIT") to support the Company's Phase 2 clinical trial of MT-401. The CPRIT award is intended to support the adjuvant arm of the Company's Phase 2 clinical trial evaluating MT-401 when given as an adjuvant therapy to patients with acute myeloid leukemia following a hematopoietic stem cell transplant. The primary objectives of the adjuvant arm of the trial are to evaluate relapse-free survival after MT-401 treatment when compared with a randomized control group. Through

the date of this filing, the Company has received $6.8 million of funds from the CPRIT grant. The Company recorded $2.7 million of grant income related to the CPRIT grant as revenue for the year ended December 31, 2023.

In September 2022, the Company received notice from the U.S. Food and Drug Administration (the "FDA") that it had awarded the Company a $2.0 million grant from the FDA's Orphan Products Grant program to support the Company's Phase 2 clinical trial of MT-401 for the treatment of post-transplant AML The Company recorded $0.4 million and $0.1 million of grant income related to the FDA grant as revenue for the year ended December 31, 2023 and December 31, 2022, respectively. As of December 31, 2023, the Company recorded $0.3 million of grant income receivable. In February 2024, the Company received $0.3 million of funds from the FDA grant.

In May 2023, the Company received notice of a $2.0 million grant from the National Institutes of Health Small Business Innovation Research program to support the development and investigation of MT-401 for the treatment of AML patients following standard-of-care therapy with hypomethylating agents. The Company recorded $0.2 million of grant income related to the SBIR grant as revenue for the year ended December 31, 2023. As of December 31, 2023, the Company recorded $0.2 million as other receivable, which represented grant income earned in advance of funds to be received from the SBIR. In February 2024, the Company received $0.2 million of funds from the SBIR grant.

All funding agencies have agreed to continue their financial support and to shift funds to the MT-401-OTS program.

In December 2022, the Company entered into a purchase agreement, or the Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, which provides that, upon the terms and subject to the conditions of the agreement, the Company has the right, but not the obligation, to sell to Lincoln Park up to $25,000,000 of shares of its common stock, or the Purchase Shares, from time to time over a 24-month term. For the year ended December 31, 2023, the Company sold 12,500 shares of its common stock under the Purchase Agreement for proceeds of approximately $33,000. In January 2023, Lincoln Park was issued 180,410 shares of stock as a commitment fee at a value of $0.5 million. On February 29, 2024, the Company terminated the Purchase Agreement with Lincoln Park effective March 1, 2024.

As described in Note 1, on June 26, 2023, the Company completed the transaction with Cell Ready pursuant to the Cell Ready Purchase Agreement for total consideration of $19.0 million. On February 22, 2024, the Company entered into a Master Services Agreement for Product Supply (the "MSA") with Cell Ready, a contract development and manufacturing organization (CDMO). Under the MSA, it is anticipated Cell Ready will perform a wide variety of services for us, including research and development, and manufacturing in support of our clinical trials. Pursuant to the MSA, the Company may contract with Cell Ready for the provision of various products and services from time to time by entering into work orders with Cell Ready.

The Company expects to continue to incur substantial losses over the next several years during its development phase.

Based on the Company's clinical and research and development plans and its timing expectations related to the progress of its programs, the Company expects that its cash and cash equivalents as of December 31, 2023, including drawdowns of available grant funds, will enable the Company to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2025. Prior to the Cell Ready transaction, there was substantial doubt regarding the Company's ability to continue as a going concern, which was alleviated by the proceeds from the transaction.

The Company has based this estimate on assumptions that may prove to be wrong, and the Company could utilize its available capital resources sooner than it currently expects. Furthermore, the Company's operating plan may change, and it may need additional funds sooner than planned in order to meet operational needs and capital requirements for product development and commercialization. Because of the numerous risks and uncertainties associated with the development and commercialization of the Company's product candidates and the extent to which the Company may enter into additional collaborations with third parties to participate in their development and commercialization, the Company is unable to estimate the amounts of increased capital outlays and operating expenditures associated with its current and anticipated clinical trials. The Company's future funding requirements will depend on many factors, as it:

- initiates or continues clinical trials of its product candidates;
- continues the research and development of its product candidates and seeks to discover additional product candidates;

- seeks regulatory approvals for any product candidates that successfully complete clinical trials;
- maintains and enforces intellectual property rights;
- enters into contract manufacturing arrangements with Cell Ready or other contract manufacturing organizations for clinical manufacturing supply;
- establishes sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any product candidates that may receive regulatory approval;
- evaluates strategic transactions the Company may undertake; and
- enhances operational, financial and information management systems and hires additional personnel, including personnel to support development of product candidates and, if a product candidate is approved, commercialization efforts.

The Company does not have sufficient sources of revenue to provide incoming cash flows to sustain its future operations beyond the fourth quarter of 2025. As outlined above, its ability to pursue its long-term planned business activities is dependent upon its successful efforts to raise additional capital and grant income.

The current macro-economic environment of decades-high inflation and concerns about an economic recession in the United States or other major markets has resulted in, among other things, volatility in the capital markets that may have the effect of reducing the Company's ability to access capital, which could in the future negatively affect the Company's liquidity. In addition, a recession or market correction due to these factors could materially affect the Company's business and the value of its common stock.

NOTE 3: SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America and pursuant to the rules and regulations of the Securities Exchange Commission ("SEC"). Any reference in these footnotes to applicable guidance is meant to refer to the authoritative U.S. generally accepted accounting principles ("GAAP") as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Principles of Consolidation

These consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Marker Cell Therapy, Inc. and GeneMax Pharmaceuticals Inc. – a dormant subsidiary that wholly owns GeneMax Pharmaceuticals Canada, Inc. All significant intercompany balances and transactions are eliminated upon consolidation.

Use of Estimates

Preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Accordingly, actual results may differ materially from those estimates. Management considers many factors in selecting appropriate financial accounting policies, controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: stock-based compensation expense and income taxes.

Cash, Cash Equivalents and Credit Risk

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents at December 31, 2023 consisted of cash and certificates of deposit in institutions in the United States. Balances at certain institutions have exceeded Federal Deposit Insurance Corporation insured limits and U.S. government agency securities.

The Company maintains cash in accounts which are in excess of the Federal Deposit Insurance Corporation ("FDIC") insured limits of $250,000. As of December 31, 2023 and December 31, 2022, the Company had approximately $1.4. million and $2.3 million, respectively in cash at financial institutions. As of December 31, 2023, the Company had approximately $13.7 million in U.S. government agency securities.

In the event cash is received from grants in advance of incurring qualifying costs, it is recorded as restricted cash until it is earned and recorded to grant income.

Discontinued Operations

The Purchased Assets sold to Cell Ready pursuant to the Cell Ready Purchase Agreement constituted a significant disposition and as such, the Company concluded that the disposition of its Purchased Assets represented a strategic shift that had a major effect on its operations and financial results. Therefore, the Purchased Assets, related party revenue, service revenue and related expenses are classified as discontinued operations for all periods presented herein. See Note 6 for further information.

Patents and Patent Application Costs

Although the Company believes that its patents and underlying technology have continuing value, the amount of future benefits to be derived from the patents is uncertain. Patent costs are, therefore, expensed as incurred.

Stock-Based Compensation

The Company incurs stock-based compensation expense related to the issuance of common stock and stock options. The Company estimates the fair value of stock options granted using the Black-Scholes option pricing model. The Black-Scholes option pricing model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility and expected option life:

Expected Term — The expected life of stock options was estimated using the "simplified method," as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant.

Expected Volatility — The Company computes stock price volatility over expected terms based on its historical common stock trading prices.

Risk-Free Interest Rate — The Company bases the risk-free interest rate on the implied yield available on U.S. Treasury zero-coupon issues with an equivalent remaining term.

Expected Dividend — The Company has never declared or paid any cash dividends on its common shares and does not plan to pay cash dividends in the foreseeable future, and, therefore, uses an expected dividend yield of zero in its valuation models.

The Company amortizes the fair value of the awards expected to vest on a straight-line basis over the requisite service period of the awards. The Company recognizes fair value of stock options granted to nonemployees as stock-based compensation expense over the period in which the related services are received as if the Company had paid cash for those services. Forfeitures are accounted for as incurred.

Research and Development Costs

Research and development expenses consist of costs associated with clinical trial programs. Costs incurred by third parties are expensed as the contracted work is performed. The Company accrues for costs incurred as the services are being provided by monitoring the status of the clinical trial or project and the invoices received from its external service providers. The Company estimates depend on the timeliness and accuracy of the data provided by the vendors regarding the status of each project and total project spending. The Company adjusts its accrual as actual costs become known. Where contingent milestone payments are due to third parties under research and development arrangements, the milestone payment obligations are expensed when the milestone events are achieved.

Income Taxes

The Company follows the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax balances. Potential deferred tax assets and liabilities are measured using enacted tax rates expected to apply to the taxable income in the years in which those differences are expected to be recovered or settled. The effect on potential deferred tax assets and liabilities of a change in tax rates is recognized in the statement of operations in the period that includes the date of allowances against deferred tax assets.

Tax benefits are recognized only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon settlement. A liability for “unrecognized tax benefits” is recorded for any tax benefits claimed in the Company’s tax returns that do not meet these recognition and measurement standards. As of December 31, 2023 and 2022, no liability for unrecognized tax benefits was required to be reported. The guidance also discusses the classification of related interest and penalties on income taxes. The Company’s policy is to record interest and penalties on uncertain tax positions as a component of income tax expense. No interest or penalties were recorded during the years ended December 31, 2023 and 2022.

Grant Income

Grant Income represents funding under cost reimbursement programs from government agencies and non-profit foundations for qualified research and development activities performed by the Company. In applying the provisions of ASC Topic 606, Revenue from Contracts with Customers (“ASC 606”), the Company determined that grants and awards are out of the scope of ASC 606 because the funding entities do not meet the definition of a “customer”, as defined by ASC 606, as there is not considered to be a transfer of control of goods or services. With respect to each grant or award, the Company determines if it has a collaboration in accordance with ASC Topic 808, Collaborative Arrangements (“ASC 808”). To the extent the grant or award is within the scope of ASC 808, the Company recognizes the award upon achievement of certain milestones as credits to research and development expenses. For grant and awards outside the scope of ASC 808, the Company applies ASC 606 by analogy, and revenue is recognized when the Company incurs expenses related to the grants for the amount the Company is entitled to under the provisions of the contract.

Loss per Common Share

Basic loss per share includes only the weighted average common shares outstanding, without consideration of potentially dilutive securities. Diluted loss per share includes the weighted average common shares outstanding and any potentially dilutive common stock equivalent shares in the calculation.

New Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed, the Company does not believe that the impact of recently issued standards that are not yet effective will have a material impact on its financial position or results of operations upon adoption.

Recently Issued Accounting Standards Not Yet Adopted

Improvements to Reportable Segment Disclosures

In November 2023, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. The ASU requires disclosures to include significant segment expenses that are regularly provided to the chief operating decision maker, among other provisions. The ASU is effective for fiscal year periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted and the ASU requires retrospective application to all prior periods presented in the financial statements. The Company is currently evaluating the standard to determine the impact of adoption to its consolidated financial statements and disclosures.

Improvements to Income Tax Disclosures

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (ASU 2023-09), which improves the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. This guidance will be effective for the annual periods beginning the year ended December 31, 2025. Early adoption is permitted. Upon adoption, the guidance can be applied prospectively or retrospectively. We do not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

NOTE 4: NET LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDERS

Basic loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the reporting period. Diluted loss per common share is computed similarly to basic loss per common share except that it reflects the potential dilution that could occur if dilutive securities or other obligations to issue common stock were exercised or converted into common stock.

The following table sets forth the computation of net loss per share for the years ended December 31, 2023 and 2022, respectively:

	For the Years Ended December 31,	
	2023	2022
Numerator:		
Loss from continuing operations	$ (14,045,895)	$ (19,775,915)
Income (loss) from discontinued operations	5,809,081	(10,154,779)
Net loss	$ (8,236,814)	$ (29,930,694)
Denominator:		
Weighted average common shares outstanding, basic	8,809,382	8,351,003
Weighted average common shares outstanding, diluted	8,809,382	8,351,003
Net earnings (loss) per share:		
Loss from continuing operations, basic and diluted	$ (1.59)	$ (2.37)
Income (loss) from discontinued operations, basic and diluted	$ 0.66	$ (1.22)
Net loss per share, basic and diluted	$ (0.94)	$ (3.58)

The following securities, rounded to the thousand, were not included in the diluted net loss per share calculation because their effect was anti-dilutive for the periods presented:

	For the Years Ended December 31,	
	2023	2022
Common stock options	738,000	886,000
Common stock purchase warrants	—	1,848,000
Potentially dilutive securities	738,000	2,734,000

NOTE 5: OTHER RECEIVABLE

Qualifying grant income earned in advance of cash received from grants is recognized as revenue and recorded as other receivable. The Company recorded $2.7 million of grant income related to the CPRIT grant for the year ended December 31, 2023. At December 31, 2023, the Company recorded $0.5 million of grant income receivable related to the CPRIT grant.

Additionally, the Company recorded $0.4 million and $0.2 million of grant income related to the FDA and SBIR grants, respectively, for the year ended December 31, 2023. At December 31, 2023, the Company recorded $0.3 million and $0.2 million of grant income receivable related to the FDA and SBIR grants, respectively.

The Company received $0.3 million and $0.2 million of funds from FDA and SBIR in February 2024, respectively.

NOTE 6: DISCONTINUED OPERATIONS

As discussed in Note 1, on June 26, 2023, the Company completed the previously announced transaction with Cell Ready for cash consideration of $19.0 million, resulting in derecognition of the Purchased Assets and a gain on sale of approximately $8.7 million, net of $63,000 in tax.

