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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, 2020

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	**45-4497941**
(State or other jurisdiction of incorporation)	(IRS Employer Identification No.)
3200 Southwest Freeway, Suite 2500 Houston, Texas	**77027**
(Address of principal executive offices)	(Zip code)

(713) 400-6400
(Telephone Number)

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. ☐

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, 2020 (the last day of the registrant's most recently completed second fiscal quarter) based on the closing sale price of $2.07 as reported on the Nasdaq Capital Market as of that date was approximately $64,600,000.

The registrant had 50,731,072 shares of common stock outstanding as of March 1, 2021.

Documents Incorporated By Reference

Portions of the registrant's proxy statement relating to registrant's 2021 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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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:

- the timing, progress and results of clinical trials of 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;
- 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 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. Such risks and uncertainties may be amplified by the COVID-19 pandemic and its potential impact on our business and the global economy. 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 and innovative peptide-based vaccines 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 selective expansion of non-engineered, tumor-specific T cells that recognize tumor associated antigens, or TAAs, which are tumor targets, and then kill tumor cells expressing those targets. These T cells are designed to recognize multiple tumor targets to produce broad spectrum anti-tumor activity. We are advancing two pipelines of product candidates as part of our MultiTAA-specific T cell program: the autologous T cells for the treatment of lymphoma, multiple myeloma, or MM, and selected solid tumors and the allogeneic T cells for the treatment of acute myeloid leukemia, or AML, and acute lymphoblastic leukemia, or ALL. Because we do not genetically engineer the MultiTAA-specific T cell therapies, we believe that our product candidates are easier and less expensive to manufacture, have lower toxicities than current engineered chimeric antigen receptor, or CAR-T, and T cell receptor-based therapies and may provide patients with meaningful clinical benefit. We are also developing innovative peptide-based immunotherapeutic vaccines for the treatment of metastatic solid tumors.

We are pursuing post-transplant AML as the lead indication for our first company-sponsored MultiTAA-specific T cell program. In April 2020, the FDA granted orphan drug designation to MT-401 for the treatment of AML after receiving an allogeneic stem cell transplant. The 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 recent 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 hematopoietic stem cell transplant, or HSCT, never relapsed [median leukemia-free survival, or LFS, not reached at a median follow-up of 1.9 years], with 11 of 15 patients 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 submitted an investigational new drug, or IND, application to the United States Food and Drug Administration, or the FDA, to initiate a Phase 2 clinical trial of MultiTAA-specific T cell therapy, which we refer to as MT-401 (zedenoleucel), in post-allogeneic HSCT patients with AML in both the adjuvant and active disease setting. The dose administered in this multicenter trial is the approximate flat dose equivalent of the current maximum tolerated dose from the ongoing Phase 1 trial. In the adjuvant setting, patients will be randomized to either MultiTAA-specific T cell therapy at approximately 90 days post-transplant versus standard of care observation, while the active disease patients will receive MT-401 following relapse post-transplant as part of a single-arm group. We expect to complete the safety lead-in portion of the trial in the first half of 2021. We anticipate that we will initiate the remainder of the Phase 2 trial in the third quarter of 2021 and complete enrollment of 20 patients in that phase of the trial in the fourth quarter of 2021 in order to report results from the active disease arm of the trial in the first quarter of 2022. We expect to begin manufacturing MT-401 for the Phase 2 trial at our cGMP manufacturing facility in the third quarter of 2021.

We reported interim data for 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 this trial, we have observed a clinical benefit 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. These T cells exhibited activity against both targeted antigens and non-targeted TAAs, indicating induction of antigen spreading. To date, we have not observed any cytokine release syndrome or neurotoxicity in this trial.

We are also evaluating the MultiTAA-specific T cell therapies in a Phase 2 clinical trial for the treatment of breast cancer and in Phase 1 clinical trials for the treatment of ALL, lymphoma, MM and sarcoma, all of which are being conducted by BCM. As of December 2020, the MultiTAA-specific T cell therapies have been generally well tolerated by all of the patients enrolled in clinical trials in hematological and solid tumor indications with no incidents of cytokine release syndrome or neurotoxicity, which are frequently associated with CAR-T therapies. Our ongoing clinical trials may be also affected by the COVID-19 pandemic. 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. We may initiate additional Phase 2 clinical trials investigating other indications in addition to our planned Phase 2 trial in post-transplant AML patients.

Pipeline

Our clinical-stage pipeline, including clinical trials being conducted by BCM and other partners, is set forth below:

Clinical Program Updates

Initiation of Phase 2 Clinical Trial of MT-401 (zedenoleucel) for the Treatment of Post-Transplant AML

In January 2021, we announced that the FDA lifted the partial clinical hold on the Phase 2 clinical trial investigating the safety and efficacy of MT-401 for the treatment of patients with AML post-transplant, permitting us to initiate the trial with the safety lead-in portion that is expected to enroll approximately six patients. Three patients will be dosed with MT-401 manufactured with the legacy reagent used in the Phase 1 trial, and three patients will be dosed with MT-401 manufactured using a new reagent from an alternative supplier. We anticipate using this supplier for clinical and commercial manufacturing of MT-401. We expect to complete the safety lead-in portion of the trial in the first half of 2021, and we continue to work to identify clinical trial sites.

In January 2021, the United States Adopted Names, orUSAN, Council and the World Health Organization International Nonproprietary Name, or WHO INN, Expert Committee adopted “zedenoleucel” as the non-proprietary name for MT-401. The USAN Council previously accepted “zelenoleucel” as the non-proprietary name for MT-401. The USAN Council forwarded the name to the WHO INN Expert Committee for additional review and clearance. The WHO INN Expert Committee revised the name to zedenoleucel to avoid a conflict with the existing INN selenomethothionine (75Se) and could evoke that the substance is selenium-labelled. The USAN Council agreed with the WHO INN Expert Committee’s revision of the name from “zelenoleucel” to “zedenoleucel.”

Our Strategy

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 have 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, we plan to advance our lead product candidates into Phase 2 clinical trials and facilitate the initiation of company-sponsored clinical trials. We are pursuing post-transplant AML as the lead indication for the MultiTAA-specific T cell program. We expect to complete the safety lead-in portion of our Phase 2 trial in post-transplant AML in the first half of 2021.

We plan to initiate in the future additional clinical trials in other tumor types based on emerging data. We expect our current Good Manufacturing Practices, or cGMP, manufacturing facility in Houston, Texas will be fully operational to support our clinical manufacturing in the first half of 2021. Until that time, we anticipate that clinical product manufacturing will be conducted at BCM's Good Manufacturing Practices, or GMP, cell manufacturing facility.

- ***Continue to collaborate with our partners and increase our internal research and development activities to improve and develop adoptive cell therapy technologies.***

We are party to a strategic alliance with BCM, pursuant to which we will sponsor selected research at BCM in support of our technology. In conjunction with this strategic alliance, BCM will conduct selected Phase 1 and Phase 2 clinical trials of our product candidates. If data from these early clinical trials are positive, we will consider the therapeutic and commercial potential for such therapies to be advanced as new product candidates for us.

In addition, we plan to use BCM facilities and our company laboratories to enable the process development required to support the Phase 2 clinical trials of our product candidates. We plan to invest in our own research and development and chemistry, manufacturing and controls, or CMC, capabilities to enhance our ability to conduct process development to optimize our manufacturing process, product quality and commercial scalability.

- ***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, the Mayo Foundation and our other major institutional partners, to advance our therapies through the clinic and into commercialization.

We are in the process of evaluating the peptide vaccine therapeutic products and programs to determine the future strategy and the proper allocation of our resources to best maximize stockholder value. In conjunction with this evaluation process we may de-emphasize or terminate certain vaccine therapeutic products or programs. Such strategic review and evaluations are a priority and an important part of our ongoing operations.

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 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 mixed 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 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.

We have observed evidence of “epitope spreading” in our clinical trials, suggesting that the MultiTAA-specific T cell therapy is inducing an enhanced response by the patient’s own T cells (specific for an expanded set of tumor-associated antigens beyond those targeted by the infused product). Correlative analyses show expansion of endogenous T cells, other than those present in the infused product, in the months following infusion. This phenomenon, also known as “antigen spreading,” is potentially important in generating a deep and durable response for a patient because it enables the killing of tumors that do not express any of the antigens initially targeted by our therapy and could be due to the lack of lymphodepletion that allows recruitment of the endogenous immune system for anti-tumor activity.

The MultiTAA-Specific T Cell Therapies

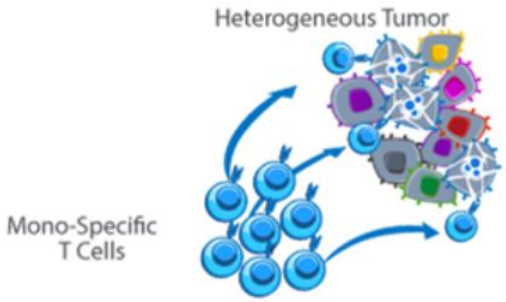
In collaboration with BCM, we are advancing two MultiTAA-specific T cell therapies through clinical development:

- *Autologous MultiTAA-specific T cell therapies* target the NY-ESO-1, PRAME, MAGE-A4, Survivin and SSX2 antigens. We recently reported updated clinical data from BCM’s Phase 1/2 clinical trial of the autologous MultiTAA therapy for the treatment of patients with pancreatic cancer, and we are currently evaluating these therapies for the treatment of patients with lymphoma, MM and other selected solid tumors in Phase 1 trials.