The assets and liabilities classified in discontinued operations as of December 31, 2023 and 2022 are as follows:

	December 31, 2023	December 31, 2022
Prepaid expenses and other current assets	$ —	$ 585,840
Total current assets of discontinued operations	—	585,840
Fixed Assets	—	12,323,143
Right of use assets	—	5,479,786
Total non-current assets of discontinued operations	—	17,802,929
Total assets of discontinued operations	**$ —**	**$ 18,388,769**
Accounts payable	$ —	$ 2,183,418
Related party deferred revenue	—	2,500,000
Short-term lease liabilities	—	577,198
Total current liabilities of discontinued operations	—	5,260,616
Long-term lease liabilities	—	7,039,338
Total non-current liabilities of discontinued operations	—	7,039,338
Total liabilities of discontinued operations	**$ —**	**$ 12,299,954**

Net loss from discontinued operations consists of the following for the years ended December 31, 2023 and 2022, respectively, excluding the gain on disposal:

	For the Years Ended December 31,	
	2023	2022
Revenues:		
Service revenue	$ 816,641	$ —
Related party service revenue	3,500,000	5,500,000
Total revenues	4,316,641	5,500,000
Operating expenses:		
Research and development	6,561,957	14,170,894
General and administrative	677,090	1,483,885
Total operating expenses	7,239,047	15,654,779
Loss from discontinued operations	$ (2,922,406)	$ (10,154,779)

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

	For the Years Ended December 31,	
	2023	2022
Continuing operations:		
Net cash used in operating activities	$ (10,341,000)	$ (21,513,000)
Net cash provided by financing activities	1,105,000	202,000
Discontinued operations		
Net cash used in operating activities	(6,099,000)	(5,459,000)
Net cash provided by (used in) investing activities	$ 18,664,000	$ (4,945,000)
Net increase (decrease) in cash and cash equivalents	$ 3,329,000	$ (31,715,000)

Related Party Service Revenue

In April 2022, the Company entered into a binding services agreement ("Wilson Wolf Agreement") with Wilson Wolf Manufacturing Corporation ("Wilson Wolf"). Mr. John Wilson is a member of the Company's board of directors and is serving as the CEO of Wilson Wolf. Wilson Wolf is in the business of creating products and services intended to simplify and expedite the transition of cell therapies and gene-modified cell therapies to mainstream society (the "Wilson Wolf Mission"). Pursuant to the Wilson Wolf Agreement, Wilson Wolf made a cash payment to the Company in the amount of $8.0 million, as consideration for certain training and research services.

In March 2023, the Company recognized the final $2.5 million of revenue pursuant to this $8.0 million agreement and an additional $1.0 million because the Work Direction was completed within one year from the onset of the Wilson Wolf Agreement, achieving the agreed milestone. The Wilson Wolf Agreement and related service obligations were completed upon achievement of this final milestone, and no obligations remain.

Service Revenue

In April 2023, the Company signed the Indapta Master Services Agreement, pursuant to which the Company provided services to Indapta. Under an executed work order of that agreement, now complete, the Company recognized $0.8 million for the services during the period ended June 30, 2023. Effective as of the closing date of the Purchase Agreement with Cell Ready, the rights and obligations to the Indapta Agreement were transferred to Cell Ready, and as such the revenues and expenses are reflected in discontinued operations.

NOTE 7: PROPERTY AND EQUIPMENT

Substantially all of the previously reported property and equipment was disposed of as a result of the Cell Ready transaction. See Note 6: Discontinued Operations for details.

NOTE 8: LEASES

Substantially all of the previously reported leases were disposed of as a result of the Cell Ready transaction. See Note 6: Discontinued Operations for details.

NOTE 9: ACCOUNTS PAYABLE, ACCRUED LIABILITIES, AND RELATED PARTY PAYABLE

Accounts payable, accrued liabilities, and related party payable consist of the following as of December 31, 2023 and 2022, respectively:

	December 31, 2023	December 31, 2022
Accounts payable	$ 961,000	$ 1,101,000
Compensation and benefits	57,000	750,000
Professional fees	303,000	518,000
Related party payable	1,330,000	—
Arbitration settlement fees	—	114,000
Tax fees	219,000	—
Other	205,000	38,000
Total accounts payable and accrued liabilities	3,075,000	2,521,000

The $1.3 million related-party payable reflects amounts payable to Cell Ready for outsourced product development and manufacturing services. This amount was paid during February 2024. See Note 14: Related Party Transactions.

NOTE 10: STOCKHOLDERS' EQUITY

Increase in Authorized Shares

During June 2022, the Company's board of directors and stockholders approved a Certificate of Amendment (the "Amendment") to the Company's Certificate of Incorporation to increase the authorized shares of common stock of the Company from 15,000,000 shares to 30,000,000 shares. The Company filed the Amendment with the Secretary of State of Delaware on May 25, 2022.

Reverse Stock Split

On January 26, 2023, the Company effected the Reverse Stock Split and a corresponding reduction in the total number of authorized shares of its common stock from 300,000,000 to 30,000,000. The Reverse Stock Split, which was approved by stockholders at an annual stockholder meeting on May 24, 2022, was consummated pursuant to a Certificate of Amendment filed with the Secretary of State of Delaware on January 26, 2023. The Reverse Stock Split was effective on January 26, 2023. All historical share and per share amounts reflected in this report have been adjusted to reflect the Reverse Stock Split.

Preferred Stock

The Company has authorized up to 5,000,000 shares of preferred stock, $0.001 par value per share, for issuance. The preferred stock will have such rights, privileges and restrictions, including voting rights, dividend conversion rights, redemption privileges and liquidation preferences, as shall be determined by the Company's board of directors upon its issuance. To date, the Company has not issued any preferred shares.

Common Stock

The Company has authorized up to 30,000,000 shares of common stock, $0.001 par value per share, for issuance. Significant 2023 and 2022 common stock transactions were as follows:

2023 Common Stock Transactions

Issuance of Stock Pursuant to ATM Agreement

During the year ended December 31, 2023, the Company sold 265,334 shares of its common stock under the ATM Agreement for net proceeds of $1.0 million.

Stock Purchase Agreement with Lincoln Park

In December 2022, the Company entered into a purchase agreement (the "Purchase Agreement") with Lincoln Park which provides that, upon the terms and subject to the conditions of the agreement, the Company has the right, but not the obligation, to sell to Lincoln Park up to $25,000,000 of shares of its common stock (the "Purchase Shares") from time to time over a 24-month term, at a variable price with certain market-based terms as defined in the Purchase Agreement. The Purchase Agreement does not exhibit any of the characteristics for liability classification under ASC Topic 480, *Distinguishing Liabilities from Equity*. Instead, the purchase agreement is indexed to the Company's own stock under ASC Subtopic 815-40, *Contracts in Entity's Own Equity*, and classified as equity. In January 2023, Lincoln Park was issued 180,410 shares of stock as a commitment fee at a value of $0.5 million. During the year ended December 31, 2023, the Company sold 12,500 shares of its common stock under the Purchase Agreement for proceeds of approximately $33,000. The Company terminated the Purchase Agreement with Lincoln Park on February 29, 2024 effective March 1, 2024.

Exercise of Stock Options

During the year ended December 31, 2023, certain outstanding options were exercised for 27,518 shares of common stock providing aggregate proceeds to the Company of approximately $0.1 million.

2022 Common Stock Transactions

Issuance of Restricted Stock Units to Executives

During the year ended December 31, 2022, upon the recommendation of the compensation committee of the Company's board of directors, and pursuant to the Company's 2020 Equity Incentive Plan, the Company's board of directors approved the issuance of a total of 37,252 shares of common stock, valued at a total of approximately $180,200, subject to restricted stock units, which were immediately vested upon grant, to certain executives as performance bonuses for performance during the year ended December 31, 2021.

Issuance of Stock Pursuant to ATM Agreement

During the year ended December 31, 2022, the Company issued and sold 60,651 shares of its common stock under the ATM Agreement for net proceeds of $202,100.

Stock Purchase Agreement with Lincoln Park

During the year ended December 31, 2022, the Company did not sell any shares of its common stock under the Purchase Agreement.

Share Purchase Warrants

A summary of the Company's share purchase warrants as of December 31, 2023 and 2022, respectively, and changes during the period is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Intrinsic Value
Balance - January 1, 2022	1,983,000	$ 44.20	1.70	$ —
Expired or cancelled	(135,000)	39.70	—	—
Balance - December 31, 2022	1,848,000	44.51	0.79	$ —
Expired or cancelled	(1,848,000)	44.51	—	—
Balance - December 31, 2023	—	$ —	—	$ —

All warrants outstanding at December 31, 2022 expired according to their terms on October 16, 2023. As of December 31, 2023, the Company had no outstanding warrants.

NOTE 11: STOCK BASED COMPENSATION

Stock Options

On May 19, 2020, the Board adopted the 2020 Equity Incentive Plan ("2020 Equity Incentive Plan") which replaced the 2014 Omnibus Stock Option Plan. The 2020 Plan was further amended effective May 2022 to increase the number of shares of common stock authorized for issuance under the plan by 850,000 shares. The 2020 Plan allows for grants of stock options, restricted shares, stock bonuses and other equity-based awards to employees and non-employee directors of the Company. Awards under the 2020 Plan may be at prices and for terms as determined by the Company's board of directors and may have vesting requirements as determined by the Board, provided that the exercise price for any stock option must be at least equal to the fair market value (as defined in the 2020 Plan) of a share of the stock on the grant date. Once granted, the exercise price of an option may not be reduced without the approval of the Company's stockholders, other than under certain limited circumstances such as a stock split or take any other action with respect to a stock option that would be treated as a repricing under the rules and regulations of the Nasdaq Stock Exchange.

Options granted under the 2020 Plan have a maximum term of ten years from the date of grant and generally vest over four years.

2023 Equity Incentive Awards

On February 27, 2023, pursuant to the Company's 2020 Equity Incentive Plan, the compensation committee of the Company's board of directors approved a total of 316,855 options to purchase the Company's common stock as equity-based incentive awards to the Company's executive officers and management team. Each option award was granted with an exercise price of $2.14 per share, the closing price of the Company's common stock on the Nasdaq Global Market on February 27, 2023, with the option award vesting in 48 equal monthly installments over a four-year period, subject to such executive officer's continued service on the applicable vesting date. Additionally, on February 27, 2023, the compensation committee of the Company's board of directors approved a total of 87,677 options to purchase the Company's common stock to non-executive employees and management team of the Company as equity-based incentive awards. Each option award was granted with an exercise price of $2.14 per share, the closing price of the Company's common stock on the Nasdaq Global Market on February 27, 2023, with the option award vesting in 48 equal monthly installments over a four-year period, subject to such employee's continued service on the applicable vesting date.

The above awards were in addition to 7,000 stock option awards issued during the three months ended March 31, 2023 to new employees upon their commencement of employment with the Company. Each option award was granted with an exercise price of $2.769 per share, the closing price of the Company's common stock on the Nasdaq Global Market on January 3, 2023, with 25% of the option award vesting in one year and the remaining 75% vesting in 36 equal monthly installments thereafter over a three-year period, subject to such employee's continued service on the applicable vesting date.

On May 10, 2023, the Company's board of directors approved a one-time share option grant of 100,000 shares of common stock to Dr. Vera for his appointment as the Company's Chief Executive Officer. The option has a term of ten years and will vest in equal annual

installments on May 10, 2024, May 10, 2025, May 10, 2026, and May 10, 2027, subject to Mr. Vera's continued service to the Company as of the applicable vesting date. Each option award was granted with an exercise price of $1.42 per share, the closing price of the Company's common stock on the Nasdaq Global Market on May 10, 2023.

On June 6, 2023, pursuant to the Company's Non-Employee Director Compensation Policy, which had previously been approved by the Company's board of directors, a total of 32,000 stock option awards were issued to independent members of the board of directors of the Company. Each option award was granted with an exercise price of $1.72 per share, the closing price of the Company's common stock on the Nasdaq Global Market on June 6, 2023. Each Option award will vest in one year subject to the director's continuance of service through June 6, 2024.

For the year ended December 31, 2023, the Company recorded incremental stock-based compensation expense of approximately $0.3 million pertaining to the modification of stock options in connection with the termination of certain employees that were hired by Cell Ready or transitioned as independent consultants. The modification provided for an acceleration of unvested options, resulting in a change in compensation expense that was immediately recognized. $0.2 million is reflected in loss from discontinued operations.

2022 Equity Incentive Awards

On February 17, 2022, pursuant to the Company's 2020 Equity Incentive Plan, the compensation committee of the Company's board of directors approved a total of 125,000 options to purchase the Company's common stock as equity-based incentive awards to the Company's executive officers. Each option award was granted with an exercise price of $4.60 per share, the closing price of the Company's common stock on the Nasdaq Global Market on February 17, 2022, with the option award vesting in 48 equal monthly installments over a four-year period, subject to such executive officer's continued service on the applicable vesting date. Additionally, on February 17, 2022, the compensation committee of the Company's board of directors approved a total of 39,500 options to purchase the Company's common stock to non-executive employees of the Company as equity-based incentive awards. Each option award was granted with an exercise price of $4.60 per share, the closing price of the Company's common stock on the Nasdaq Global Market on February 17, 2022, with the option award vesting in 48 equal monthly installments over a four-year period, subject to such employee's continued service on the applicable vesting date.

The above awards were in addition to 17,500 stock option awards issued during the three months ended March 31, 2022 to new employees upon their commencement of employment with the Company. Each option award was granted with an exercise price of $10.00 per share, the closing price of the Company's common stock on the Nasdaq Global Market on January 3, 2022, with 25% of the option award vesting in one year and the remaining 75% vesting in 36 equal monthly installments thereafter over a three-year period, subject to such employee's continued service on the applicable vesting date.

21,000 stock option awards were issued during the three months ended June 30, 2022 to new employees upon their commencement of employment with the Company. Each option award was granted with an exercise price of $4.30 per share, the closing price of the Company's common stock on the Nasdaq Global Market on April 1, 2022, with 25% of the option award vesting in one year and the remaining 75% vesting in 36 equal monthly installments thereafter over a three-year period, subject to such employee's continued service on the applicable vesting date.

10,000 stock option awards were issued during the three months ended September 30, 2022 to new employees upon their commencement of employment with the Company. Each option award was granted with an exercise price of $3.50 per share, the closing price of the Company's common stock on the Nasdaq Global Market on July 1, 2022, with 25% of the option award vesting in one year and the remaining 75% vesting in 36 equal monthly installments thereafter over a three-year period, subject to such employee's continued service on the applicable vesting date.

Additionally, 7,000 stock option awards were issued during the three months ended December 31, 2022 to new employees upon their commencement of employment with the Company. Each option award was granted with an exercise price of $3.73 per share, the closing price of the Company's common stock on the Nasdaq Global Market on October 3, 2022, with 25% of the option award vesting in one year and the remaining 75% vesting in 36 equal monthly installments thereafter over a three-year period, subject to such employee's continued service on the applicable vesting date.

Also, pursuant to the Company's Non-Employee Director Compensation Policy, which had previously been approved by the Company's board of directors, 40,000 stock option awards were issued during the year ended December 31, 2022 to independent members of the

board of directors of the Company. Each option award was granted on May 24, 2022 with an exercise price of $3.377 per share, the closing price of the Company's common stock on the Nasdaq Global Market on May 24, 2022. Each option award vested over one year subject to the director's continuance of service through May 24, 2023.

As of December 31, 2023, approximately 1.1 million shares of common stock are available to be issued under the 2020 Plan.

Stock Options

A summary of the Company's stock option activity for the years ended December 31, 2023 and December 31, 2022, is as follows:

	Number of Shares	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding as of January 1, 2022	768,623	$ 54.69	$ —	7.7
Granted	260,000	4.68	—	7.8
Canceled/Expired	(142,450)	36.78	—	—
Outstanding as of December 31, 2022	886,173	42.90	—	7.3
Granted	544,532	1.99	—	5.6
Exercised	(27,518)	3.29	—	—
Canceled/Expired	(665,292)	30.41	—	—
Outstanding as of December 31, 2023	737,895	$ 25.42	$ 1,317,000	7.6
Options vested and exercisable	404,343	$ 43.53	$ 244,000	6.6

The Black-Scholes option pricing model is used to estimate the fair value of stock options granted under the Company's share-based compensation plans. The weighted average assumptions used in calculating the fair values of stock options that were granted during the years ended December 31, 2023 and 2022, respectively, were as follows:

	For the Years Ended December 31,	
	2023	2022
Exercise price	$ 1.99	$ 4.70
Expected term (years)	6.0	5.9
Expected stock price volatility	91 %	85 %
Risk-free rate of interest	4 %	2 %
Expected dividend rate	0 %	0 %

The following table sets forth stock-based compensation expenses recorded during the respective periods:

	For the Years Ended December 31,	
	2023	2022
Stock Compensation expenses:		
Research and development	$ 338,000	$ 783,000
General and administrative	520,000	2,522,000
Stock compensation in continuing operations	858,000	3,305,000
Stock compensation in discontinued operations	725,000	2,039,000
Total stock compensation expenses	$ 1,583,000	$ 5,344,000

At December 31, 2023, the total stock-based compensation cost related to unvested awards not yet recognized was $0.4 million. The expected weighted average period compensation costs to be recognized was 1.8 years. Future option grants will impact the compensation expense recognized.

NOTE 12: GRANT INCOME

CPRIT

In August 2021, the Company received notice of a Product Development Research award totaling approximately $13.1 million from CPRIT to support the Company's Phase 2 clinical trial of MT-401. The CPRIT award is intended to support the adjuvant arm of the Company's Phase 2 clinical trial evaluating MT-401 when given as an adjuvant therapy to patients with acute myeloid leukemia following a hematopoietic stem cell transplant. The primary objectives of the adjuvant arm of the trial are to evaluate relapse-free survival after MT-401 treatment when compared with a randomized control group.

If restricted cash received from grants in advance of incurring qualifying costs, it is recorded as deferred revenue and recognized as revenue when qualifying costs are incurred. There was no restricted cash recorded as of December 31, 2023 and December 31, 2022. If qualifying grant income is earned in advance of cash received from grants, it is recognized as revenue and recorded as other receivable.

The Company recorded $2.7 million and $3.4 million of grant income related to the CPRIT grant as revenue for the years ended December 31, 2023 and 2022, respectively. At December 31, 2023, the Company had recorded $0.5 million as other receivable, which represented grant income earned in advance of the next tranche of funds to be received from CPRIT.

FDA

In September 2022, the Company received notice from the FDA that it had awarded the Company a $2.0 million grant from the FDA's Orphan Products Grant program to support the Company's Phase 2 clinical trial of MT-401 for the treatment of post-transplant AML. The Company recorded $0.4 million and $0.1 million of grant income related to the FDA grant as revenue for the years ended December 31, 2023 and December 31, 2022, respectively. As of December 31, 2023, the Company recorded $0.3 million as other receivable, which represented grant income earned in advance of funds to be received from the FDA. In February 2024, the Company received $0.3 million of funds from the FDA grant.

SBIR

In May 2023, the Company announced it had received a $2.0 million grant from the National Institutes of Health Small Business Innovation Research program to support the development and investigation of MT-401 for the treatment of AML patients following standard-of-care therapy with hypomethylating agents. The Company recorded $0.2 million of grant income related to the SBIR grant as revenue for the year ended December 31, 2023. As of December 31, 2023, the Company recorded $0.2 million as other receivable, which represented grant income earned in advance of funds to be received from the SBIR. In February 2024, the Company received $0.2 million of funds from the SBIR grant.

All funding agencies have agreed to continue their financial support and to shift funds to the MT-401-OTS program.

NOTE 13: LEGAL PROCEEDINGS

From time to time, the Company may be party to ordinary, routine litigation incidental to their business. The Company knows of no material, active or pending legal proceedings against the Company, nor is the Company involved as a plaintiff in any material proceeding or pending litigation. There are no proceedings in which any of the Company's directors, officers or affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest adverse to the Company's interest.

NOTE 14: RELATED PARTY TRANSACTIONS

The following table sets forth related party transaction expenses recorded for the years ended December 31, 2023 and 2022, respectively.

	For the Years Ended December 31,	
	2023	2022
Baylor College of Medicine	$ 13,000	$ 1,142,000
Bio-Techne Corporation	—	101,000
Cell Ready	1,330,000	—
Wilson Wolf Manufacturing Corporation	277,000	265,000
Total Research and development	$ 1,620,000	$ 1,508,000

$1.3 million of related party transactions are included in accounts payable and accrued liabilities as of December 31, 2023. See Note 9 for additional information.

Agreements with The Baylor College of Medicine (“BCM”).

In November 2018, January 2020 and February 2020, the Company entered in Sponsored Research Agreements with BCM, which provided for the conduct of research for the Company by credentialed personnel at BCM’s Center for Cell and Gene Therapy.

In September 2019, May 2020 and July 2021, the Company entered into Clinical Supply Agreements with BCM, which provided for BCM to provide to the Company multi tumor antigen specific products.

In October 2019, the Company entered in a Workforce Grant Agreement with BCM, which provided for BCM to provide to the Company manpower costs of projects for manufacturing, quality control testing and validation run activities.

In August 2020, the Company entered in a Clinical Trial Agreement with BCM, which provided for BCM to provide to the Company investigator-initiated research studies.

BCM is also a shareholder of the Company’s common stock.

The Company has also entered into a Clinical Site Agreement with BCM, which provided for BCM to conduct clinical trials for the Company and is a part of continuing operations.

Purchases from Bio-Techne Corporation.

The Company is currently utilizing Bio-Techne Corporation and two of its brands for the purchases of reagents, primarily cytokines. Mr. David Eansor is a member of the Company’s board of directors and was serving as the President of the Protein Sciences Segment of Bio-Techne Corporation. Mr. Eansor resigned from Bio-Techne Corporation on March 1, 2022, and as such, two months of transactions in 2022 are included in the table above.

Purchases from Wilson Wolf.

The Company is currently utilizing Wilson Wolf for the purchases of cell culture devices called G-Rexes. Mr. John Wilson is a member of the Company’s board of directors and is serving as the CEO of Wilson Wolf Manufacturing Corporation.

Purchases from Cell Ready, LLC.

The Company is currently utilizing Cell Ready, LLC for its clinical manufacturing supply and product development. Mr. John Wilson is a member of the Company’s board of directors and is serving as the CEO of Cell Ready, LLC. On February 22, 2024, we entered into a Master Services Agreement for Product Supply (the “MSA”) with Cell Ready. Cell Ready, which is owned by one of our directors and shareholders, Mr. John Wilson, is a contract development and manufacturing organization (CDMO). Under the MSA, it is anticipated Cell Ready will perform a wide variety of services for us, including research and development, and manufacturing in support

of our clinical trials. Pursuant to the MSA, the Company may contract with Cell Ready for the provision of various products and services from time to time by entering into work orders with Cell Ready. If the services involve the supply of product, Cell Ready is required to supply such product in conformance with the product requirements set forth in the applicable work order(s). Under the MSA, Cell Ready is to use only personnel with sufficient qualifications and experience to supply the services contemplated by the MSA, provide its personnel with adequate training and assume full responsibility for its personnel's compliance with the MSA. Further, Cell Ready is required to provide the Company with assistance and cooperation in order for the Company to obtain and maintain all necessary regulatory approvals, at the Company's expense. Also on February 22, 2024, the Company entered into Work Order #1 under the MSA, pursuant to which Cell Ready will provide the Company with GMP drug product for Marker MT-401 and/or MT-601. The services include the delivery of final drug product and quality control testing. The Company also requested Cell Ready to provide general support services in connection therewith. The total projected sum (inclusive of taxes) for the services under Work Order #1 are not anticipated to exceed $750,000. The services will cover the anticipated manufacturing costs for the first quarter of 2024. Additional Work Orders are expected to be generated for the remainder of 2024.

NOTE 15: INCOME TAXES

The Company has no federal income tax expense due to operating losses incurred for the years ended December 31, 2023 and 2022. The Company recognized $4,000 in state tax expense for the year ended December 31, 2023.

The effects of temporary differences that give rise to significant portions of the deferred tax assets as of December 31, 2023 and 2022 are as follows:

	For the Years Ended December 31,	
	2023	2022
Deferred Tax Assets		
Net Operating Loss Carryforward	$ 29,352,000	$ 30,072,000
Stock Compensation	2,598,000	5,642,000
Capitalized R&E	7,026,000	4,818,000
Research and Development	733,000	733,000
	39,709,000	41,265,000
Less: Valuation Allowance	(39,709,000)	(41,265,000)
Total Deferred Tax Assets	$ —	$ —
Total Deferred Tax Liabilities	$ —	$ —
Net Deferred Tax Assets/(Liabilities)	**$ —**	**$ —**

The Company assesses the likelihood that deferred tax assets will be realized. To the extent that realization is not likely, a valuation allowance is established. Based upon the history of losses, management believes that it is more likely than not, that future benefits of deferred tax assets will not be realized and has established a full valuation allowance for the years ended December 31, 2023 and 2022. The Company has research and development tax credit carryforwards of $733,000 available to offset future federal income taxes. The research and development tax credit carryforwards begin to expire in 2030.

The Company has approximately $131.8 million of federal and $38.4 million of state Net Operating Losses ("NOL"s) that may be available to offset future taxable income, if any. The federal net operating loss carryforwards of $38.0 million, if not utilized, will expire between 2030 and 2037. The federal net operating loss carryforwards of $93.8 million generated in 2018 and thereafter are subject to an 80% limitation on taxable income, do not expire and will carry forward indefinitely. The state net operating loss carryforwards of $21.7 million, if not utilized, will begin to expire in 2035. The state net operating loss carryforwards of $16.6 million generated in 2018 and thereafter are subject to an 80% limitation on taxable income, do not expire and will carry forward indefinitely.

In accordance with Section 382 of the Internal Revenue code, the usage of the Company's net operating loss carryforwards may be limited in the event of a change in ownership. A full Section 382 analysis has not been prepared and NOLs could be subject to limitation under Section 382.

Effective for tax years beginning after December 31, 2021, taxpayers are required to capitalize any expenses incurred that are considered incidental to research and experimentation (R&E) activities under IRC Section 174. While taxpayers historically had the option of deducting these expenses under IRC Section 174, the December 2017 Tax Cuts and Jobs Act mandates capitalization and amortization of R&E expenses for tax years beginning after December 31, 2021. Expenses incurred in connection with R&E activities in the US must be amortized over a 5-year period if incurred, and R&E expenses incurred outside the US must be amortized over a 15-year period. R&E activities are broader in scope than qualified research activities considered under IRC Section 41 (relating to the research tax credit). For the year ended December 31, 2023 and 2022, the Company performed an analysis based on available guidance and determined that it will continue to be in a loss position even after the required capitalization and amortization of its R&E expenses. The Company will continue to monitor this issue for future developments, but it does not expect R&E capitalization and amortization to require it to pay cash taxes now or in the near future.

The Company's income tax returns for 2019 to 2023 are still open and subject to audit. In addition, net operating losses arising from prior years are also subject to examination at the time they are utilized in future years.

For the years ended December 31, 2023 and 2022, the expected tax expense (benefit) from continuing operations based on the U. S. federal statutory rate is reconciled with the actual tax provision (benefit) as follows:

	For the Years Ended December 31,			
	2023		2022	
	Amount	Percent of Pretax Loss	Amount	Percent of Pretax Loss
U.S. federal statutory rate	$ (2,948,000)	21.00 %	$ (4,153,000)	21.00 %
State taxes, net of federal benefit	(20,000)	0.14 %	(28,000)	0.14 %
Tax rate change	(9,000)	0.06 %	10,000	(0.05)%
Permanent Differences				
- Other permanent differences	25,000	(0.18)%	288,000	(1.46)%
Change in valuation allowance	(1,556,000)	11.08 %	2,864,000	(14.48)%
Deferred true-up	4,512,000	(32.14)%	1,019,000	(5.15)%
Income tax provision/(benefit)	$ 4,000	(0.04)%	$ —	0.00 %

The Company recognized approximately $4,000 in state tax expense for the year ended December 31, 2023.

ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. As of December 31, 2023, and 2022, there were no unrecognized tax benefits. The Company recognizes accrued interest and penalties as income tax expense. No amounts were accrued for the payment of interest and penalties at December 31, 2023 and 2022. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position in the next year.

NOTE 16: SUBSEQUENT EVENTS

On February 22, 2024, the Company entered into a Master Services Agreement for Product Supply (the "Agreement") with Cell Ready, a contract development and manufacturing organization (CDMO). Cell Ready is owned by one of the Company's directors and shareholders, Mr. John Wilson. See Note 1 and Note 14.

On February 29, 2024, Marker Therapeutics, Inc. (the "Company") delivered notice to Lincoln Park Capital Fund, LLC, an Illinois limited liability company ("LPC"), terminating the Purchase Agreement, dated December 12, 2022 (the "Purchase Agreement"), with LPC effective March 1, 2024 (the "Termination Date"). The Company projects a financial runway through the fourth quarter of 2025 and does not anticipate an immediate need for capital acquisition.

Exhibit 4.0

MARKER Therapeutics

NUMBER

SHARES

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

CUSIP 57055L 20 6

SEE REVERSE FOR CERTAIN DEFINITIONS AND LEGENDS

This certifies that

SPECIMEN

is the record holder of

FULLY PAID AND NONASSESSABLE SHARES OF COMMON STOCK, $0.001 PAR VALUE PER SHARE, OF

MARKER THERAPEUTICS, INC.

transferable on the books of the Corporation in person or by duly authorized attorney upon surrender of this Certificate properly endorsed. This Certificate is not valid until countersigned by the Transfer Agent and registered by the Registrar.

WITNESS the facsimile seal of the Corporation and the facsimile signatures of its duly authorized officers.

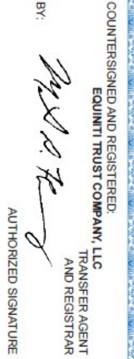
Dated:

PRESIDENT

TREASURER

COUNTERSIGNED AND REGISTERED:
EQUINITI TRUST COMPANY, LLC
TRANSFER AGENT AND REGISTRAR

BY:



AUTHORIZED SIGNATURE

CERTIFICATE OF STOCK

HERITAGE BANKNOTE

The Corporation shall furnish without charge to each stockholder who so requests a statement of the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock of the Corporation or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Such requests shall be made to the Corporation's Secretary at the principal office of the Corporation.