- *Allogeneic MultiTAA-specific T cell therapies* target the WT1, NY-ESO-1, PRAME, and Survivin antigens. The stem cell transplant donor is used as the source of the cells manufactured for our allogeneic therapies. We are pursuing post-transplant AML as the lead indication for the MultiTAA-specific T cell program using our allogeneic therapies.

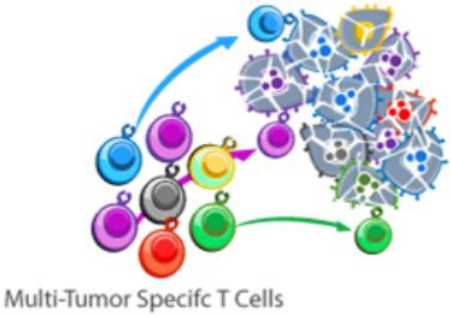
While the blood source and the antigens for stimulation differ between the autologous and allogeneic therapies, the manufacturing process for each product is identical.

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 therapy 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 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. Of note, data suggest that this strategy may be responsible for recruitment and activation of unique cancer-killing cells from the patient's own immune repertoire to participate in cancer eradication, further minimizing the possibility for tumor cell escape.



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 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.

- **Non-gene modified.**

Unlike CAR and TCR-based approaches, our 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 can be manufactured at a fraction of the cost of a gene-modified T cell product, with substantially reduced complexity of manufacturing.

- **No need for lymphodepletion before infusion.**

Unlike CAR-T therapies, which require lymphodepletion of a patient's existing T cells so that they will not compete with the infused therapy, the MultiTAA-specific T cell therapies work with the natural capabilities of T cells to target cancer and do not require lymphodepletion prior to infusion.

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

As of December 2020, the MultiTAA-specific T cell therapy has been generally well tolerated by all of the patients enrolled in clinical trials in hematological and solid tumor indications with no incidences of cytokine release syndrome or neurotoxicity. In these trials, there has been only one Grade 3 adverse reaction considered possibly related to the therapy. This appears to compare favorably with published CD19 CAR-T studies that have been associated with substantial tolerability concerns, including one Phase 1 trial in which 95% of patients had Grade 3 or higher adverse events during treatment.

- **Appears to drive endogenous immune responses.**

In our clinical trials, we have observed evidence of "epitope spreading" in the treated patients, meaning that the MultiTAA-specific T cell therapy is potentially inducing an enhanced response by the patient's own T cells (specific for an expanded set of tumor-associated antigens beyond those targeted by the infused product). Correlative analyses show expansion of endogenous T cells, other than those present in the infused product, in the months following infusion. This phenomenon, also known as "antigen spreading," is potentially important in generating a deep and durable response for a patient, because it enables the killing of tumors that do not express any of the antigens initially targeted by our therapy and could be due to the lack of lymphodepletion that allows recruitment of the endogenous immune system for anti-tumor activity.

- **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 five different tumor-associated antigens. The five antigen targets can be recognized by a very wide range of T cells, which we believe facilitates robust killing of targeted cancer cells.

MT-401 for the Treatment of Post-Transplant AML

We have submitted an IND to the FDA to initiate a Phase 2 clinical trial in post-allogeneic HSCT patients with AML in both the adjuvant and active disease setting, which may become pivotal pending the results of the interim analysis. The dose administered in this multicenter trial is the current maximum tolerated dose from the Phase 1/2 trial. In the adjuvant setting, patients will be randomized to either MT-401 at approximately 90 days post-transplant versus standard of care observation, while the active disease patients will receive MT-401 following relapse post-transplant as part of a single-arm group.

We have initiated the Phase 2 trial, beginning with a safety lead-in portion that is expected to enroll approximately six patients. Three patients will be dosed with MT-401 manufactured using the legacy reagent used in the Phase 1 trial, and three patients will be dosed with MT-401 manufactured using a reagent from an alternative supplier. We anticipate using this supplier for clinical and commercial supply of MT-401. We expect to complete the safety lead-in portion of the trial in the first half of 2021. The safety lead-in will be followed by the 160-patient portion of the trial at approximately 20 transplant centers. Group 1 will comprise 120 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 will comprise 40 active disease patients in a single arm, with primary endpoints of complete remission and duration of complete remission.

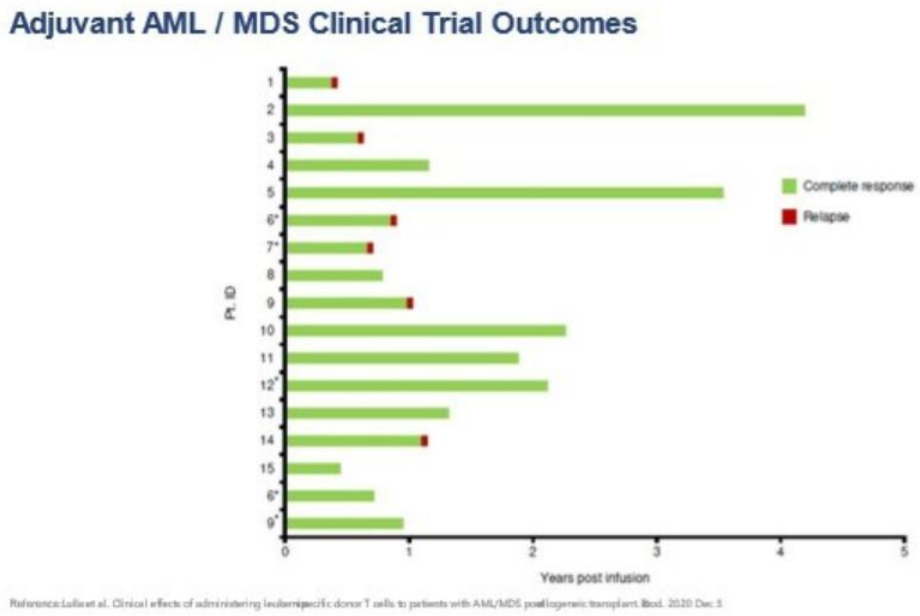
Clinical Development of Our MultiTAA-Specific T Cell Therapies by BCM

The following clinical trials are being conducted by BCM pursuant to our strategic alliance. If data from these early clinical trials are positive, we will consider the therapeutic and commercial potential for such therapies to be advanced as new product candidates for us. In each trial, correlative studies showed significant expansion of MultiTAA-specific T cells, as well as significant evidence of epitope spreading with expansion of endogenous T cells specific for tumor-associated antigens that were not targeted by the MultiTAA-specific T cell therapy.

Acute Myeloid Leukemia

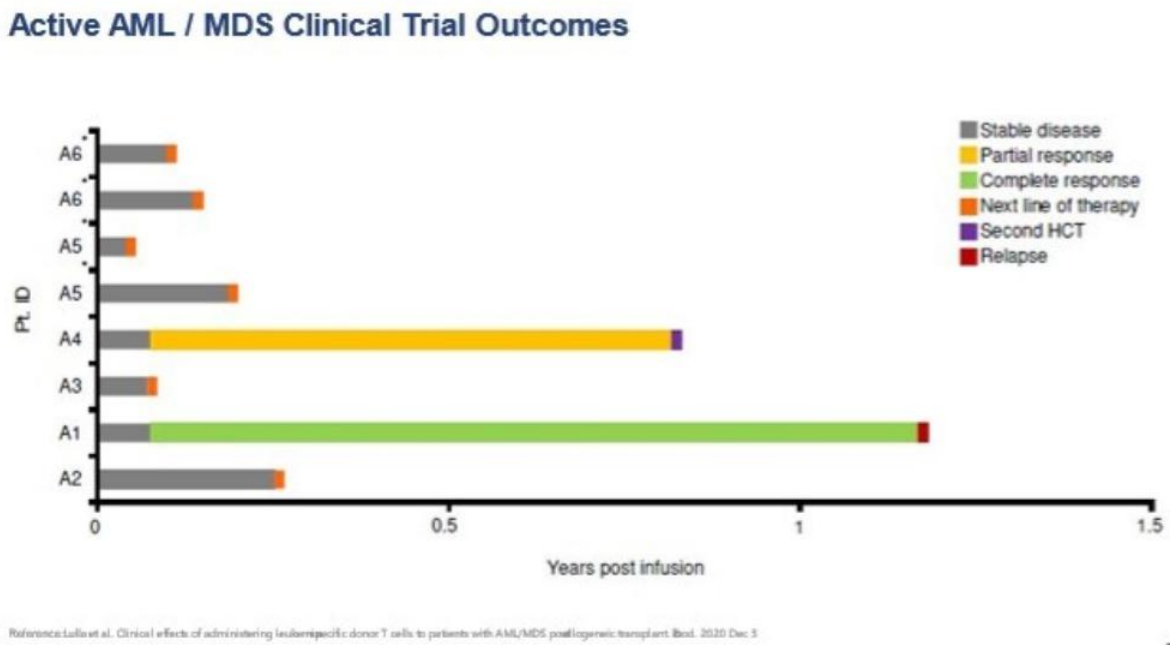
We are pursuing post-transplant AML as the lead indication for the MultiTAA-specific T cell program. Currently, available treatments for post-transplant AML patients are limited and include donor lymphocyte infusion, which has an approximately 15% overall response rate but a 30% to 50% risk of severe 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, we treated patients in remission and with active disease post-transplant. As reported in a recent publication by Lulla et al. and illustrated below, 11 of the 17 patients in the adjuvant disease setting dosed with the MultiTAA-specific T cell therapy after receiving an allogeneic HSCT never relapsed [median LFS not reached at a median follow-up of 1.9 years], with 11 of 15 patients 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%].