KEEP THIS CERTIFICATE IN A SAFE PLACE. IF IT IS LOST, STOLEN, OR DESTROYED THE CORPORATION WILL REQUIRE A BOND INDEMNITY AS A CONDITION TO THE ISSUANCE OF A REPLACEMENT CERTIFICATE.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM – as tenants in common
TEN ENT – as tenants by the entireties
JT TEN – as joint tenants with right of survivorship and not as tenants in common
COM PROP – as community property

UNIF GIFT MIN ACT – .... Custodian .... (Cust) (Minor) under Uniform Gifts to Minors Act.................... (State)

UNIF TRF MIN ACT – .... Custodian (until age ....) (Cust) .... under Uniform Transfers (Minor) to Minors Act.................... (State)

Additional abbreviations may also be used though not in the above list.

FOR VALUE RECEIVED, ______________________________ hereby sell(s), assign(s) and transfer(s) unto

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

____

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING ZIP CODE, OF ASSIGNEE)

____

____

____ shares

of the capital stock represented by within Certificate, and do hereby irrevocably constitute and appoint

____ attorney-in-fact

to transfer the said stock on the books of the within named Corporation with full power of the substitution in the premises.

Dated ______________________________

X ____

X ____

Signature(s) Guaranteed:

NOTICE: THE SIGNATURE TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATSOEVER.

By ______________________________

THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION, (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM), PURSUANT TO S.E.C. RULE 17Ad-15. GUARANTEES BY A NOTARY PUBLIC ARE NOT ACCEPTABLE. SIGNATURE GUARANTEES MUST NOT BE DATED.

DESCRIPTION OF SECURITIES

The following descriptions of the common stock of Marker Therapeutics, Inc., or the Company, Delaware law and certain provisions of the Company's certificate of incorporation and bylaws are summaries. These summaries are qualified in the entirety by reference to the provisions of the Delaware General Corporation Law, or the DGCL, and the complete text of the Company's certificate of incorporation and bylaws, which are incorporated by reference as Exhibits 3.1 and 3.4, respectively, of the Company's Annual Report on Form 10-K to which this description is also an exhibit.

Authorized Capital Stock

The certificate of incorporation authorizes the Company to issue up to 30,000,000 shares of common stock, $0.001 par value per share, and 5,000,000 shares of preferred stock, $0.001 par value per share. The Company's board of directors may establish the rights and preferences of the preferred stock from time to time.

Common Stock

Voting Rights

Holders of the Company's common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. As a result, the holders of a plurality of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose. All other matters to be voted on by the Company's stockholders must be approved by a majority of the votes cast on the matter unless otherwise provided by law, the certificate of incorporation or the bylaws of the Company.

Dividends

Holders of common stock are entitled to receive ratably any dividends as may be declared by the Company's board of directors, subject to any preferential dividend rights of any series of preferred stock that the board of directors may designate and issue in the future.

Liquidation

In the event of the liquidation, dissolution or winding up of the Company, the holders of common stock are entitled to receive ratably the net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, subscription, redemption or conversion rights. There are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that the board of directors may designate and issue in the future.

Preferred Stock

The Board is authorized, subject to any limitations prescribed by law, without further vote or action by the stockholders, to issue from time to time shares of preferred stock in one or more series. Each such series of preferred stock shall have such number of shares, designations, preferences, voting powers, qualifications, and special or relative rights or privileges as shall be determined by the Board, which may include, among others, dividend rights, voting rights, liquidation preferences, conversion rights and preemptive rights. The terms selected by the Board in the future could decrease the amount of earnings and assets available for distribution to holders of shares of common stock or adversely affect the rights and powers, including voting rights, of the holders of shares of common stock without any further vote or action by the stockholders. As a result, the rights of holders of our common stock will be subject to,

and may be adversely affected by the rights of any preferred stock that may be issued by us in the future, which could have the effect of decreasing the market price of our common stock.

Anti-Takeover Provisions

Section 203 of the Delaware DGCL

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

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

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

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

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

Certificate of Incorporation and Bylaws

Because the Company’s stockholders do not have cumulative voting rights, stockholders holding a plurality of the shares of the Company’s common stock outstanding will be able to elect all of the Company’s directors. The bylaws also provide that directors may be removed by the stockholders upon the vote of a majority of the shares entitled to vote an election of directors, and if a director was elected by a voting group of stockholders, only stockholders from that voting group may vote to remove such director, and such vacancy may be filled only by the stockholders of that voting group. Furthermore, the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

The bylaws provide that only a majority of the authorized directors on the Company's board of directors, the chairman of the board or the chief executive officer to call a special meeting of stockholders. The bylaws also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and specify requirements as to the form and content of a stockholder's notice.

The combination of these provisions may make it more difficult for the Company's existing stockholders to replace the board of directors as well as for another party to obtain control of the Company by replacing the board of directors. Since the board of directors has the power to retain and discharge the Company's officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for the board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of the Company.

These provisions are intended to enhance the likelihood of continued stability in the composition of the Company's board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce the Company's vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for the Company's shares and may have the effect of delaying changes in control or management of the Company. As a consequence, these provisions may also inhibit fluctuations in the market price of the Company's stock that could result from actual or rumored takeover attempts. The Company believes that the benefits of these provisions, including increased protection of the potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure the Company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Transfer Agent and Registrar

The transfer agent and registrar for the Company's common stock is Equiniti Trust Company. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219.

Listing on Nasdaq

The common stock is listed on the Nasdaq Capital Market under the symbol "MRKR."

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MASTER SERVICES AGREEMENT FOR PRODUCT SUPPLY

THIS MASTER SERVICES AGREEMENT FOR PRODUCT SUPPLY **("Agreement")** is made and entered into as of February 22nd, 2024 (the **"Effective Date")** by and between **Marker Therapeutics, Inc.,** a Delaware corporation (hereinafter referred to as **"Marker")** and Cell Ready LLC, a Minnesota limited liability company having a principal place of business at 2100 Old Highway 8 NW, St. Paul, MN 55112 (hereinafter referred to as **"Supplier").** Marker and Supplier may be referred to individually as a **"Party"** and collectively, as the **"Parties".**

RECITALS

WHEREAS, Marker wishes to purchase cells and services from Supplier and Supplier wishes to supply cells and services to Marker.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

1. DEFINITIONS

1.1 **"Affiliate"** shall mean, with respect to a Person, any Person that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with, such first Person for so long as such Person controls, is controlled by or is under common control with, such first Person. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" shall mean: (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interests of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.2 **"Anticorruption Law"** shall mean all Applicable Law relating to anti-bribery or anticorruption, including those which prohibit the corrupt payment, offer, promise, or authorization of the payment or transfer of anything of value (including gifts or entertainment), directly or indirectly, to any government official to obtain a business advantage; such as, the U.S. Foreign Corrupt Practices Act of 1977, as amended from time to time, and all national and international laws enacted to implement the OECD Convention on Combating Bribery of Foreign Officials in International Business Transactions.

1.3 **"Applicable Law"** shall mean all applicable laws, statutes, ordinance, rules, regulations, directives and guidelines of the relevant government or Regulatory Authorities that are applicable to the Services performed under this Agreement or any applicable Work Order, and the supply, use, marketing or sale of the Marker Product.

1.4 **"Background IP"** shall mean any Intellectual Property either: (a) owned or controlled by a Party prior to the Effective Date; or (b) developed or acquired by a Party

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independently from performance under this Agreement without the use of, reliance on, or access to the other Party's Confidential Information.

1.5 **"Batch"** shall mean a specific quantity of Product that is intended to be of defined character and quality, within the Specifications, and is produced during one (1) cycle of Product manufacture as defined by the applicable Batch record.

1.6 **"Business Day"** shall mean any day on which commercial banks in Houston, Texas are generally open for business.

1.7 **"Certificate of Analysis"** shall mean the certificate provided by Supplier to Marker listing tests performed, test dates and test results confirming that each Batch of Product meets the Specifications.

1.8 **"Claim"** shall mean any claim, demand, proceeding, action, liability, suit, expense, fine, penalty, damage, loss and cost (including legal and other professional advisers' fees).

1.9 **"Confidential Information"** has the meaning set forth in Section 11.1.

1.10 **"Deliverables"** shall mean all work product to be provided by Supplier to Marker under each Work Order.

1.11 **"Event of Default"** shall mean at any time Supplier: (a) files in any court pursuant to any statute a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of Supplier, or of its assets; (b) proposes a written agreement of composition for extension of its debts; (c) is served with an involuntary petition against it, filed in any insolvency proceeding which is admitted in the court; (d) makes an assignment for the benefit of its creditors; (e) becomes unable to pay any amounts it owes when due; or (f) materially breaches this Agreement and fails to cure the breach within thirty (30) calendar days following receipt of written notice of such breach by Marker.

1.12 **"cGMP"** shall mean the current good manufacturing practices in effect to support the manufacture of Product and promulgated by Regulatory Authorities in the United States or in any given country, including the requirements set forth in U.S. C.F.R. (Title 21, Parts 210-211), FDA guidance documents and PICS GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS PART I, dated 1 February 2022.

1.13 **"Multi-TAA"** shall mean non-genetically engineered T cells that recognize cancer cells through their native T cell receptors.

1.14 **"Marker Materials"** shall mean the materials, if any, that are provided by or on behalf of Marker or an Affiliate of Marker to Supplier for use in the performance of Services, which materials are specified in the applicable Work Order.

1.15 **"Marker Product"** shall mean any Marker finished drug product incorporating Multi-TAA.

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1.16 **"Marker Technology"** shall mean all data, specifications, instructions, processes, formulas, technology, expert opinions and information, including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety, manufacturing and quality control data, methodologies, techniques, and formulations and information provided by or on behalf of Marker or an Affiliate of Marker to Supplier or its designee for use in the performance of the Services related to the Product.

1.17 **"Intellectual Property"** shall mean, in any and all jurisdictions throughout the world, all: (a) Patents; (b) know-how, trade secrets, technology, developments, inventions, and ideas; (c) trademarks and service marks, including all applications and registrations thereof and the goodwill connected with the use of and symbolized by the foregoing; (d) copyrights, including all applications and registrations related to the foregoing; and (e) all other intellectual property and other proprietary rights.

1.18 **"Invention"** shall mean any discoveries, developments, innovations, modifications, updates, enhancements, improvements, and inventions (whether or not patentable) that are conceived, developed, or reduced to practice.

1.19 **"OFAC"** shall mean the U.S. Treasury Department's Office of Foreign Assets Control.

1.20 **"Patents"** shall mean any patents (including reissues, reexaminations and extensions) and patent applications (including divisions, continuations, continuations-in-part and substitute applications) in any country or territory.

1.21 **"Permitted Subcontractor"** has the meaning set forth in Section 3.2.

1.22 **"Person"** shall mean any individual, sole proprietorship, partnership, limited

partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.23 **"Product"** shall mean Multi-TAA to be supplied by Supplier to Marker pursuant to a Work Order.

1.24 **"Product Requirements"** shall mean, with respect to a Batch of Product: (a) this Agreement; (b) all applicable Specifications; (c) the applicable requirements of the Quality Agreement; (d) the requirements of Applicable Law; and (e) any other requirements expressly stated in the applicable Work Order, including cGMP.

1.25 **"Quality Agreement"** shall mean a quality agreement to be entered into between the Parties (as may be amended, reinstated or replaced from time to time), which will specify the roles, responsibilities, procedures and standards by which the Parties will coordinate and implement the operational and quality assurance activities needed to efficiently achieve regulatory compliance objectives set by the Parties in connection with the Services and activities conducted pursuant to this Agreement.

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1.26 "**Regulatory Approval**" shall mean, in any given country, the granting by the Regulatory Authorities in that country of all approvals that are necessary for the manufacturing, distributing, marketing, sale, pricing and reimbursement of the Marker Product.

1.27 "**Regulatory Authority**" shall mean any government regulatory authority responsible for granting Regulatory Approval, including the U.S. Food and Drug Administration ("FDA").

1.28 "**Regulatory Materials**" shall mean regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals or other filings made to, received from or otherwise conducted with a Regulatory Authority in connection with the research, manufacturing, development, or commercialization of the Marker Product in a particular country or jurisdiction.

1.29 "**Representatives**" shall mean the respective employees, officers, directors, consultants, Affiliates and agents of a Party.

1.30 "**Service Charges**" shall mean the agreed charges for the performance of the Services as set forth in the applicable Work Order.

1.31 "**Service Requirements**" shall mean: (a) this Agreement; (b) the requirements of Applicable Law; and (c) any requirements expressly stated in a Work Order.

1.32 "**Services**" shall mean the specified development and manufacturing services to be provided by Supplier or Permitted Subcontractors as set forth in a Work Order.

1.33 "**Specifications**" shall mean those specifications for a Product set out in a Work Order, as may be modified or amended from time to time by mutual written agreement of the Parties.

1.34 "**Tax**" shall mean any form of tax or taxation, levy, duty, charge, social security charge, contribution or withholding of whatever nature (including any related fine, penalty, surcharge, or interest).

1.35 "**Term**" has the meaning set forth in Section 12.1.

1.36 "**Third Party**" shall mean an entity other than a Party or its Affiliates.

1.37 "**U.S. Trade Controls**" shall mean any laws and regulations administered and maintained by the United States Government and any agency thereof pertaining to economic sanctions and export controls, including the U.S. Department of Commerce's Export Administration Regulations and the various economic sanctions programs promulgated by OFAC.

1.38 "Work Order(s)" shall mean a written document, substantially in the form of Schedule 1, specifying: (a) the Services to be conducted by Supplier; (b) the applicable Product(s) that are the subject of the relevant Services; (c) the Marker Materials to be provided for the Services; (d) the Specifications for the Product; (e) the Deliverables to be supplied in connection therewith; and (f) any other applicable requirements, including whether cGMP is applicable, as

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mutually agreed to by the Parties, which document shall be incorporated by reference into this Agreement.

2. SCOPE OF AGREEMENT

2.1 **Structure.** This Agreement sets out the master terms and conditions under which Marker and its Affiliates may contract with Supplier for the provision of various Services from time to time by entering into Work Orders with Supplier.

2.2 **Work Orders.** If the Parties agree that Supplier shall provide certain Services, the Parties shall negotiate a Work Order with respect to such Services; which the Parties shall complete, execute and deliver at such time. Each Work Order incorporates the terms of this Agreement by reference and will be governed by the terms and conditions of this Agreement. In the event of a conflict between the terms of this Agreement and the terms of a Work Order, the terms of this Agreement will govern, unless the Work Order expressly identifies a specific deviation to the terms of this Agreement, and any such deviation shall be strictly limited to that particular Work Order.

3. SERVICES

3.1 **Provision of Services.** Supplier shall provide the Services to Marker and its Affiliates in conformance with the Service Requirements and within the timeframe and target dates set forth in the applicable Work Order. Supplier shall cooperate with the reasonable written instructions and requests of Marker and its Representatives with respect to the Services, *provided* that such instructions and requests do not contradict Service Requirements or Supplier's standard operating procedures.

3.2 **Permitted Subcontractors.** Supplier shall not subcontract or sublicense its rights or obligations under this Agreement without the prior written consent of Marker or its applicable Affiliate (any Third Party to whom Marker grants consent pursuant to this Section 3.2 being a **"Permitted Subcontractor").** Supplier shall remain fully and unconditionally obligated and responsible for the full and complete performance of all of its obligations under the terms and conditions of this Agreement whether or not such performance is carried out by Supplier or any of its Permitted Subcontractors. Each Permitted Subcontractor must be subject to, and Supplier shall require each Permitted Subcontractor to comply with, all of the terms applicable to Supplier under this Agreement.

4. SUPPLY OF PRODUCT

4.1 **Supply of Product.** If the Services involve the supply of Product, Supplier shall supply such Product to Marker in conformance with the Product Requirements and shall manufacture such Product at the Supplier facility specified for manufacture in the Work Order.

4.2 **Marker Materials.** Supplier will obtain all raw materials and components to be used in the performance of Services under a Work Order other than the Marker Materials specified in such Work Order. Marker shall deliver to Supplier all amounts of Marker Materials specified in the Work Order. Marker shall provide Supplier with all relevant information in its possession concerning the Marker Materials, including the stability, storage and safety thereof. Marker

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acknowledges and agrees that Supplier shall not be responsible for testing the Marker Materials to confirm compliance with specifications or any other quality matters unless set forth in a Work Order or if requested by Marker and agreed to by Supplier; however, Supplier agrees to notify Marker of any visually obvious defect or damage to the Marker Materials received by Supplier prior to performing any Services with the Marker Materials. Any impacts on the Delivery Date (as defined below) or Product meeting the Product Requirements that result from the Marker Materials being defective or damaged shall, other than due to Supplier's failure to comply with a Work Order, relieve Supplier of the requirements of Section 4.4, and the applicable Work Order shall be amended to account for changes in the Delivery Date and other affected terms.

4.3 **Shipping.** Supplier shall ship only Products which have been manufactured in accordance with the applicable Product Requirements. Supplier shall ship such conforming Products for delivery on the delivery date set forth in the applicable Work Order (the **"Delivery Date")** together with such accompanying documentation (including any applicable Certificate of Analysis) as set forth in the applicable Work Order. Supplier shall ship the Products EXW Supplier's facility (Incoterms 2020) using such freight carrier as is notified by Marker to Supplier in the applicable Work Order. All Product supplied hereunder will be delivered free and clear of all encumbrances and liens.

4.4 **Failure to Deliver.** If Supplier is unable to deliver the full quantity of Products as set forth on the applicable Work Order on or before the Delivery Date therefor **("Delay"),** Supplier shall: (a) promptly notify Marker of such Delay (Products Delayed thereunder, **"Delayed Products");** (b) deliver the amount of Products that it is able to deliver, if any, pursuant to Section 4.3; and (c) discuss with Marker in good faith an alternative delivery date for the Delayed Products **("New Delivery Date").** Supplier agrees that in the event the Delay is due to failure to meet Product Requirements for the applicable Products other than such failure being a result of using the Marker Materials, then Supplier shall either (i) rework and/or reprocess such Delayed Products in accordance with the Product Requirements as soon as reasonably possible, or (ii) deliver replacement Products, in each case (i) or (ii), within ninety (90) calendar days of Marker's receipt of notice pursuant to this Section 4.4 or such other time frame as may be agreed between the Parties at no additional charge unless otherwise set forth in the applicable Work Order.

4.5 **Inspection.** Marker shall visually inspect Product promptly following delivery, and if Marker determines that the Product is not in accordance with the Product Requirements, the Certificate of Analysis or contains obvious defects **("Defective Product"),** Marker shall promptly notify Supplier in writing of the same within thirty (30) calendar days following delivery. Upon receipt of notification that a Product is a Defective Product, other than as a result of any action or inaction on the part of Marker, including the failure to store or handle such Defective Product in accordance with the Specifications therefor, at Marker's option, Supplier shall: (a) rework and/or reprocess such Defective Products in accordance with the Product Requirements as soon as reasonably possible; or (b) deliver replacement Products, in each case (a) or (b), within ninety (90) calendar days of Marker's notice pursuant to this Section 4.5 or such other time frame as may be agreed between the Parties at no additional charge unless otherwise set forth on the applicable Work Order.

4.6 **Latent Defects.** Notwithstanding Section 4.5, Supplier shall remain liable to Marker and its Affiliates, as appropriate, for any Product that is determined to be Defective Product

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subsequently and which Product could not reasonably have been determined to be Defective Product earlier pursuant to Section 4.5. Upon discovery of such defect, Marker shall promptly (i.e., within three (3) Business Days) notify Supplier in writing specifying the relevant defect and rejecting the relevant shipment. Upon receipt of such notice, the Parties shall discuss in good faith a rework or reprocess of the impacted lots together with a timeline for delivery. Notwithstanding anything to the contrary, Marker's failure to notify Supplier of applicable defects under this Section 4.6 within one (1) year of Marker's receipt of the Product shall release Supplier of its obligations under this Section 4.6. For clarity, any release under this Section 4.6 shall not affect any of Supplier's other responsibilities, obligations, or liabilities that it may otherwise have under this Agreement.

4.7 **Disputes.** If Supplier disputes that the relevant Product is a Defective Product under Section 4.5 or Section 4.6, either Party may propose to submit the Product to an agreed reputable independent testing laboratory for determination, in which case the Parties shall cooperate to provide such Product to such laboratory. If the independent testing laboratory agrees with Marker's determination, Supplier shall bear all costs for such testing; otherwise Marker shall bear all such testing costs. The results of such testing shall be binding on the Parties, absent manifest error.

4.8 **Quality Agreement, Quality Control.** The Parties agree to negotiate in good faith and enter into the Quality Agreement within ninety (90) calendar days following the Effective Date. Supplier and Marker shall each comply with, and shall each cause their Permitted Subcontractors and Affiliates, as applicable, to comply with their respective obligations as set forth in the Quality Agreement. Supplier or any Third Party approved by Marker and Supplier shall perform quality control testing of the Product. Supplier is responsible for quality assurance review, approval, and Batch release prior to its shipping of each Batch of Product to Marker to ensure that the Product complies with the Product Requirements. Supplier shall promptly notify Marker within two (2) Business Days, if Supplier becomes aware that any Products or Services do not meet the Product Requirements or Service Requirements, as applicable.

5. PERSONNEL AND MANAGEMENT

5.1 Supplier shall: (a) only use personnel with sufficient qualifications and experience in order to supply the Services; (b) provide its personnel with adequate training; and (c) assume full responsibility for its personnel's compliance with this Agreement.

5.2 Each Party will identify a primary contact **("Responsible Person")** who shall be responsible for exchanging information and updates concerning the Services and keeping Supplier and Marker, as applicable, informed. Each Party shall also designate a member of its senior management responsible for making necessary strategic decisions and managing the resolution of disputes between the Parties which cannot be resolved at a lower level. Each Responsible Person shall be available to attend regular scheduled meetings (as agreed between the Parties) and ad hoc meetings as needed with the senior management members to discuss matters relating to the Services.

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6. REGULATORY COOPERATION

6.1 **General Assistance**. Supplier shall provide Marker with assistance and cooperation, as Marker reasonably requires, in order for Marker to obtain and maintain Regulatory Approvals. The costs and fees associated with such assistance and cooperation shall be borne by Marker or as otherwise mutually agreed between the Parties. As specified in the applicable Work Order, the Parties shall agree on which Regulatory Approvals are to be obtained. As between the Parties, Marker will own all Regulatory Materials submitted by Marker to the Regulatory Authorities and all Regulatory Approvals resulting from such submissions.

6.2 Regulatory Approvals for the Facility. Supplier shall obtain and maintain all approvals, licenses, registrations, or authorizations of any federal, state, or local regulatory agency, department, or other governmental entity (other than Regulatory Approvals, which will be obtained and maintained by Marker) that are required to manufacture and ship the Product at Supplier's facility and perform the Services supporting process development.

7. PAYMENTS AND RELATED OBLIGATIONS

7.1 **Service Charges, Invoices**. In consideration of the provision of the Services, Marker shall pay to Supplier the applicable Service Charges and reimbursement of reasonable pass-through costs for expenses therefor to the extent actually incurred by Supplier in the performance of the Services. Supplier shall invoice Marker as set out in the applicable Work Order on the terms set out therein. Where payment intervals or invoicing arrangements are not specified in the applicable Work Order, Supplier will submit monthly invoices in arrears for Services performed and expenses incurred during such period. Supplier shall provide to Marker on request, all documents and information reasonably required to support such invoice. [

7.2 **Payment Method, Currency**. Marker shall pay all undisputed amounts within thirty (30) calendar days of invoice receipt. All payments made by Marker under this Agreement shall be made in United States dollars. Any undisputed invoiced amount that is not paid by Marker when due shall bear interest at the rate of eighteen percent (18%) per annum from the calendar day following the due date until paid in full or the maximum rate allowed by law, whichever is less. In the event there is an undisputed amount which is invoiced by Supplier but not paid by Marker for more than three (3) months after the due date, such event shall be considered a material breach by Marker of this Agreement.

7.3 **Taxes**. All Service Charges stated, and any other payments made by Marker to Supplier under this Agreement: (a) are inclusive of any Taxes, including without limitation any excise, sales, use, or value added (VAT), if any; and (b) shall be made free and clear and without deduction or withholding for any Taxes, except as required by Applicable Law. Marker and its Affiliates shall have no obligation to pay, and Supplier shall be solely responsible for, any Taxes or fees that are based upon Supplier's income or receipts or otherwise with respect to the performance of the Services hereunder.

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8. INTELLECTUAL PROPERTY

8.1 Ownership

8.1.1 Background IP. Each Party shall retain ownership of the entire right, title, and interest in and to its Background **IP.** For the avoidance of doubt, Marker Background IP includes the Marker Materials, Marker Technology, and any of Marker's Confidential Information provided by or on behalf of Marker to Supplier for the performance of the Services.

8.1.2 **Foreground IP.** As between the Parties: (a) Marker shall solely and exclusively own all right, title and interest (including all Intellectual Property) in and to any and (i) all Deliverables, and (ii) all Inventions derived from Marker's Background IP made by or on behalf of Supplier in its performance of the Services **("Marker Foreground IP");** and (b) Supplier shall solely and exclusively own all right, title and interest (including all Intellectual Property) in and to any and all Inventions derived from Supplier's Background IP made by or on behalf of Supplier in the performance of the Services, subject to and without limiting Marker's ownership of its Background IP and Marker Foreground **IP ("Supplier Foreground IP").**

8.1.3 **Duty to Assign and Cooperate.** Supplier hereby assigns, and agrees to assign, all Marker's Background **IP** it has in its possession (if any) and all Marker Foreground IP to Marker. Supplier agrees to execute all documents and other instruments and perform any actions necessary or desirable to confirm and perfect such assignment, including without limitation, any copyright assignment or patent assignment provided by Marker. At Marker's request, Supplier shall promptly record any such patent assignment with the United States Patent and Trademark Office. Marker shall reimburse Supplier for any reasonable out-of-pocket expenses actually incurred and fully documented by Supplier in fulfilling its obligations under this Section 8.1.3.

8.2 **Licenses**

8.2.1 Supplier and its applicable Affiliates hereby grant to Marker and its Affiliates a non-exclusive, perpetual, irrevocable, transferable, assignable, fully-paid up, royalty-free, worldwide license (with the right to grant sublicenses through multiple tiers) to and under any of Supplier's Background IP and Supplier Foreground IP to the extent such are incorporated or embedded in the Deliverables or in the process of generating or manufacturing the Deliverables and reasonably necessary or useful for Marker to make, have made, manufacture, have manufactured, use, have used, offer for sale, sell, import, and otherwise exploit such Deliverable.

8.2.2 Marker and its applicable Affiliates hereby grant to Supplier until termination or expiry of the applicable Work Order and for a period not exceeding the Term of this Agreement, a non-exclusive, fully paid-up, royalty-free, non-transferable, non-sublicensable (other than to Permitted Subcontractors and solely to the extent necessary for the provision of the Services hereunder) limited license under and to Marker's Background IP made available to Supplier pursuant to a Work Order solely to the extent required for Supplier to provide the Services under such Work Order on the terms and conditions of this Agreement.

8.3 **No Other Rights.** No license or other right is or shall be created or granted hereunder by implication, estoppel or otherwise. All licenses and rights are or shall be granted only as expressly provided in this Agreement. All rights not expressly granted by a Party under this

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Agreement are reserved by such Party and may be used by such Party for any purpose, and each Party retains exclusive ownership of its respective Intellectual Property.

9. WARRANTIES

9.1 **Mutual Representations and Warranties.** Each Party represents and warrants the following:

9.1.1 **Corporate Power.** Such Party is duly organized and validly existing under the laws of the jurisdiction of its organization and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof and its obligations hereunder.

9.1.2 **Due Authorization.** Such Party is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder. The person executing this Agreement on such Party's behalf has been duly authorized to do so by all requisite corporate action.

9.1.3 **Binding Agreement; No Conflicts.** This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor, to such Party's knowledge, does it violate any Applicable Law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

9.1.4 **Compliance.** Each Party shall conduct its activities under this Agreement in accordance with all Applicable Laws, including Anticorruption Law.

9.2 **Marker Warranties.** Marker represents and warrants to Supplier that as of the Effective Date and during the Term: (a) all Marker Materials, Marker's Background IP Information and Confidential Information provided by or on behalf of Marker will be suitable for the Services; and (b) Supplier's use of the Marker Materials, Marker's Background IP and Confidential Information for the purpose of the Services will not, to Marker's knowledge as of the date of delivery of the relevant Marker Materials, Marker Background IP, or Confidential Information to Supplier, infringe any Third Party's Intellectual Property.

9.3 **Supplier Warranties**

9.3.1 **Product.** Supplier represents and warrants to Marker and its Affiliates that any Product delivered to Marker pursuant to a given Work Order shall conform to the Product Requirements. Supplier further represents and warrants that Product, at the time of delivery to Marker, shall not be adulterated or misbranded within the meaning of the United States Food, Drug and Cosmetic Act, if applicable.

9.3.2 **Intellectual Property.** Supplier represents and warrants to Marker and its Affiliates that the provision of the Services and Marker's or its Affiliates' receipt and use of those Services (including any Deliverable) shall not, to the best of Supplier's knowledge as of the date of provision of the applicable Services and the date of delivery of the relevant Services or Deliverables to Marker or its Affiliates, infringe or misappropriate any Intellectual Property of any Third Party.