Reference: Lulla et al. Clinical effects of administering leukemia-specific donor T cells to patients with AML/MDS post allogeneic transplant. Blood. 2020 Dec 3

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. As shown below, 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 graft-versus-host disease. 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 this trial, BCM plans to enroll approximately 45 patients with advanced or borderline resectable pancreatic adenocarcinoma in three arms: Arm A, which includes patients with unresectable/metastatic disease who are responding to standard first-line chemotherapy; Arm B, which includes patients with progressive disease or therapy intolerance; and Arm C, which includes patients with surgically resectable disease. A total of 31 patients were administered the MultiTAA-specific T cell therapy: 13 patients in Arm A, 10 patients in Arm B and eight patients in Arm C.

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. T cells exhibited activity against both targeted antigens as well as non-targeted TAAs, including MAGE-A2B and AFP, indicating induction of antigen/epitope spreading. No cytokine release syndrome or neurotoxicity has been observed in any arm of the trial to date.

Arm A

Arm A is 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 or will complete 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.

For 12 of the 13 patients, sufficient cells for all six planned doses were generated; two doses were available for the remaining patient.

- Out of the 13 evaluable patients (best overall response):
    - 4 patients experienced objective responses after administration of MultiTAA cells;
    - 1 patient experienced a radiographic complete response occurring at month 9 after starting chemotherapy;
    - 3 patients experienced partial responses per RECIST occurring at 6-9 months after starting chemotherapy;
    - 6 patients experienced stable disease;
    - 1 patient experienced a mixed response (some lesions increased in size and others decreased for a net zero change in size of tumor lesions);
- Patients had durable cancer control with 9 of the 13 patients exceeding historical control of overall survival;
- 5 patients enrolled in the study were not administered MultiTAA-specific T cells, either because of disease progression (4 patients) which made them ineligible for treatment, or because insufficient starting material from the patient was available for manufacturing (1 patient);
- Evidence of epitope-spreading was observed in all responders, suggesting that the MultiTAA T cell therapy triggered the recruitment of a broader endogenous immune system response for improved anti-tumor activity; and
- 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, along with broad-based epitope spreading, with significant expansion of endogenous T cells specific for other tumor specific antigens.

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Arm B

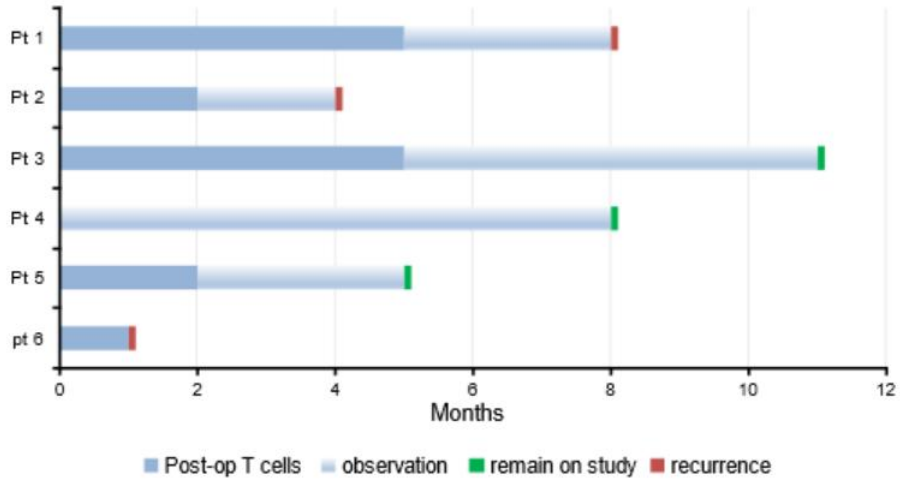
Arm B is designed to evaluate the use of MultiTAA-specific T cell therapy as a second-line therapy for patients who have failed first-line chemotherapy. The patients in this chemo-refractory arm are either ineligible for chemotherapy or have progressed on chemotherapy and have received or are receiving up to six doses of MultiTAA-specific T cell therapy as a monotherapy. The following graphic depicts the best clinical assessment of the 10 evaluable patients in Arm B:

Pt	Best RECIST response on T cells	Best clinical assessment
1	Progressive Disease	Clinically stable
2	Stable Disease	Clinically stable; off other therapy
3	(Not Assessed)	Clinical decline
4	(Not Assessed)	Clinical decline
5	Progressive Disease	Clinically stable
6	Progressive Disease	Clinical decline
7	Stable Disease	Clinically stable
8	Stable Disease	Clinically stable
9	Progressive Disease	Clinical Decline
10	Pending Reassessment	Clinically stable

Among the patients who saw clinical disease stabilization, significant expansion of the infused MultiTAA-specific T cell therapy was observed, along with broad-based epitope spreading, with significant expansion of endogenous T cells specific for other tumor-specific antigens.

Arm C

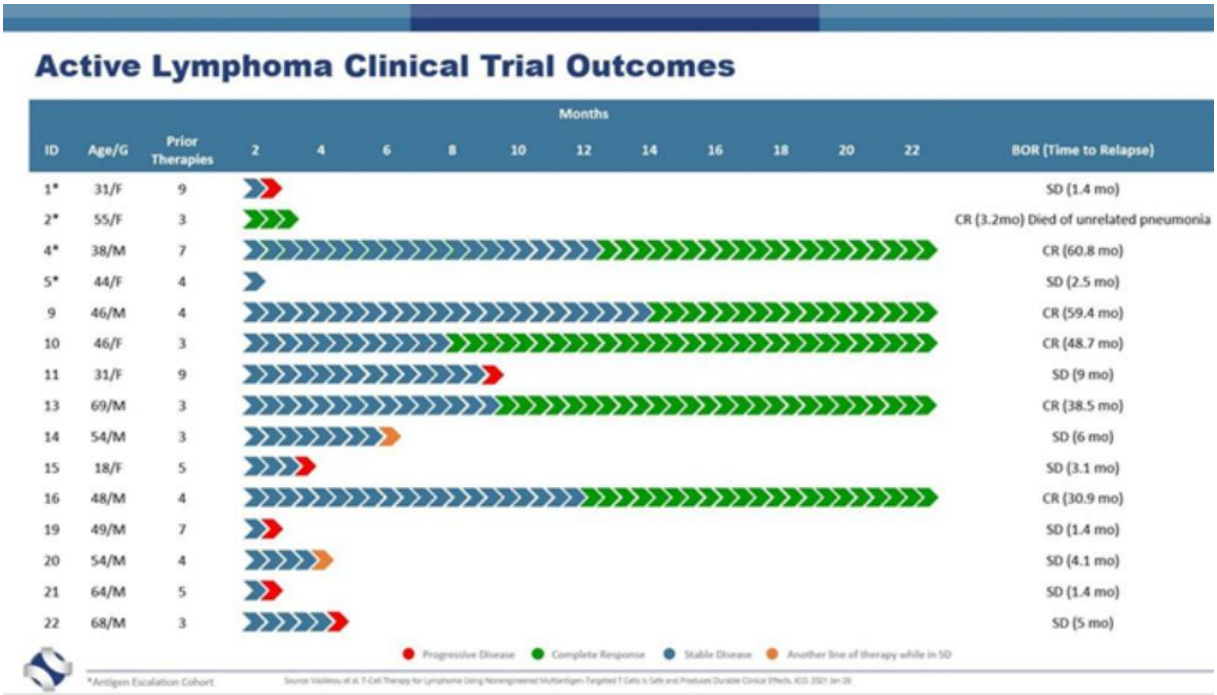
Arm C is designed to assess T cell infiltration and expansion. These patients with borderline surgically resectable disease received or will receive a dose of MultiTAA-specific T cell therapy following chemotherapy, radiotherapy or combination and prior to surgical resection and up to five additional doses of T cells after surgery. In the patients evaluable in Arm C, MultiTAA-specific T cells were measurable in meaningful numbers as detected by correlative analysis of resected tumor, and significant expansion of the infused MultiTAA-specific T cells was observed, along with broad-based epitope spreading, with significant expansion of endogenous T cells specific for other tumor specific antigens. All eight patients in the adjuvant setting have received at least the pre-surgery dose of MultiTAA-specific T cells. Only two of the eight treated patients had all of the per-protocol MultiTAA-specific T cell infusions. One patient has not yet received any post-operative MultiTAA-specific T cells despite remaining in the trial on an observational basis. Five patients are still in the trial, while three patients had recurrence of disease. Two patients have not yet undergone surgery. As illustrated below with respect to the six patients treated in Arm C (excluding the two patients who have not yet undergone surgery), three of the patients in Arm C remain in the trial, while three patients had recurrence of disease:



Lymphoma

BCM is currently evaluating the MultiTAA-specific T cell therapy 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, which we refer to as the active lymphoma group, all of whom had completed a follow-up period beyond three months post-infusion. These patients were heavily pre-treated and, on average, 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 were between two and over five years after being infused with the MultiTAA-specific T cell therapy with the exception of one CR patient who died of an unrelated pneumonia. Responses in all six patients who entered CR were associated with an expansion of infused T cells, as well as induction of antigen spreading.



We also treated 17 patients, including one patient who was treated a second time after a relapse, in remission, which we refer to as the 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, suggesting that the MultiTAA-specific T cell therapy might serve as a standard-of-care maintenance therapy for lymphoma patients in remission.

Further, data from this trial show “epitope spreading,” or expansion of patients’ endogenous T cells (specific for an expanded set of tumor-associated antigens beyond those targeted by the infused therapy) in the months following infusion. Significantly, we have observed this effect even though some patients in this trial received doses that had not yet been antigen-escalated to the full antigen dose.

Acute Lymphoblastic Leukemia

BCM is currently evaluating the MultiTAA-specific T cell therapy in a Phase 1 clinical trial for the treatment of patients with ALL. Leukemic relapse is one of the primary causes of treatment failure in HSCT recipients. Like post-transplant AML patients, post-transplant ALL patients have limited treatment options, with donor lymphocyte infusions similarly associated with the risk of life-threatening graft-versus-host disease. While CAR-T therapies have shown potent anti-leukemia activity in post-transplant ALL patients, CD19-CAR-T cell therapies target a single antigen, carrying the inherent risk of immune escape, and are most effective in malignancies of B-cell lineage. In contrast, the MultiTAA-specific T cell therapy targets multiple antigens expressed in both B- and T-cell ALL.

In this trial, as reported in February 2019 we had treated 18 patients. Of the seven evaluable patients:

- All evaluable patients were up to 28 months in CCR;

- One patient experienced relapse displayed mixed donor/recipient chimerism after transplant, but remained in CCR for 6 months; and

- Patients who remained in CCR had been durable for between four to 28 months, with a median of 16 months.

Multiple Myeloma

BCM is currently evaluating the MultiTAA-specific T cell therapy in a Phase 1b/2a clinical trial for the treatment of patients with MM. In this trial, we are treating both active and adjuvant post-autologous stem cell transplant MM patients both within 90 days and more than 90 days post-transplant. We have not seen a meaningful difference in response rates or durability between the two arms and intend to standardize future trials based upon a protocol wherein patients will receive MultiTAA-specific T cell therapy immediately post-transplant.

As reported in a recent publication by Lulla et al., of the 12 patients that had been treated in the active MM group with a median of 3.5 prior lines:

- One patient had a CR;

- Two patients achieved partial responses; and

- Nine patients had stable disease following initial MultiTAA-specific T cell infusion.

Of the nine patients that had been treated in the adjuvant MM group, all nine patients had remained in CCR, with a median follow-up of 21 months. Only two patients had relapsed at months seven and 13 after infusion while the remaining patients remain in CCR at a median follow-up of 27.5 months.

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 the allogeneic stem cell transplant donor (in the case of the allogeneic T cells). 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, spanning the target antigens are combined with antigen presenting cells and 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.

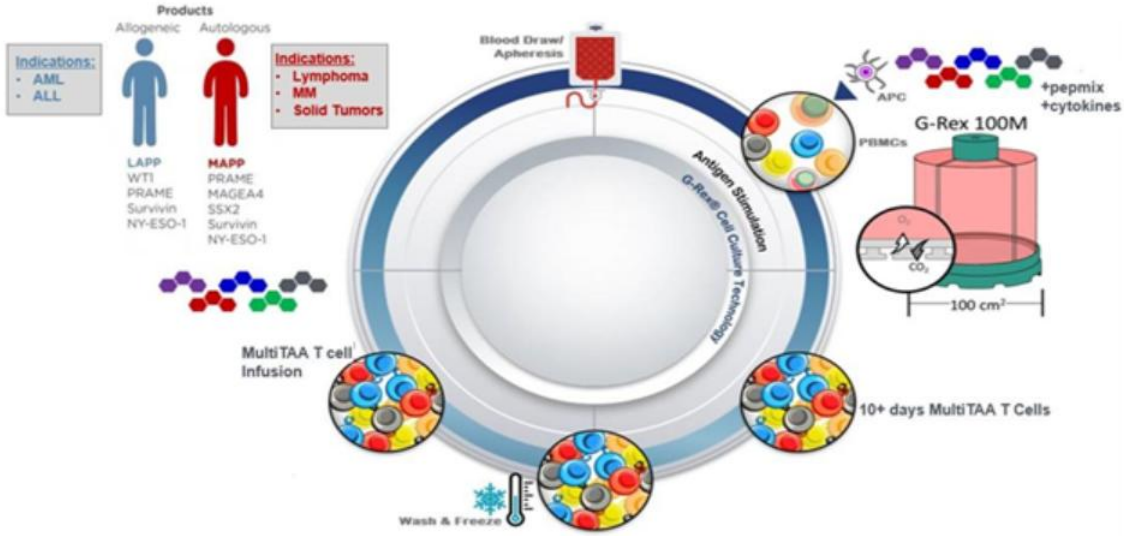
The G-Rex is a cell culture device manufactured by Wilson Wolf used by many cell therapy developers, both in commercial and academic settings. The device allows a user to introduce cells, medium and other reagents into a cell culture chamber, which has a gas-permeable membrane at its bottom. The cells 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 are co-cultured with antigen-presenting cells that have been 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, AML or myeloma ranges from 5 to 20 million cells per meter squared (corresponding to typical doses of 10 to 40 million cells per adult patient). These cell doses represent a significantly smaller dose of cells, when compared to CAR-T or TCR therapies. As a result, our therapy requires only a very small infusion volume that can be administered to patients within minutes at an outpatient center. Due to the low incidence of adverse events with our therapies, patients do not need to be hospitalized and monitored overnight. Instead, the patients are evaluated for any immediate infusion-related reactions and can then usually be discharged within two hours.

Our manufacturing process is illustrated below:



Our Peptide-Based Immunotherapeutic Vaccines: TPIV200 and TPIV100/110

In addition to our MultiTAA-specific T cell therapies, we are developing peptide-based immunotherapeutic vaccines that are designed to precisely target breast and ovarian cancer cells, in contrast to standard therapies for the treatment of cancer that target both cancer cells and normal cells. Our peptide vaccines are derived from naturally processed T cell-targeted antigens. We believe that our peptide vaccines are potentially effective standalone therapies but may also enhance the efficacy of other immunotherapy approaches, including our own MultiTAA-specific T cell therapies. Our multipeptide approach is fundamentally different from traditional vaccine therapies that have generally targeted a major histocompatibility complex, or MHC, class I-restricted epitope and have historically performed poorly as stand-alone treatments. We are currently evaluating TPIV200 for the treatment of breast cancers that overexpress FRa in multiple Phase 2 clinical trials and TPIV100 for the treatment of breast cancers that overexpress HER2/neu in Phase 1b and Phase 2 clinical trials.

We are in the process of evaluating the peptide vaccine therapeutic products and programs to determine the future strategy and the proper allocation of our resources to best maximize stockholder value. In conjunction with this evaluation process we may de-emphasize or terminate certain vaccine therapeutic products or programs. Such strategic review and evaluations are a priority and an important part of our ongoing operations.

TPIV200 for the Treatment of FRa-Overexpressed Breast and Ovarian Cancers

FRa is overexpressed in over 80% of breast cancers and over 90% of ovarian cancers. The only treatment options for these cancers are surgery, radiation therapy and chemotherapy, creating a very important and urgent clinical need for a new therapeutic strategy. Time to recurrence is relatively short for ovarian cancer and survival prognosis is extremely poor after recurrence. In the United States alone, every year there are 22,350 new ovarian cancer diagnoses and 268,600 new breast cancer diagnoses, of which 10% are diagnoses of triple-negative breast cancer.

TPIV200 is composed of a mixture of five FRa-derived immunogenic peptides adjuvanted with low-dose granulocyte-macrophage colony-stimulating factor, or GM-CSF, and is designed to activate both the $CD4^+$ and $CD8^+$ T cell compartments in order to activate a patient's T cells against the targets. Recent developments in immunology suggest that both $CD4^+$ and $CD8^+$ activation support a robust immune response.