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9.3.3 **Permits.** Supplier represents and warrants to Marker and its Affiliates that it has, and its Permitted Subcontractors have, and will maintain during the Term of this Agreement all licenses, permits and similar authorizations of governmental and regulatory authorities necessary for Supplier to comply with all of its obligations pursuant to this Agreement, including without limitation health, safety and environmental permits.

9.3.4 **Non-debarment.** Supplier represents and warrants that: (a) it has not been debarred or suspended by the FDA or similar actions by any other Regulatory Authority having jurisdiction; and (b) it shall not engage anyone (as a Permitted Subcontractor, Representative or otherwise) who has been debarred by the FDA or similar actions by other Regulatory Authority having jurisdiction, for performing Services under this Agreement.

9.3.5 **Professional Standards.** Supplier represents and warrants that: (a) it and its Permitted Subcontractors, as applicable, possess the necessary expertise to perform the Services hereunder consistent with professional standards of the industry; and (b) the Services will be performed in a professional and workmanlike manner consistent with professional standards of the industry.

9.3.6 **Use of Marker Materials.** To the extent Marker or its Affiliate provides Marker Materials in connection with the provision of the Services, Supplier represents and warrants that Supplier and its Permitted Subcontractors will use the Marker Materials only for the manufacture of Product and the performance of Services and not for any other purposes without the express written permission of Marker.

10. INDEMNIFICATION, LIABILITY AND INSURANCE

10.1 **Indemnification by Supplier.** Supplier shall indemnify, defend and hold harmless Marker and its Representatives from and against all Third Party Claims resulting from or arising out of any: (a) breach by Supplier of any of Supplier's representations, warranties, covenants or obligations under this Agreement; or (b) any negligence, gross negligence or willful misconduct of Supplier or any Supplier Representative, in each case except to the extent that any such Claim arises out of any negligence, gross negligence or willful misconduct of, or breach of this Agreement by Marker and/or its Representatives.

10.2 **Indemnification by Marker.** Marker shall indemnify, defend and hold harmless Supplier and its Representatives from and against all Third Party Claims resulting from or arising out of any: (a) breach by Marker of any of Marker's representations, warranties, covenants or obligations under this Agreement; or (b) any negligence, gross negligence or willful misconduct of Marker or any Marker Representative, in each case except to the extent that any such Claim arises out of any negligence, gross negligence or willful misconduct of, or breach of this Agreement by Supplier and/or its Representatives.

10.3 **Indemnification Procedure.** A Party (the **"Indemnitee")** which intends to claim indemnification under Section 10.1 or Section 10.2, as applicable, shall promptly (i.e., within twenty (20) calendar days of receipt) notify the other Party (the **"Indemnitor")** in writing of any Claim in respect of which the Indemnitee or any of its directors, officers, employees or agents intend to claim such indemnification, *provided* that the failure to provide timely notice to the Indemnitor shall release the Indemnitor from any liability to the Indemnitee but only to the extent the Indemnitor is prejudiced thereby. The Indemnitee shall permit and shall cause its employees and agents to permit the Indemnitor to assume the defense of any such Claim with qualified counsel at the Indemnitor's

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sole cost and expense, *provided, however,* that if there exists or is reasonably likely to exist a conflict of interest that would make it inappropriate in the judgment of the Indemnitee in its reasonable discretion for the same counsel to represent both the Indemnitee and the Indemnitor, the Indemnitee shall be able to obtain its own counsel at the expense of the Indemnitor. The Indemnitee may participate in such defense through counsel of its own selection at the Indemnitee's sole cost and expense. Neither Party shall settle or consent to entry of judgment of any such Claim without the other Party's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed; *provided* that the Indemnitee shall be deemed to have granted such consent if either: (a) such settlement does not adversely affect the Indemnitee and does not impose any obligation or liability on the Indemnitee which cannot be assumed and performed in full by the Indemnitor; or (b) such settlement involves only the payment of money by the Indemnitor or its insurer. The Indemnitor shall not be responsible for any attorneys' fees or other costs incurred other than as provided in this Agreement. The Indemnitee, its employees and its agents shall provide reasonable and good faith assistance (including but not limited to documents and testimony) to the Indemnitor and its legal representatives, at the Indemnitor's expense, in the investigation and defense of any Claim covered by this indemnification.

10.4 **Limitation of Liability.** TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW AND EXCEPT WITH RESPECT TO: (A) A CLAIM ARISING OUT OF FRAUD, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT; (B) ANY AMOUNTS PAYABLE PURSUANT TO SECTION 10.1 OR SECTION 10.2; OR (C) ANY BREACH OF SECTION 11, IN NO EVENT SHALL EITHER PARTY, ITS DIRECTORS, OFFICERS, EMPLOYEES, AGENTS OR AFFILIATES BE LIABLE TO THE OTHER PARTY FOR ANY LOSS OF PROFIT, INCOME, BUSINESS INTERRUPTIONS, DIMINUTION OF VALUE OR LOSS OF OPPORTUNITY OR ANY INDIRECT, INCIDENTAL, MULTIPLE, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES (EACH INCLUDING BUT NOT LIMITED TO LOSS OF PROFIT, INCOME, BUSINESS INTERRUPTIONS, DIMINUTION OF VALUE OR LOSS OF OPPORTUNITY) WHATSOEVER THAT IN ANY WAY ARISE OUT OF, RELATE TO, OR ARE A CONSEQUENCE OF, ITS PERFORMANCE OR NON-PERFORMANCE HEREUNDER, WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN PUT ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES, ARISING OUT OF THIS AGREEMENT.

10.5 **Insurance.** Each Party shall maintain an appropriate level of insurance, either through insurance policies, self insurance, or a mixture thereof, sufficient to cover its liabilities and obligations under this Agreement.

11. CONFIDENTIALITY

11.1 **Confidential Information.** The Parties have given to each other prior to the Effective Date, and, in connection with this Agreement, may in the future provide to each other Confidential Information. As used herein, **"Confidential Information"** shall mean any information of a confidential and proprietary nature disclosed prior to the Effective Date or during the Term by or on behalf of a Party to this Agreement to the other Party, either directly or indirectly, whether in graphic, written, electronic or oral form, identified at the time of disclosure as confidential, or which would reasonably be understood or otherwise deemed to be confidential. It is agreed and understood that the terms of this Agreement shall be deemed the Confidential Information of each of the Parties,

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and that all reports and other information provided by or on behalf of a Party to this Agreement shall be deemed the Confidential Information of such Party.

11.2 **Confidentiality and Non-Use.** Subject to Section 11.3 and Section 11.4, the recipient of a disclosing Party's Confidential Information shall maintain such Confidential Information in strict trust and confidence, and shall disclose such Confidential Information only to its Representatives, attorneys, accountants and advisors who have a reasonable need to know such Confidential Information and who are bound by obligations of confidentiality and non-use no less restrictive than those set forth herein. Subject to Section 11.3 and Section 11.4, the recipient of the disclosing Party's Confidential Information shall use such Confidential Information solely to exercise its rights and perform its obligations under this Agreement (including the right to use and disclose such Confidential Information in applications and filings to Regulatory Authorities), unless otherwise mutually agreed in writing. The recipient of the other Party's Confidential Information shall protect and keep secret such Confidential Information using the same degree of care that it uses to protect its own confidential and proprietary information of a similar nature and importance (but in any event no less than reasonable care).

11.3 **Exclusions.** Confidential Information shall not include information that: (a) is in the recipient's possession prior to receipt from the disclosing Party, as evidenced by the recipient's contemporaneous records; (b) is or becomes, through no fault of the recipient, publicly known; (c) is furnished to the recipient by a Third Party without breach of a duty to the disclosing Party; or (d) is independently developed by the recipient without use of, application of or access to the disclosing Party's Confidential Information, as evidenced by the recipient's contemporaneous records.

11.4 **Authorized Disclosure.** A Party may disclose the Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances; *provided,* that the recipient, to the extent possible, shall give the disclosing Party prior written notice (or, to the extent prior notice is not possible, written notice as soon as possible) of the proposed disclosure and shall cooperate fully with the disclosing Party to minimize the scope of any such required disclosure, to the extent possible and in accordance with Applicable Law: (a) prosecuting or defending litigation; (b) complying with applicable governmental laws and regulations or rules of a securities exchange; and (c) if otherwise legally compelled to disclose such Confidential Information. In the event of a limited disclosure of the disclosing Party's Confidential Information under this Section 11.4, the receiving Party shall continue to treat such information as the disclosing Party's Confidential Information for all other purposes and subject to this Section 11.

11.5 **Termination.** All obligations of confidentiality and non-use imposed under this Section 11 shall expire ten (10) years after the date of expiration or termination of this Agreement.

12. TERM AND TERMINATION

12.1 **Term.** The term of this Agreement shall commence on the Effective Date and continue in full force and effect for a period of three (3) years **("Term").** The Term may be extended upon mutual written agreement of the Parties.

12.2 **Work Orders**

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12.2.1 Each Work Order shall commence on the effective date thereof and shall terminate upon the completion of the Services specified thereunder unless earlier terminated in accordance with Section 12.3. If the term of a Work Order extends past the expiry of this Agreement, the applicable terms and conditions of this Agreement shall continue in full force and effect until completion of such Work Order.

12.2.2 Expiration or earlier termination of any one (1) Work Order pursuant to Section 12.3 shall not affect the effectiveness of any other Work Order and each effective Work Order shall continue in full force and effect unless specifically terminated or expired under the terms of such Work Order and/or this Agreement.

12.3 **Termination Rights**

12.3.1 **Insolvency.** This Agreement may be terminated by either Party upon written notice if the other Party: (a) files in any court pursuant to any statute a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such Party, or of its assets; (b) proposes a written agreement of composition for extension of its debts; (c) is served with an involuntary petition against it, filed in any insolvency proceeding which is admitted in the court; or (d) makes an assignment for the benefit of its creditors. The Party affected shall immediately notify the other Party in writing of the occurrence of any of the foregoing events.

12.3.2 **Material Breach.** A Party may terminate this Agreement for material breach by the other Party, *provided* that the non-breaching Party shall give the breaching Party written notice of such breach and if the breaching Party fails to cure the breach within thirty (30) calendar days following receipt of such written notice, then the non-breaching Party may immediately terminate this Agreement.

12.3.3 **Mutual Agreement.** This Agreement and any Work Order may be terminated upon mutual written agreement of the Parties.

12.4 **Effect of Termination**

12.4.1 **Termination of Work Orders.** The termination of this Agreement shall automatically and without further action by either Party terminate all Work Orders that are outstanding on the effective date of termination; however, termination of any Work Order shall not terminate this Agreement.

12.4.2 **Payment of Amounts Due.** Expiration or termination of this Agreement or any Work Order for any reason shall not exempt Marker from paying to Supplier any amounts owing at such time. Supplier shall provide a final invoice to Marker, which invoice shall be paid in accordance with Section 7.2.

12.4.3 **Return of Property.** Each Party shall promptly return, or at the other Party's request destroy, any Confidential Information of the other Party in such Party's possession or control at such time within thirty (30) calendar days following the termination *(provided* that each Party may retain one (1) copy solely to the extent required by Applicable Law) and Supplier shall promptly return to Marker, at Marker's expense, any unused Marker Materials that are in Supplier's possession or control, if any.

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12.4.4 **Assistance.** In the event this Agreement is terminated by Marker, Supplier shall provide all reasonable assistance for further reasonable cost to Marker to facilitate the orderly transfer of the provision of Services to Marker or to enable a Third Party to commence the provision of all or part of the Services.

12.5 **Survival.** Termination or expiration of this Agreement through any means and for any reason shall not relieve the Parties of any obligation accruing prior thereto, nor shall it prejudice any rights and remedies of either Party under this Agreement or in law or in equity. Sections 1, 4.5, 4.6, 4.7, 6, 8, 9.3.1, 10, 11, 12.4, 12.5, 14, 15, and 16 shall survive the termination or expiration of this Agreement.

13. [Section intentionally left blank]

14. RECORDS AND INSPECTIONS

14.1 **Records.** Supplier shall and shall cause its Permitted Subcontractors to maintain clear, complete, accurate, and up to date records of all Services provided in connection with this Agreement, including all time, costs and expenses incurred in the provision of the Services, and all personnel, and materials used in connection with the provision of the Services **("Records").** Supplier shall maintain such Records in a stable form for the period required by Applicable Law, or if not legally required, for a period of five (5) years after completion of the applicable Work Order. Supplier shall promptly deliver all Records to Marker at any time at Marker's request. Without limiting the foregoing, Supplier shall maintain any production, control, or distribution Records, and any information associated with a Batch, for at least one (1) year after the expiration date of the Batch, and Supplier will maintain all Records for all components, drug product containers, closures, and labeling for at least one (1) year after the expiration date.

14.2 **Audits.** Upon at least thirty (30) calendar days prior written notice from Marker, but no more than once per year during the Term, except for justifiable cause, Supplier shall make available or cause its Permitted Subcontractors to make available, to Marker and its Representatives: (a) the Records; (b) Supplier's facilities; or (c) the facilities of its Permitted Subcontractors, solely to ascertain compliance by Supplier with the terms of this Agreement, the Quality Agreement or any applicable Work Order (each, an **"Audit").** An Audit shall not exceed three (3) Business Days and shall be conducted by no more than two (2) auditors. Supplier shall cooperate fully with such Audit and shall be reimbursed for its reasonable costs for such Audit. Supplier may reasonably restrict Marker's and its Representatives' access to the facility as it deems necessary. Marker and its Representatives shall comply with all applicable Supplier policies and procedures while on site at Supplier. In addition, on a monthly basis Supplier will provide to Marker complete and accurate Records reflecting the then-current financial condition of Supplier (including with respect to Supplier's working capital, income, revenues, and expenses). Supplier agrees to promptly (and in all cases within forty eight (48) hours) notify Marker of any material change to Supplier's financial condition.

14.3 **Regulatory Authority Inspections.** Supplier shall facilitate on-site inspections of its facility conducted by Regulatory Authorities. If Supplier receives any notice or request from an applicable Regulatory Authority relating to an inspection of its Records or facilities, Supplier shall notify Marker in writing within five (5) Business Days of receipt thereof, to the extent such inspection relates to the provision of the Services. To the extent not prohibited by the applicable Regulatory Authority, Supplier shall permit (and shall cause its Permitted Subcontractors to permit)

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Marker and/or its designated Representatives to be present for any such inspection and shall provide Marker with a copy of all correspondence and reports or such other materials that it or its Permitted Subcontractor(s) receives from such Regulatory Authority in connection therewith within five (5) Business Days of receipt. Supplier may redact any other customer information from such correspondence and reports prior to providing such to Marker. Any expenses or costs incurred by Supplier for Regulatory Authority inspections that are directly related to the Product shall be borne by Marker.