Clinical Development

Phase 1 Clinical Trial in Advanced Breast and Ovarian Cancer

In this Phase 1 clinical trial, completed by Mayo Clinic in 2015, 21 patients with advanced breast or ovarian cancer who had undergone standard surgery and adjuvant treatment were treated with one cycle of cyclophosphamide, followed by intradermal vaccination of TPIV200 on day one of a 28-day cycle for a maximum of six vaccination cycles. In the trial, 20 of 21 patients generated T cell responses. These responses developed slowly over the course of the vaccination cycles, with a median time to maximal immunity of five months. Over 90% of patients developed robust and durable antigen-specific immune responses against FRa without regard for HLA type, which aligns with the intended mechanism of action of the vaccine, and 89% of the patients responded to multiple epitopes included in the TPIV200 vaccine, with most patients demonstrating T cell immunity to three or more epitopes. Further, all 16 patients in the observation stage generated T cell responses that lasted over six months.

TPIV200 was well-tolerated, with only one Grade 3 drug-related adverse event. In a two-year patient follow-up analysis, the 10 enrolled ovarian cancer patients had longer median progression-free survival time of 528 days than the 313 days historically reported for the standard-of-care chemotherapy treatment. All patients were alive at the final follow-up. None of the 7 breast cancer patients had experienced a recurrence.

Phase 2 Clinical Trials in Triple-Negative Breast Cancer

Triple-negative breast cancer is one of the most difficult cancers to treat and represents a clear unmet medical need. With the support of a $13.3 million grant from the Department of Defense, the Mayo Foundation is conducting a 280-patient Phase 2 clinical trial of TPIV200 in patients with triple-negative breast cancer, which began enrolling patients in late 2017 and is still recruiting patients.

On June 21, 2016, we announced the initiation of a randomized four-arm Phase 2 trial of TPIV200 for the treatment of patients with Stage 1 to Stage 3 triple-negative breast cancer who have completed initial surgery and chemo/radiation therapy. This open-label, 80-patient clinical trial is designed to evaluate dosing regimens, pre-treatment, efficacy and immune responses. In the trial, we are evaluating a high dose and a low dose of TPIV200, each of which will be tested both with and without cyclophosphamide prior to vaccination. To date, there have been no drug-related serious adverse events reported. Based on a preliminary analysis of 34 patients enrolled in the triple negative breast cancer trial as of September 30, 2019, 31 patients showed meaningful immune response to vaccine treatment. These data are subject to final review by independent biostatistical analysis. As of December 31, 2020, 16 of the patients treated have shown disease progression following treatment with TPIV200.

Phase 2 Clinical Trial in Combination With Durvalumab for Patients with Ovarian Cancer

On April 21, 2016, we announced our participation in an ovarian cancer trial sponsored by Memorial Sloan Kettering Cancer Center, or MSKCC, in collaboration with AstraZeneca Pharmaceuticals in ovarian cancer patients who are not responsive to platinum, a commonly used chemotherapy for ovarian cancer. This open-label Phase 2 trial of TPIV200 in 40 patients is designed to evaluate the effects of combination therapy with AstraZeneca's checkpoint inhibitor durvalumab (anti-PD-L1). Interim results from the first 27 patients were presented at the AACR-Rivkin Symposium in September 2018; safety of the combination was shown in these heavily pretreated patients and a subset of patients exhibited durable disease stabilization. Objective response rate and progression-free survival with combination treatment was not superior from the expected efficacy of durvalumab as a monotherapy. However, post-immunotherapy follow-up was suggestive of improved clinical benefit from standard therapies, as the majority of patients' post-progression went on to receive subsequent standard therapy with durable clinical benefit, creating a rationale for exploration of these agents in combination with chemotherapy. Although we have no business relationship with AstraZeneca, we paid for half of the costs of this trial, in addition to providing TPIV200.

TPIV 100/110 for the Treatment of HER2/neu-Overexpressed Breast Cancers

HER2/neu amplification/overexpression results in an effective therapeutic target in breast and gastric cancer. Over-expressed HER2 is detected predominantly in malignancies of epithelial origin, such as breast, gastric, esophageal, colorectal, salivary gland, pancreatic, epithelial ovarian, endometrial, and bladder carcinomas, as well as gallbladder and extrahepatic cholangiocarcinomas. HER2 is over-expressed in approximately 25% of breast cancers and its expression is associated with unfavorable pathologic features and aggressive disease if not treated with targeted therapies, relative to other forms of breast cancer. While the outcome of patients with HER2 positive breast cancer has significantly improved in the past few decades with an advent of anti-HER2 therapies, a substantial number of resected patients with all types of breast cancer subsequently develop metastatic disease. The continued prevalence of these cancers represents a high unmet medical need, justifying the targeted development of immunotherapeutic strategies.

We have added a MHC class I-restricted peptide, which we licensed from the Mayo Foundation on April 16, 2012, to the four MHC class II-restricted peptides present in TPIV100, resulting in TPIV 110 after the five peptides are mixed with GM-CSF. We have amended the existing IND to incorporate the fifth peptide and will use TPIV110 in future trials with the goal of producing an even more robust vaccine activating both $CD4^+$ (helper) and $CD8^+$ (killer) T cells.

On June 7, 2016, we announced that we had exercised our option agreement with Mayo Foundation and signed a worldwide license agreement to TPIV100. The license gives us the right to develop and commercialize the technology in any cancer indication in which the HER2/neu antigen is overexpressed. As part of this agreement, the IND for the HER2/neu Phase 1 trial was transferred from Mayo Foundation to us for Phase 2 clinical trials of TPIV100. See "—Mayo Foundation for Medical Education and Research Relationships—Mayo HER2/neu License."

Clinical Development

Phase 1 Clinical Trials in HER2/neu$^{\pm}$ Breast Cancer

In the Phase 1 trial of 20 patients conducted at the Mayo Clinic, TPIV100 was well tolerated. Nineteen of the twenty evaluable patients showed robust T-cell immune responses to the antigens in the vaccine. An additional secondary endpoint incorporated into this trial was a two-year follow-on recording the time to disease recurrence in the participating breast cancer patients.

On March 14, 2017, we announced that our partners at the Mayo Clinic received a $3.8 million grant from the Department of Defense to conduct a Phase 1b trial of TPIV100 in ductal carcinoma in situ, or DCIS, an early form of breast cancer. We are working closely with the Mayo Foundation on this clinical trial by providing clinical and manufacturing expertise, as well as providing GMP vaccine formulations under contract. The trial is expected to enroll 40 – 45 women with DCIS and commenced such enrollment during the first quarter of 2019. If the trial is successful and subject to receiving marketing approval from the FDA, we believe that TPIV100 may eventually augment or even replace standard surgery and chemotherapy, and potentially could become part of a routine immunization schedule for preventing breast cancer in healthy women.

Phase 2 Clinical Trials in HER2/neu^{+} Breast Cancer

On October 10, 2018, we announced that the Mayo Clinic had been awarded a grant of $11 million from the Department of Defense intended to cover the costs of a large randomized, double-blind Phase 2 trial of TPIV100. We are working closely with the Mayo Foundation on this clinical trial by providing clinical and manufacturing expertise, as well as providing GMP vaccine formulations under contract. In this trial, 190 patients will be randomized, in a 2:1 fashion, to receive TPIV100 plus maintenance ado-trastuzumab emtansine, or T-DM1, or maintenance T-DM1with placebo plus GM-CSF. The trial will evaluate whether the administration of vaccine during T-DM1 maintenance therapy in patients with residual disease post-neoadjuvant chemotherapy effectively blocks disease recurrence and the development of metastatic breast cancer. By prevention of recurrence and metastasis, the expectation is that mortality associated with breast cancer will be decreased.

Manufacturing

In January 2021, we announced that we had completed the construction and qualification of our cGMP manufacturing facility in Houston, Texas. Our facility will allow for production of MultiTAA-specific T cell products according to FDA guidelines and is designed to be scalable using modular processes. We have initiated the technology transfer process and expect the facility to be fully operational in the first half of 2021. Until that time, we will continue to rely on BCM to manufacture our MultiTAA-specific T cell therapies, as well as the raw materials, our active pharmaceutical ingredients, or APIs, and finished solid dose products for our peptide vaccines for clinical uses, including our Phase 2 trial in AML. We anticipate using our manufacturing facility to produce commercial supply of any approved product candidates.

Our supply chain for manufacturing raw materials, API, peptide vaccines and MultiTAA-specific T cell therapies ready for distribution and commercialization is a multi-step process. Establishing and managing the supply chain requires a significant financial commitment and the creation and maintenance of numerous third-party contractual relationships.

Third-party manufacturers supply us with raw materials for the peptide vaccines, and other third-party manufacturers convert these raw materials into API or convert the API into final dosage form. For most of our peptide vaccine candidates, once our raw materials are produced, we rely on different third parties to manufacture the API, to make finished drug product and to lyophilize, package and label the finished product. While we currently have focused on single vendors for manufacturing of peptide, formulation development, and lyophilization and vialing, we have access to numerous other vendors, if required.

Competition

Our drug discovery, development and ultimate commercialization activities face, and will continue to face, intense competition from organizations such as pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies. We face significant competition from organizations, particularly fully integrated pharmaceutical companies that are pursuing pharmaceuticals which are competitive with our drug candidates. Our product candidates may compete with product candidates from a number of companies, which are developing various types of similar in vivo T-cell immunotherapies and therapeutic cancer vaccines to treat cancer, including: Advaxis Inc., Merck/Immune Design, Celldex, BN Immunotherapeutics, Immunocellular, SELLAS Life Sciences Group, Inc. (formerly) Galena BioPharma, NuGenerex Immuno-Oncology (formerly) Antigen Express, Transgene S.A., and Bavarian Nordic. In addition, other adoptive T-cell therapies, monoclonal antibodies and checkpoint inhibitors also provide competition in the oncology space. In these areas, competitors include Iovance, Immatics, NexImmune, Repertoire Immune Medicines, Tessa Therapeutics, Adaptimmune, Mana Therapeutics, Bluebird Bio, Cellectis, Kuur Therapeutics, Juno Therapeutics/Celgene/Bristol Myers Squibb, Kite Pharma/Gilead, Novartis, Roche Pharmaceuticals, Merck & Co, AstraZeneca plc and Medimmune, LLC. We believe that our non-engineered T cells therapy and our in vivo T-cell therapy approaches will be synergistic and may improve therapies being developed by these 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; or
- other classes of therapeutic agents.

We face, and will continue to face, intense 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 1,490,813 shares of our common stock and warrants to acquire 540,643 shares of our common stock in connection with the merger we completed in October 2018. 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.

Mayo Foundation for Medical Education and Research Relationships

We have exclusively licensed the intellectual property for our TPIV100/110 HER2/neu breast cancer vaccine and TPIV200 folate receptor alpha vaccine product candidates from the Mayo Foundation for Medical Education and Research, or the Mayo Foundation.

As part of our business strategy, we establish business relationships, including collaborative arrangements, with other companies and medical research institutions to assist in the clinical development of certain of our drugs and drug candidates and to provide support for our research programs.

Below is a brief description of our significant business relationships and collaborations and related license agreements with Mayo Foundation that expand our pipeline and provide us with certain rights to existing and potential new products and technologies.

Following approval of the IND by the FDA in July 2011, we executed a Sponsored Research Agreement with the Mayo Foundation for the clinical trial.

Mayo Patent & Know-How License

On March 25, 2012, we entered into a Patent & Know-How License Agreement with the Mayo Foundation pursuant to which we licensed certain intellectual property rights from the Mayo Foundation for the development and commercialization of certain products, methods and processes property relating to a proprietary HER2/neu technology.

The Mayo Foundation granted us a license (with a right to sublicense) on a worldwide basis to make, sell and use products for prophylactic and therapeutic use. This license is an exclusive license for products that are based on the licensed intellectual property and non-exclusive for products that are based on Mayo Foundation know–how and materials. The intellectual property licensed includes U.S. patents 9,814,767 (estimated expiration date February 15, 2033) and 10,117,919 (estimated expiration date February 15, 2033) and European patent 2814836 (estimated expiration date February 15, 2033).

Under this agreement, and subject to certain exceptions, we are responsible for, among other things, developing the technology under the Patent Rights to bring Licensed Products (as defined in the agreement) to market and costs of filing, prosecution and maintenance of the Patent Rights. Mayo Foundation controls the prosecution and maintenance of the Patent Rights in consultation with us.

The Mayo Foundation granted this license in exchange for an upfront payment of $250,000 that we paid in three installments. In addition to the upfront payment, we are to pay an annual license maintenance fee, milestone fees, royalty fees (which will be subject to a minimum annual royalty fee once royalty fees are due), a percentage of sublicense income (if applicable), and a $2,000,000 diligence fee if we fail to initiate a Phase 2 clinical trial for a Licensed Product prior to the eighth anniversary of the agreement.

We have agreed to indemnify and hold Mayo Foundation harmless from any damages caused as a result of (1) the practice or exercise of any rights and assignments granted pursuant to the agreement by or on behalf of us, any affiliate, or any sub-licensee; (2) research, development, design, manufacture, distribution, use, sale, importation, exportation or other disposition of Licensed Products; (3) our, any affiliates, or any sub-licensee's act or omission; and (4) third party suits for patent infringement involving a Licensed Product.

The term of this agreement runs from March 25, 2012 until the date of the last to expire of the Valid Claims (as defined in the agreement), provided that Mayo Foundation may terminate the agreement if, among other matters, (1) 45 days after providing us with notice of a material breach of this agreement, we fail to cure such breach, (2) we fail to initiate a Phase 3 clinical trial for a Licensed Product prior to the tenth anniversary of the agreement, and (3) we cease to conduct business in the normal event of operations or become insolvent or bankrupt. We may voluntarily terminate the agreement at any time upon written notice to Mayo Foundation.

Mayo HER2/neu License

On May 4, 2016, we entered into a License and Assignment Agreement with Mayo Foundation, or the Mayo Foundation HER2/neu License, pursuant to which we licensed certain intellectual property rights from the Mayo Foundation for the development and commercialization of certain products, methods and processes property relating to any cancer indication in which the HER2/neu antigen is overexpressed. The Mayo Foundation HER2/neu License resulted from our exercise of an option that was issued pursuant to a Technology Option Agreement that we entered into with the Mayo Foundation on May 25, 2010.

The Mayo Foundation granted us a license (with a right to sublicense) on a worldwide basis to make, sell and use products for therapeutic use against breast, ovarian, lung and any other cancers that overexpress HER2/neu antigens. This license is an exclusive license for products that are based on the licensed intellectual property and non-exclusive for products that are based on Mayo Foundation know–how and materials. The intellectual property licensed includes European patent 2215111 (estimated expiration date October 30, 2028).

Under the Mayo Foundation HER2/neu License, and subject to certain exceptions, we are responsible for, among other things, developing the technology under the Patent Rights to bring Licensed Products (both as defined in the Mayo Foundation HER2/neu License) to market and costs of filing, prosecution and maintenance of the Patent Rights. Mayo Foundation has sole control over the protection, defense, enforcement, maintenance abandonment and other handling of the Know-How (as defined in the Mayo Foundation HER2/neu License) and Materials (as defined in the Mayo Foundation HER2/neu License).

The Mayo Foundation granted this license in exchange for an initial payment of $300,000. The Mayo Foundation assigned to us IND #14749, and we assumed all responsibility and liability for this investigational new drug application. In addition to the initial payment, we are to pay an annual license maintenance fee, milestone fees, royalty fees (which will be subject to a minimum annual royalty fee once royalty fees are due) and, if applicable, a percentage of sublicense income.

We have agreed to indemnify and hold Mayo Foundation harmless from any damages caused as a result of (1) the practice or exercise of any rights and assignments granted pursuant to the agreement by or on behalf of us or any sub-licensee; (2) research, development, design, manufacture, distribution, use, sale, importation, exportation or other disposition of Licensed Products; (3) our or any sub-licensee's act or omission, including negligence or willful misconduct; and (4) third party suits for patent infringement involving a Licensed Product.

The term of this agreement runs from May 4, 2016 until the date of our last obligation to make payments under the agreement, provided that Mayo Foundation may terminate the agreement if, among other matters, (1) 30 days after providing us with notice of a material breach of this agreement, we fail to cure such breach, (2) 90 days after providing us with written notice, we fail to meet either of the following diligence events (a) initiate a Phase 2 clinical trial for a Licensed Product prior to the second anniversary of the agreement and, once initiated, keep current on all of our Phase 2 funding obligations and (b) initiate a Phase 2b or 3 clinical trial for a Licensed Product prior to the fifth anniversary of the agreement, (3) we fail to make a sale of a Licensed Product by May 4, 2026, and (4) we cease to conduct business in the normal event of operations or become insolvent or bankrupt. We may voluntarily terminate the agreement at any time upon written notice to Mayo Foundation.

Mayo Folate Receptor Alpha License

On July 21, 2015, we entered into a License and Assignment Agreement with Mayo Foundation, or the Mayo Foundation FRa License, pursuant to which we licensed certain intellectual property rights from the Mayo Foundation for the development and commercialization of certain products, methods and processes property relating to a Folate Receptor Alpha immunotherapeutic vaccine comprised of a set of unique peptide epitopes targeting breast, lung and ovarian cancer. The Mayo Foundation FRa License resulted from our exercise of an option that we acquired from Ayer Special Situations Fund I, LP, or Ayer, that was issued pursuant to a Technology Option Agreement that Ayer entered into with the Mayo Foundation on March 19, 2014.

The Mayo Foundation granted us a license (with a right to sublicense) on a worldwide basis to make, sell and use products for therapeutic use against breast, ovarian, lung and other cancers that overexpress Folate Receptor Alpha. This license is an exclusive license for products that are based on the licensed intellectual property and non-exclusive for products that are based on Mayo Foundation know–how and materials. The intellectual property that is licensed includes US patents 8,486,412 (estimated expiration date April 3, 2029), 8,858,952 (estimated expiration date March 10, 2031), 9,243,033 (July 10, 2027) and 9,915,646 (estimated expiration date June 1, 2027).