14.4 **Notice of Regulatory Actions.** Supplier shall inform Marker of any regulatory or government actions (including but not limited to warning letters) or change in the regulatory status (including but not limited to the GMP compliance status) of any part of its (or its Permitted Subcontractor's) facilities within five (5) Business Days of becoming aware thereof. To the extent Supplier sends any comments or responses to any Regulatory Authority or other competent government authority in relation thereto, Supplier shall, unless prohibited by Applicable Law, allow Marker to review and comment on any such comments or responses that solely relate to the Products or Services under this Agreement reasonably in advance of submission.

15. DISPUTE RESOLUTION

15.1 **Exclusive Dispute Resolution Mechanism.** The Parties and Guarantors agree the procedures set forth in this Section 15 shall be the exclusive mechanism for resolving any disputes, controversies or claims (collectively, **"Disputes")** between the Parties and/or Guarantors that arise from time to time pursuant to this Agreement relating to any Party's or Guarantor's rights and/or obligations hereunder that cannot be resolved through good faith negotiation between the Parties or Guarantors.

15.2 **Executive Resolution.** Any Dispute, other than Disputes regarding quality under the Quality Agreement, must first be submitted to the officers designated below, or their appointed representatives, for attempted resolution by good faith negotiations for a period of at least thirty (30) calendar days.

For Marker CEO (or the CEO's designee)

For Supplier CEO (or the CEO's designee)

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If the representatives of the Parties or Guarantors designated in accordance with the above are not able to resolve any Dispute within such thirty (30) calendar day period, either Party or Guarantor (as applicable) may invoke the provisions set forth in Section 15.3. The Parties agree to comply with any Dispute process set forth in the Quality Agreement for all quality related Disputes.

15.3 **Jurisdiction and Venue.** Each Party and Guarantor irrevocably and unconditionally: (a) consents and submits to the jurisdiction of the state and federal courts located in the County of Harris, Texas, for purposes of any action, suit or proceeding arising out of or relating to this Agreement; (b) waives, to the fullest extent it may legally and effectively do so, any objection which it may now or hereafter have to the laying of venue of any such action or proceeding in any such State or Federal court located in the County of Harris, Texas; and (c) waives, to the fullest extent permitted by Applicable Law, the defense of an inconvenient forum to the maintenance of such action or proceeding in any such State or Federal court. Each Party and Guarantor agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by Applicable Law. Each Party and Guarantor irrevocably consents to service of process in the manner provided for notices in Section 16.8 other than by electronic mail. Nothing in this Agreement will affect the right of any Party or Guarantor to serve process in any other manner permitted by Applicable Law. EACH PARTY AND GUARANTOR HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE ACTIONS OF ANY PARTY IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE AND ENFORCEMENT HEREOF.

15.4 **Preliminary Injunctions.** Notwithstanding anything herein to the contrary, a Party or Guarantor may seek equitable relief, including a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the court(s) on the ultimate merits of any Dispute.

15.5 **Confidentiality.** All proceedings and decisions of the court(s) shall be deemed Confidential Information of each of the Parties and shall be subject to Section 11 hereof.

16. MISCELLANEOUS

16.1 **Entire Agreement.** The Parties and Guarantors acknowledge that this Agreement, together with all Work Orders, the MTA, and the Quality Agreement sets forth the entire agreement and understanding of the Parties and Guarantors and except as set out herein, supersedes all prior written or oral agreements or understandings with respect to the subject matter hereof. In the event of a conflict between a term or condition of the MTA and a term or condition of this Agreement, the term or condition of this Agreement shall control. The Quality Agreement shall control with respect to all matters expressly set forth therein.

16.2 **Publicity; Use of Names.** Except as permitted under Section 11, neither Party nor any Guarantor shall issue, publish, or disseminate or cause to be issued, published or disseminated any press release or public communication relating to this Agreement, its terms or any of the

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transactions contemplated herein, or use the name of the other Party or any Guarantor without the prior written consent of the other Party or Guarantor (as applicable).

16.3 **Governing Law**. This Agreement shall be governed by, and construed and interpreted, in accordance with the internal laws of the State of Texas, without giving effect to any choice of law rule that would cause the application of the laws of any jurisdiction other than the internal laws of the State of Texas to the rights and duties of the Parties and Guarantors.

16.4 **Further Assurances**. From time to time on and after the Effective Date, each Party and the Guarantors shall at the reasonable request of the other Party: (a) deliver to such other Party such records, data or other documents consistent with the provisions of this Agreement; (b) execute, and deliver or cause to be delivered, all such assignments, consents, documents or further instruments of transfer or license; and (c) take or cause to be taken all such other actions, as such other Party may reasonably deem necessary or desirable in order for such Party to obtain the full benefits of this Agreement and the transactions contemplated hereby.

16.5 **Independent Contractors**. The relationship of Marker, its Affiliates, Supplier, and the Guarantors established by this Agreement is that of independent contractors. Nothing in this Agreement shall be constructed to create any other relationship between Marker or its Affiliates, on the one hand, and Supplier or any Guarantor, on the other hand. Neither Party nor any Guarantor shall have any right, power or authority to bind the other or assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other.

16.6 **Assignment**. Neither Party may assign or transfer this Agreement in whole or in part without the prior written consent of the other Party, except that either Party may make an assignment of this Agreement, without the other Party's consent to an Affiliate or to a Third Party successor to all or substantially all of the business or product to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction; *provided* that any such permitted successor or assignee is obligated pursuant to a written agreement to assume performance of this Agreement or such rights and obligations. Any permitted assignment shall be binding on the successors of the assigning Party. No Guarantor shall have the right to assign or transfer this Agreement or any of its obligations hereunder, in whole or in part, whether by operation of law or otherwise, without the prior written consent of Marker, which may be granted or withheld in Marker's sole discretion. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.6 shall be null and void.

16.7 **No Third Party Beneficiaries**. This Agreement is neither expressly nor impliedly made for the benefit of any party other than the Parties and the parties indemnified pursuant to Section 10 and there are no intended Third Party beneficiaries except for the parties indemnified pursuant to Section 10.

16.8 **Notices**. All notices and other communications required or permitted hereunder shall be in writing and shall be deemed to be received: (a) four (4) Business Days after mailing when mailed by registered or certified mail, postage prepaid; (b) one (1) Business Day after delivery to reputable overnight delivery service; (c) when sent by confirmed electronic mail if sent during normal business hours of the recipient, and if not, then on the next Business Day; or

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(d) upon receipt when delivered by hand or by messenger, addressed as follows, or to such other addresses as the parties may provide each other from time to time:

If to Marker: Marker Therapeutics, Inc.
9350 Kirby Drive, Suite 300
Houston TX 77054
Attn: Juan Vera, President and CEO
Email: [****]

If to Cell Ready: Wilson Wolf Manufacturing
2100 Old Highway 8 NW
St. Paul, MN 55112
Attn: John Wilson
Email: [****]

16.9 **Costs and Expenses**. Except as otherwise provided in this Agreement, each Party and Guarantor shall bear its own costs and expenses (including legal and accounting fees) arising out of or in connection with the preparation, negotiation and implementation of this Agreement.

16.10 **Amendment**. No modification of any of the terms of this Agreement, or any amendments thereto, shall be deemed to be valid unless in writing and signed by the Party against whom enforcement is sought. No course of dealing or usage of trade shall be used to modify the terms and conditions herein.

16.11 **No Waiver**. Any delay or failure by a Party to enforce its rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except only in the event of an express written and signed waiver as to a particular matter for a particular period of time. The remedies herein provided are cumulative and not exclusive of any remedies provided by law.

16.12 **Severability**. If any provision of this Agreement or any other document delivered under this Agreement is prohibited or unenforceable in any jurisdiction, it shall be ineffective in such jurisdiction only to the extent of such prohibition or unenforceability and such prohibition or unenforceability shall not invalidate the balance of such provision to the extent it is not prohibited or enforceable nor the remaining provisions hereof, nor render unenforceable such provision in any other jurisdiction, unless the effect of rendering such provision ineffective would be to substantially deviate from the expectations and intent of the respective Parties and Guarantors in entering into this Agreement. In the event any provisions of this Agreement shall be held to be invalid, illegal or unenforceable, the same shall be amended and interpreted so as best to accomplish the Parties' and Guarantors' original intent (within the limits of Applicable Law), so as not to affect the validity or enforceability of this Agreement.

16.13 **Construction of this Agreement**. Except where the context otherwise requires, wherever used, the use of any gender shall be applicable to all genders, and the word "or" is used in the inclusive sense identified with the phrase "and/or." When used in this Agreement, "including" shall mean "including without limitation". References to either Party include the

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successors and permitted assigns of that Party. References to either Guarantor include the successors and permitted assigns of that Guarantor. All references to the singular shall include the plural where applicable. References to a "Section" shall be to such section in this Agreement and shall be deemed to include all subsections therein. The headings of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The Parties and Guarantors have each consulted counsel of their choice regarding this Agreement, and, accordingly, no provisions of this Agreement shall be construed against either Party or any Guarantor on the basis that the Party or Guarantor drafted this Agreement or any provision thereof. The official text of this Agreement and any schedules hereto, any notice given or accounts or statements required by this Agreement and any dispute proceeding related to or arising hereunder, shall be in English. In the event of any dispute concerning the construction or meaning of this Agreement, reference shall be made only to this Agreement as written in English and not to any other translation into any other language. References herein to "this Agreement" shall include this Agreement and the executed Work Orders.

16.14 **Counterparts.** This Agreement and any amendment or supplement hereto may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall constitute one (1) and the same instrument. This Agreement shall become binding when any number of counterparts, individually or taken together, shall bear the signatures of both Parties and both Guarantors. This Agreement may be executed and delivered by facsimile or any other electronic means, including ".pdf' or ".tiff' files and any facsimile or electronic signature shall constitute an original for all purposes.

[Signature Page Follows]

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IN WITNESS WHEREOF, the Parties hereto have each caused this Agreement to be executed by their duly authorized officers as of the Effective Date.

Marker Therapeutics, Inc.	**Cell Ready LLC**
By: /s/Juan Vera	By: /s/John Wilson
Name: Juan Vera	Name: John Wilson
Title: Chief Executive Officer	Title: Chief Executive Officer

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SCHEDULE 1

FORM OF WORK ORDER

WORK ORDER #

THIS WORK ORDER (the "Work Order") is made and entered into as of this ________ day of ________ (the "Effective Date") by and between Marker Therapeutics, Inc., a Delaware corporation with offices at 9350 Kirby Drive, Suite 300, Houston TX 77054 (hereinafter referred to as "Marker") and **Cell Ready, LLC.,** a Minnesota corporation having a principal place of business at 2100 Old Highway 8 NW St. Paul, MN 55112 (hereinafter referred to as "Supplier"). Marker and Supplier may be referred to individually, as a "Party" and collectively, as the "Parties".

RECITALS

WHEREAS, Marker and Supplier entered into that certain Master Services Agreement for Product Supply dated February 22, 2023 (the "Master Services Agreement"), which allows Marker to request services from Supplier from time to time.

WHEREAS, in accordance with Section 2.2 of the Master Services Agreement, this Work Order sets out the Services to be supplied by Supplier to Marker.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

17. INTERPRETATION

17.1 This Work Order incorporates the terms of the Master Services Agreement by reference. All defined terms in the Master Services Agreement shall have the same meaning in this Work Order unless otherwise stated.

18. TERM AND TERMINATION

18.1 This Work Order shall commence on the Effective Date set out above and shall expire upon the completion of the supply of the Services unless terminated earlier in accordance with the Master Services Agreement.

19. SERVICES AND SERVICE CHARGES

19.1 Supplier shall provide the Services and Deliverables as set out in Appendix A to this Work Order to Marker.

19.2 Service Charges for the provision of the Services under this Work Order shall be *[for a total sum anticipated not to exceed [ ]* as set out in Appendix B to this Work Order.

20. PAYMENT TERMS

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20.1 All invoices for payment under this Work Order shall be submitted to:

Marker Therapeutics, Inc.
Address: 9350 Kirby Drive, Suite 300, Houston TX 77054
[****]

Supplier invoices under this Work Order shall be made payable to:

Bank Account no:[****]

Name and Address of Bank:[****]

US Routing no:[****]

Swift Code:N/A

Name and Address of a/c Holder:[****]

21. ADDITIONAL TERMS AND CONDITIONS

21.1 Any terms and conditions additional to those set out above and in the Master Services Agreement are set out in Appendix C to this Work Order.

[Signature Page Follows]

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IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this Work Order as of the Effective Date.

Marker Therapeutics, Inc.	**Cell Ready LLC**
By: [TEMPLATE - DO NOT SIGN]	By: [TEMPLATE - DO NOT SIGN]
Name: Juan Vera	Name: John Wilson
Title: President and CEO	Title: CEO

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APPENDIX A TO WORK ORDER #

(SERVICES)

[INSERT DESCRIPTION OF THE SERVICES TO BE PROVIDED UNDER THE WORK ORDER INCLUDING ANY DELIVERABLES AND ANY TIMELINE/ PROJECT MILESTONES AGREED.]

[ATTACH/INSERT ANY AGREED DESCRIPTION OF SERVICES REQUIREMENTS, PRODUCT REQUIREMENTS, SPECIFICATIONS, ANY DELIVERABLES OR ANY EXCEPTION TO GMP REQUIREMENT.]

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APPENDIX B TO WORK ORDER #

(SERVICE CHARGES)

PART A: SERVICE CHARGES

[ADD DETAILS OF SERVICE CHARGES (SPECIFY CURRENCY) OR INSERT DOCUMENT THAT SPECIFIES THE SERVICE CHARGES/BUDGET.]

PART B: PAYMENT INTERVALS

[INSERT THE DATES OR EVENTS ON WHICH INSTALMENTS ARE TO BE INVOICED AND THE AMOUNT OF EACH INSTALLMENT.]

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APPENDIX C TO WORK ORDER #

(ADDITIONAL TERMS AND CONDITIONS)

Exhibit 10.9

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WORK ORDER #1

GMP-Q1-2024

Marker GMP manufacturing

Proposal on February 22nd, 2024

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CellReady

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THIS WORK ORDER #1 (the **"Work Order")** is effective and entered into as of this 22' day of February, 2024 (the **"Effective Date")** by and between **Marker Therapeutics, Inc.,** a Delaware corporation with offices at 9350 Kirby Drive, Suite 300, Houston, TX 77054, USA (hereinafter referred to as **"Marker"** or **"Client")** and **Cell Ready, LLC.,** a Minnesota corporation having a principal place of business at 2100 Old Highway 8 NW St. Paul, MN 55112 (hereinafter referred to as **"Supplier"** or **"CellReady").** Marker and Supplier may be referred to individually, as a **"Party"** and collectively, as the **"Parties".**

SECTION 1: RECITALS

RECITALS

WHEREAS, Marker and Supplier entered into a Master Services Agreement for Product Supply dated February 22", 2024 (the **"Master Services Agreement"),** which allows Marker to request agreed upon services from Supplier.