Under the Mayo Foundation FRa License, and subject to certain exceptions, we are responsible for, among other things, developing the technology under the Patent Rights to bring Licensed Products (both as defined in the Mayo Foundation FRa License) to market and costs of filing, prosecution and maintenance of the Patent Rights. Mayo Foundation has sole control over the protection, defense, enforcement, maintenance abandonment and other handling of the Know-How (as defined in the Mayo Foundation FRa License) and Materials (as defined in the Mayo Foundation FRa License).

The Mayo Foundation granted this license in exchange for an initial upfront payment of $350,000. The Mayo Foundation assigned to us IND # 14546, and we assumed all responsibility and liability for this investigational new drug application. In addition to the initial upfront payment, we are to pay additional upfront payments, an annual license maintenance fee, milestone fees, royalty fees (which will be subject to a minimum annual royalty fee once royalty fees are due), and, if applicable, a percentage of sublicense income.

We have agreed to indemnify and hold Mayo Foundation harmless from any damages caused as a result of (1) the practice or exercise of any rights and assignments granted by the Mayo Foundation FRa License by or on behalf of us or any sub-licensee; (2) research, development, design, manufacture, distribution, use, sale, importation, exportation or other disposition of Licensed Products; (3) our or any sub-licensee's act or omission, including negligence or willful misconduct; and (4) third party suits for patent infringement involving a Licensed Product.

The term of this agreement runs from July 21, 2015 until the date of our last obligation to make payments under this agreement, provided that the Mayo Foundation may terminate this agreement if, among other matters, (1) 30 days after providing us with notice of a material breach of this agreement, we fail to cure such breach, (2) 90 days after providing us with written notice, we fail to meet either of the following diligence events (a) initiate a Phase 2 clinical trial for a Licensed Product prior to the 2nd anniversary of the Mayo Foundation FRa License and, once initiated, keep current on all of our Phase 2 funding obligations and (b) initiate a Phase 2b or 3 clinical trial for a Licensed Product prior to the 5th anniversary of the Mayo Foundation FRa License, (3) we fail to make a sale of a Licensed Product by July 21, 2025 and (4) we cease to conduct business in the normal event of operations or become insolvent or bankrupt. We may voluntarily terminate the Mayo Foundation FRa License at any time upon written notice to Mayo Foundation.

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 the 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 — in other words, the rights obtained under exclusive license arrangements such as those pursuant to our BCM License Agreement and our Mayo Foundation licenses. 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 to identify and license 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 or licensed to us in the future, will afford protection against competitors with similar technology. In addition, no assurances can be given that the patents issued 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 the courts uphold existing or future patents containing broad claims over technology used by us, 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. There are also opportunities to obtain an extension of patent coverage for a product in certain countries, which adds further complexity to the determination of patent life.

We currently have a number of issued and pending patents covering composition of matter of our PolyStart technology and methods of using our PolyStart technology, including: U.S. 9,364,523 (estimated expiration date March 17, 2035); U.S. 9,655,956 (estimated expiration date March 17, 2035); U.S. 9,988,643 (estimated expiration date March 27, 2035); and U.S. 10,030,252 (estimated expiration date March 17, 2035)

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 more economical 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 applications we will acquire, or license will result in the issuance of 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 in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. 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 United States Patent and Trademark Office, or 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 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 the 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 POLYSTART and “Marker Therapeutics.” We currently have the trademark “TapImmune” registered with the USPTO. 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; 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 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 covered health care professionals 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. 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 remain judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. 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 December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress as part of the Tax Cuts and Jobs Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it is unclear when a decision will be made. Although the Supreme Court has yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs 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 also unclear how the Supreme Court ruling, 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% per fiscal year through 2030, except for a temporary suspension from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken, and reduced payments to several types of Medicare providers. 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 released a final rule on September 24, 2020, effective November 30, 2020, providing guidance 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 pending review by the Biden administration until March 22, 2021. 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. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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, 2020, we had 44 full-time employees. There were 32 in research, development, quality, CMC and clinical and 12 were in finance, legal, human resources or 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. Approximately 80% 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." On October 17, 2018, we completed a business combination with a Delaware corporation that was then known as "Marker Therapeutics, Inc.," or Private Marker, in accordance with the terms of the Agreement and Plan of Merger and Reorganization dated as of May 15, 2018, or the Merger Agreement, by and among us, Private Marker and Timberwolf Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of TapImmune, or Merger Sub, pursuant to which, among other matters, Merger Sub merged with and into Private Marker, with Private Marker continuing as a wholly owned subsidiary of TapImmune and the surviving corporation of the merger. In connection with the merger, we changed our name from "TapImmune, Inc." to "Marker Therapeutics, Inc." and Private Marker changed its name to "Marker Cell Therapy, Inc." and became our wholly owned subsidiary. Our principal executive offices are located at 3200 Southwest Freeway, Suite 2500, Houston, Texas 77027, 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 development 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.
- Our business and operations are likely to be adversely affected by the evolving and ongoing COVID-19 global pandemic.
- 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 may not be successful in establishing our own manufacturing infrastructure for supply of our requirements of product candidates for use in clinical trials and for commercial sale. Until our new manufacturing facility is fully operational, we will be dependent on third-party vendors to design, build, maintain and support our manufacturing and cell processing facilities.
- 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 development 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 and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

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, 2020 will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2021. 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.

Risks Related to the Development of our Product Candidates

Our business and operations could be adversely affected by the evolving and ongoing COVID-19 global pandemic.

Our business and operations could be adversely affected by the effects of the recent and evolving COVID-19 virus, which was declared by the World Health Organization as a global pandemic. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including state and local orders across the United States that, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings and events and order cessation of non-essential travel. In response to public health directives and orders, we have implemented work-from-home policies for many of our employees, including at our headquarters in Houston, Texas, which is currently subject to an order that requires all non-essential businesses to cease in-person operations.

Remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the COVID-19 pandemic may negatively impact productivity and, to date, have disrupted our ongoing research and development activities and delayed certain of our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. 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.

The COVID-19 pandemic may also affect the conduct of our clinical trials. Although we have begun enrolling patients in the safety lead-in portion of 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 U.S. Food and Drug Administration, or the FDA, requirements to move forward with the trial, which together have resulted in a delay in our timelines for this trial. Our ongoing and future clinical trials may be also affected by the COVID-19 pandemic. Patient enrollment and clinical site initiation may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. 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 COVID-19, which would adversely impact clinical trial operations. The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts 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 at the time of this Form 10-K, such as the ultimate geographic spread of the disease, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat 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. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section.

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 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 five 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 the ongoing COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO staff who are healthcare providers to COVID-19 or prioritization of resources toward the pandemic. 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 require extensive research and development and 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 anticipate that the COVID-19 pandemic will delay our planned timelines for our Phase 2 trial of MT-401 for the treatment of post-transplant AML, which may impact our cost estimates for this trial. 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 require extensive research and development and have substantial manufacturing costs. 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 the COVID-19 pandemic may also 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.

The COVID-19 pandemic is also likely to cause disruptions to our clinical programs. For example, we expect that we will be delayed in initiating our Phase 2 trial of MT-401 for post-transplant AML per previously communicated timelines. The COVID-19 pandemic may also result in difficulties in initiating clinical sites and enrolling patients, the diversion of healthcare resources away from clinical trials and other challenges related to travel or quarantine policies that may impede patient movement or interrupt healthcare services.

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 with a safety lead-in portion. 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 at Baylor College of Medicine, or BCM, 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.

For example, we have been delayed in initiating our planned Phase 2 trial of MT-401 for post-transplant AML due to the COVID-19 pandemic, including as a result of delays related to the partial clinical hold, which the FDA lifted in January 2021 and delays in our ability to enroll the first three patients in the safety lead-in portion of the trial required by the FDA. The pandemic may also impact our other clinical programs. 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. 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 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 may not be successful in establishing our own manufacturing infrastructure for supply of our requirements of product candidates for use in clinical trials and for commercial sale. Until our new manufacturing facility is fully operational, we will be dependent on third-party vendors to design, build, maintain and support our manufacturing and cell processing facilities.

We currently do not operate our own facility that may be used as our clinical-scale manufacturing and processing facility. We currently rely on third-party contract manufacturing organizations, or CMOs, for manufacture of our product candidates. For early 2021, we anticipate that we will initially rely partially on the cGMP manufacturing facility within BCM for the manufacturing of our MultiTAA-specific T cell therapy-based product candidates. BCM has continued to restrict access to its facilities due to the COVID-19 pandemic, and manufacturing activities for MT-401 are ongoing albeit at a slower pace. If the cGMP manufacturing facility of BCM, which does manufacture for itself and other parties, 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. 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.