WHEREAS, in accordance with the Master Services Agreement, this Work Order sets out the Services to be provided by Supplier to Marker.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is acknowledged, the Parties hereto agree to the following:

1. INTERPRETATION

1.1 This Work Order incorporates the terms of the referenced Master Services Agreement. All defined terms in the Master Services Agreement shall have the same meaning in this Work Order unless otherwise stated.

2. TERM AND TERMINATION

2.1 This Work Order shall commence on the Effective Date as specified above and shall expire upon the completion of the delivery of the Services unless terminated earlier in accordance with the Master Services Agreement.

3. SERVICES AND SERVICE CHARGES

3.1 Supplier shall provide the Services and Deliverables as set out in Section 3 of this Work Order to Marker.

3.2 Total projected sum (taxes included) for services specified in this Work Order is not anticipated to exceed **[****].** The Final cost of materials and applicable taxes may vary from lot to lot, as outlined in Section 5 of this Work Order.

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4. PAYMENT TERMS

4.1 All invoices for payment under this Work Order shall be submitted to:

Marker Therapeutics, Inc.

Address: 9350 Kirby Drive I Suite 300 I Houston, TX 77054 I USA
[****]

Supplier invoices under this Work Order shall be made payable to:

Bank Account no: [****]

Name and Address of Bank: [****]

US Routing no: [****]

Swift Code: N/A

Name and Address of a/c Holder: [****]

S. ADDITIONAL TERMS AND CONDITIONS

5.1 Any terms and conditions in addition to those specified above and in the Master Services Agreement are set out in the Quality Agreement and IT service agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this Work Order as of the Effective Date.

Marker Therapeutics, Inc.		**Cell Ready LLC**	
By:	/s/Juan Vera	By:	/s/John Wilson
Name:	Juan Vera	Name:	John Wilson
Title:	Chief Executive Officer	Title:	Chief Executive Officer

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SECTION 2: EXECUTIVE SUMMARY

Marker Therapeutics, (Client) is currently developing a Multi-TAA cell therapy for cancer treatment and has requested that CellReady provide a proposal for GMP manufacturing of drug products suitable for use

in Phase I/II clinical trials.

CellReady Overview. CellReady is a Contract Development and Manufacturing Organization (CDMO). It is on a mission to greatly simplify CGT manufacturing and save years of time and millions of dollars for every client. CellReady is wholly owned by John Wilson, a co-inventor G-Rex® technology which is widely used to create Cell and Gene Modified Cell Therapy (CGT) drug products including commercially approved therapies. With vast expertise in G-Rex® centric manufacturing processes, deep experience in the business of taking CGT drugs to market, a robust network of subject matter experts, and a business philosophy grounded in the law of abundance, CellReady is the go-to place for every CGT company.

Proposed Scope of Work. Based on CellReady's experience in developing scalable manufacturing processes for cell therapy products and the Marker's stated needs, CellReady is proposing the following manufacturing program:

[****]([****]x) GMP manufacturing runs of Marker MT-401 and/or MT-601: Cost is based on use of fresh or frozen donor starting material, one (1) G-Rex500M-TF per run, QC testing, and QA release for each of the [****] ([****]) runs. QC testing includes viability, sterility, purity, impurities, identity, mycoplasma, and endotoxin.

Not included: GMP material cost, ancillary material cost, stability program, immuno-monitoring and contract for long-term liquid nitrogen storage.

Note: **At Marker's request,** there will be no Aseptic Process Simulation or Engineering Runs at this time.

See the proposed timeline in section 4 below.

Marker has also asked CellReady to provide **general support services** as follows:

- Legacy Materials storage in LN2 tanks
- Storage of Cytokines
- Immuno monitoring assay
- Potency & Phenotyping assay
- Program Management
- IT services
- Document updates (MT-601)

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SECTION 3: PROPOSED STATEMENT

The table below summarizes the proposed scope of work for this **Work Order #1.** Please note that the scope of work and pricing is based on information provided to date and CellReady's understanding of the Client's needs. CellReady welcomes the opportunity to refine the scope of work as necessary to best meet the Client's objectives.

[****]x GMP Lot with lx GRex of Marker 401 and/or 601	Cost includes manufacturing of the lx GRex500 runs, QC testing, and QA release for all runs. QC testing includes viability, sterility, purity, impurities, identity, mycoplasma, and endotoxin. Not included: GMP material cost, ancillary material cost, stability program, Immuno monitoring and contract for long-term liquid nitrogen storage. ● Final bagged and labeled DP (one lot) ● Copies of executed and reviewed batch records ● Copies of data and documents in CellReady format, as ● requested, for support of regulatory submission ● Certificate of Analysis. *See below batch release specification table CellReady shall provide to Client, as request, all the raw data collected from each run related with the product characterization including without limitation cell number, viability, phenotype data, etc.
Legacy Materials storage in LN2 tanks	- $[****] per quadrant utilization per month Includes: handling, LN2 supply, LN2 tank maintenance and documentation Projected utilization = 16x quadrants
Storage of Cytokines	Storage in -80°C fridge of approximately [****] of cytokines. Materials storage fee is 1% of the total value a year
[****]x Immuno monitoring assay.	The procedure scope is limited to: 1. The receipt and storage of samples received in PAXgene Blood RNA No charge 2. PBMC isolation and cryopreservation for samples received in Sodium Heparin Tubes. $[****] per sample
[****]x Potency & Phenotyping assay	Potency —The procedure is performed as part of the multi-TAA specific T cells product release testing. The cryopreserved drug product is thawed and tested to evaluate specificity against predetermined target antigens using ELISpot. $[****] per assay Immunophenotyping - The procedure is performed as part of the multi-TAA specific T cells product in-process and release testing to characterize the expression level of markers expressed by the cells throughout the manufacturing process. The assay is also performed to determine the purity and impurity levels of the drug product. $[****] per assay
Program Management	Overall program governance, project management, and coordination Development and maintenance of Project Plan
[****]	● [****] ● [****] ● [****] - [****] ● [****]
Document updates Mrk 601	MT-601: Full end to end master batch record update

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Batch release specifications

Viability by Dye Exclusion	[****]	>[****]% viable
Bacterial Endotoxin	[****]Assay ([****])	≤ [****] EU/kg
Sterility	[****] ([****])	No Growth at Day [****] for Aerobic, Anaerobic media
Mycoplasma	[****] ([****])	[****]
Purity by Immunophenotyping	[****] [****]	≥[****]% [****] cells
Impurities by Immunophenotyping	[****] QC-SOP-0051	≤[****]% [****]cells
HLA Typing	[****]Low Resolution molecular ([****])	HLA match between donor and [****] cells
Potency	[****]	[****]

SECTION 4: ESTIMATED PROJECT TIMELINES

Length of engagement will be for [****] ([****]x) runs, with a projected processing time of 10 days, plus QC time [****] days. Total [****], from Apheresis receipt to shipment readiness.

Work Order Start Date: 1 January 2024
Work Order End Date: 31 March 2024

Scheduling:

GMP Manufacturing activities timeline will be executed as per the plan below.

- January 2024: Ox Patients
- February 2024: [****] Patient
- March 2024: [****] Patient

Start Days (D0s) will be scheduled according to each patient's onboarding plan. [****].

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SECTION 5: PRICING AND DELIVERABLES

Unless specified as materials cost, below cost summary includes labor and overhead for CellReady to execute and deliver on the below items.

Project and Expected Outcome	Pricing	Deliverables and Service Details
[****]x GMP Lot with lx GRex of Marker 401 and/or 601 Cost includes manufacturing of the lx GRex500 runs, QC testing, and QA release for all runs. QC testing includes viability, sterility, purity, impurities, identity, mycoplasma, and endotoxin. Not included: GMP material cost, ancillary material cost, stability program, Immuno monitoring and contract for long-term liquid nitrogen storage.	$[****]	- Final bagged and labeled DP (one lot) - Copies of executed and reviewed batch records - Copies of data and documents in CellReady format, as . requested - Certificate of Analysis
Legacy Materials storage in LN2 tanks	$[****]	- $500 per quadrant utilization per month **Includes:** handling, LN2 bottles, LN2 tank maintenance and documentation Projected utilization 16x quadrants
Storage of Cytokines	$[****]	Storage in -80 fridge of approximately [****] of cytokines. Materials storage fee is 1% of the total value a year
[****]**x Immuno monitoring assay.**	$[****]	The procedure scope is limited to: 3. The receipt and storage of samples received in PAXgene Blood RNA tubes as well as. [****] per sample 0. PBMC isolation and cryopreservation for samples received in Sodium Heparin Tubes. [****] per sample
[****]**x Potency & Phenotyping assay**	$[****]	Potency —The procedure is performed as part of the multi-TAA specific T cells product release testing. The cryopreserved drug product is thawed and tested to evaluate specificity against pre-determined target antigens using ELISpot. [****] per assay Immunophenotyping - The procedure is performed as part of the multi-TAA specific T cells product in-process and release testing to characterize the expression level of markers expressed by the cells throughout the manufacturing process. The assay is also performed to determine the purity and impurity levels of the drug product. $5,000 per assay
Program Management	$[****]	Overall program governance, project management, and coordination Development and maintenance of Project Plan ***Note:*** *Actual Program Leadership costs will be dependent on the number of batches performed/year.*
[****]	$[****]	-[****]
Document updates Mrk 601	$[****]	**MT-601:** full end to end master batch record update
Estimated Pass-Through Costs [****]x GMP runs	$[****]	**Includes: GMP material, ancillary, peptides and lot's processing fees.** [****]
Project Cost	$[****]	**Plus applicable taxes**
Credits from Marker's current inventory at CellReady	($[****])	
Estimated taxes (8.25%)	$[****]	
Total Work Order Cost	$[****]	

Portions of this exhibit have been redacted pursuant to Item 601(b)(2) of Regulation S-K as (i) not material and (ii) likely to cause competitive harm if publicly disclosed. Omissions are designated as "**". The Company hereby undertakes to furnish unredacted copies of this exhibit upon request by the Securities and Exchange Commission; provided, however, that the Company may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for such unredacted copies of this exhibit.**

PAYMENT SCHEDULE

GMP Manufacturing Services: 50% of the total service cost is due at signing with 50% to be billed upon completion of services.

Pass-through Costs: All pass-through costs, including raw materials, supplies, or other consumables, outsourced testing, shipping and handling, and storage beyond R&D timelines will be billed at the end of the WO with an added [****]% procurement fee. Upon completion of Project Activities of this Work Order, CellReady will provide a reconciliation to Marker of prepaid raw material costs against actual costs and issue an invoice or credit note to Marker equal to the variance between the two.

Payment Schedule: Unless otherwise agreed in writing, payment shall be due net thirty (30) days from the date of the invoice.

MANUFACTURING SERVICES AGREEMENT, IT AGREEMENT AND QUALITY AGREEMENT

A Manufacturing Services Agreement (MSA), [****] and a Quality Agreement (QA) have been established between CellReady and Marker, which detail the terms and conditions under which the companies agree to operate.

CONFIDENTIALITY AND COMMUNICATION

Under the current CDA in place between Marker and CellReady, the pricing listed in this proposal is confidential. CellReady will operate in accordance with the CDA and treat all details related to this project as strictly confidential.

Exhibit 21.1

SUBSIDIARIES

Marker Cell Therapy, Inc.

GeneMax Pharmaceuticals, Inc.

GeneMax Pharmaceuticals Canada, Inc.

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Marker Therapeutics, Inc. on Form S-3, No. 333-228059 and No. 333-258687 and on Form S-8 File No. 333-223900, No. 333-228056, 333-239136 and 333-266797 of our report dated March 25, 2024, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of Marker Therapeutics, Inc. as of December 31, 2023 and 2022 and for the two years in the period ended December 31, 2023, which report is included in this Annual Report on Form 10-K of Marker Therapeutics, Inc. for the year ended December 31, 2023.

/s/ Marcum LLP

Marcum LLP
Houston, TX
March 25, 2024

CERTIFICATION PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Juan Vera, certify that:

1. I have reviewed this Annual Report on Form 10-K of Marker Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2024

/s/ Juan Vera

By: **Juan Vera**
Title: President, Chief Executive Officer and Treasurer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Juan Vera, certify that:

1. I have reviewed this Annual Report on Form 10-K of Marker Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2024

/s/ Juan Vera

By: **Juan Vera**
Title: President, Chief Executive Officer and Treasurer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Marker Therapeutics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Juan Vera, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 25, 2024

/s/ Juan Vera
Juan Vera
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Marker Therapeutics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Juan Vera, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 25, 2024

/s/ Juan Vera
Juan Vera
Principal Financial Officer

MARKER THERAPEUTICS, INC.
INCENTIVE COMPENSATION RECOUPMENT POLICY

EFFECTIVE NOVEMBER 17, 2023

1. INTRODUCTION

The Board of Directors (the "***Board***") of Marker Therapeutics, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Compensation Committee***" means the Compensation Committee of the Board.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

“***Exchange Act***” means the U.S. Securities Exchange Act of 1934, as amended.

“***Executive Officer***” means the Company’s president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company’s parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

“***Financial Reporting Measures***” means measures that are determined and presented in accordance with the accounting principles used in preparing the Company’s financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return (“***TSR***”). A measure need not be presented in the Company’s financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

“***Incentive Compensation***” means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

“***Lookback Period***” means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company’s fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

“***Recoverable Incentive Compensation***” means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

“***SEC***” means the U.S. Securities and Exchange Commission.

4. RECOUPMENT

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any

action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. ADMINISTRATION

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. SEVERABILITY

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. NO IMPAIRMENT OF OTHER REMEDIES

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("**SOX 304**") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time ; provided, however, that compensation recouped pursuant to this policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. AMENDMENT; TERMINATION

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. SUCCESSORS

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. REQUIRED FILINGS

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

* * * * *

MARKER THERAPEUTICS, INC.
INCENTIVE COMPENSATION RECOUPMENT POLICY

FORM OF EXECUTIVE ACKNOWLEDGMENT[1]

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the Marker Therapeutics, Inc. Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Marker Therapeutics, Inc. (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

____
Name: ______________________________
Title: ______________________________
Date: ______________________________

[1] This acknowledgment is optional and is not required by Rule 10D-1 or the Listing Standards. The acknowledgment puts executives on notice of the clawback requirements and may aid the Company in its efforts to enforce the Policy and recoup amounts already paid, particularly from former executives. The acknowledgment also minimizes diligence otherwise required to confirm which arrangements are subject to potential recoupment under the Policy, not all of which would necessarily cross-reference a clawback policy maintained by the Company from time to time.