In order to further develop our business as currently planned and to conduct our planned clinical studies, including our Phase 2 trial of MT-401, we expect that our cGMP manufacturing capacity will be fully operational in the first half of 2021 following the completion of the technology transfer process. We have completed qualification of our manufacturing facility and believe it is capable of supporting our manufacturing needs with respect to our clinical trials, particularly with pivotal studies. We expect that the establishment of our own manufacturing facility will provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long-term margins. In order to transfer our MultiTAA-specific T cell manufacturing from or expand our manufacturing capabilities beyond BCM pursuant to our development plans, we will need access to the standard operating procedures and the specific batch production records that are used to manufacture the product candidates. If BCM does not support the transfer of our manufacturing processes or impedes our ability to transfer the manufacturing processes of its product candidates to us, our planned clinical trials and additional necessary manufacturing capabilities will be delayed, which will adversely affect our ability to conduct and further develop our business as currently planned.

Establishment of our own manufacturing facility is subject to many risks. We have limited prior experience in establishing a manufacturing facility and, although we have made significant progress towards initiating clinical production in our cGMP manufacturing facility, we may encounter challenges given the complexity of manufacturing cell therapies. We will also compete for the small number of individuals with expertise in cell therapy manufacturing. Even with an operational facility, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures, 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 and/or commercialization plans. 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 will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we or our CMOs 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 the specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of this equipment and materials, we rely or may rely on sole-source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our product candidates.

We will 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, we will purchase equipment and reagents critical for the manufacture of our product candidates from Wilson Wolf (a company controlled by our director John Wilson), Almac, JPT Peptide Technologies and other suppliers. Some of our 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.

As we continue to develop and scale our manufacturing process, we may need to obtain rights to and supplies of specific materials and equipment to be used as part of that process. 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 or scaling up of our manufacturing capabilities. If we, or any of our third-party suppliers encounter such difficulties, our ability to supply 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 MultiTAA-specific T cell therapy-based product candidates are manufactured for each particular patient, we will be required to maintain a chain of identity with respect to the patient's/donor'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.

Currently, our product candidates are manufactured using processes developed by BCM, our third-party research institution collaborator. Although we are working to develop our own 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 are developing improved methods for generating and selecting T cells, and to develop methods for large-scale production of our current product candidates that are in accordance with current cGMP procedures. Developing a new, scaled-up, pharmaceutical manufacturing process that can 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 is subject to many uncertainties and difficulties. We 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 (including our new in-house facility) 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 will be able to develop such manufacturing process, or that our partners will thereafter be able to establish and operate such a production facility.

We may have difficulty demonstrating that the product candidates produced from our new processes are identical to the existing products. The FDA may require additional clinical testing before permitting a larger clinical trial with the new processes, and such drug product may not be as efficacious in the new clinical trials. 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.

Catastrophic events may disrupt our business.

Our corporate headquarters and cGMP manufacturing facility are located in Houston, Texas. 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, such as the COVID-19 pandemic, that impacts our corporate headquarters or other facilities, 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.

Risks Related to our Reliance on Third Parties, Including BCM

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 and Chief Development 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 Phase 2 clinical trials with respect to our product candidates, as well as continued access to our clinical data, and (ii) product manufacturing and 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 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. 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.

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 Peter Hoang, our President and Chief Executive Officer, Juan Vera, M.D., our Chief Development and Scientific Officer, and Mythili Koneru, M.D., Ph.D. our Chief Medical Officer as well as others. The loss of the services of any of our executive officers, 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 are companies such as Juno Therapeutics/Celgene/Bristol-Myers Squibb, Roche/Genentech, Merck, Novartis, Kite Pharma/Gilead, Amgen, Pfizer, and GlaxoSmithKline, which already have products on the market or in development. Other companies, such as Cellectis, Bluebird Bio, and Adaptimmune, which are focused on genetically engineered T cell technologies to treat cancer, may also be competitors. Furthermore, companies such as Iovance, Immatics, NexImmune, WindMIL Therapeutics, Mana Therapeutics, Tessa Therapeutics and Repertoire Immune Medicines are developing non-genetically modified T cell therapies such as tumor infiltrating lymphocytes and marrow infiltrating lymphocytes therapies that may compete with our product candidates. All these companies, and most of our other current and potential competitors 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. Universities and public and private research institutions in the U.S. and around the world are also potential competitors. 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.

Our lead product candidate is a therapy to treat post-allogeneic HSCT patients with AML. Currently, there are numerous companies that are developing various alternate treatments for AML. Accordingly, we face significant competition in the AML treatment space from multiple companies. 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 a small patient population that suffers from AML. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never 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 federal ACA enacted in 2010, 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 Phase II 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 certain of Dr. Vera, our Chief Development and Scientific Officer, and John Wilson, our director, could limit their time and availability to us, and create, or appear to create, conflicts of interest.

Dr. Vera is a co-founder and member 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. Accordingly, Dr. Vera may have other commitments that would, at times, limit his availability to us. Other research being conducted by Dr. Vera may, at times, receive higher priority than research on our programs, which may, in turn, delay the development or commercialization of our product candidates.

In addition, John Wilson is a co-founder, member and director of Allovir and is a director of our company. Both of these individuals have certain fiduciary or other obligations to us and certain fiduciary or other obligations to Allovir and, in the case of Dr. Vera to 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, they may be faced with decisions that could have different implications for us than for Allovir. Consequently, there is no assurance that these members of our board and management will always act in our best interests in all situations should a conflict arise.

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 European patent will not be found invalid or unenforceable if challenged.

Most of our intellectual property rights are currently licensed from BCM and the Mayo Foundation, 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 one of our licensors 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, 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 uphold the validity of patents and to prevent 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 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 were 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 licensors 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 licensors. 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. If they do so, then they 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 involve 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 will be 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.

We have limited intellectual property rights outside the United States. 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 can 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.

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 and the Mayo Foundation 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. Similarly, we are also required to pay both substantial milestone payments and royalties to the Mayo Foundation based on our revenues from sales of our products utilizing those licensed technologies. There is no assurance that we will be successful in meeting all of the milestones in our licenses in the future on a timely basis or at all.

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 world-wide exclusive licenses from the Mayo Foundation on (i) a novel set of Class II HER2/neu peptide antigens, (ii) a novel Class I HER2/neu antigen, and (iii) a novel set of Class II Folate Receptor Alpha peptide antigens. 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 owners of the patent rights underlying the technologies that we license do not properly maintain or enforce the patents and intellectual property underlying those properties,
- the Mayo Foundation or 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 the Mayo Foundation or 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 Mayo Foundation or 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, unenforceable, lack sufficient written description or enablement, or that the claims of the issued patents 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 licensors, 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 licensors. 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 licensors. 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 drug 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, 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) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or 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. Since January 2017, President Trump signed executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, 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 December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. Further, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it is unclear when a decision will be made. Although the Supreme Court has yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs 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 also unclear how the Supreme Court ruling, other such litigation, 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, providers are subject to Medicare payment reductions of 2% per fiscal year through 2030, except for a temporary suspension from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken. 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.

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, 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 released a final rule on September 24, 2020, effective November 30, 2020, providing guidance 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 pending review by the Biden administration until March 22, 2021. 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. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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.

It is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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, particularly in light of the recent presidential election, 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.

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 the ongoing COVID-19 pandemic and related global economic uncertainty;
- major catastrophic events;
- departures of key personnel;
- events affecting BCM, Mayo Clinic, Mayo Foundation for Medical Education and Research 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 Global Market 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, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, 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.

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. To the extent that we sell equity securities or convertible debt securities, 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, 2020, we had 50.7 million shares of our common stock issued and outstanding. 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, 2020, there were outstanding warrants to purchase up to approximately 20.8 million shares of our common stock at a weighted average exercise price of $4.47 per share, and options exercisable for an aggregate of approximately 6.0 million shares of common stock at a weighted average exercise price of $6.22 per share. 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

Our business and operations would suffer in the event of cybersecurity/information systems risk.

Cybersecurity incidents have increased in number and severity recently and it is expected that these trends will continue. Despite the implementation of security measures, our internal computer systems, and those of our manufacturers and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, successful breaches, employee malfeasance, or human or technological error, war and telecommunication and electrical failures. In addition, our systems safeguard important confidential personal data regarding our subjects. If a disruption event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, 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.

Should we be affected by such an incident, we may incur substantial costs and suffer other negative consequences, which may include investigation costs and costs to engage specialized consultants; remediation costs, such as liability for stolen assets or information, repairs of system damage, and incentives to customers or business partners in an effort to maintain relationships after an attack; and litigation and legal risks, including regulatory actions by state and federal regulators. 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.

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 NOLs generated in tax years beginning on or prior to December 31, 2017 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 federal NOLs generated in tax years beginning after December 31, 2020 is subject to certain limitations. It is uncertain if and to what extent various states will conform to the Tax Act.

In addition, under Section 382 and Section 383 of the Internal Revenue Code of 1986, as amended, or, the Code, and corresponding provisions of state law, 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.

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 example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or Tax Act, enacted many significant changes to the U.S. tax laws, including changes in corporate tax rates, the utilization of our NOLs and other deferred tax assets, the deductibility of expenses, and the taxation of foreign earnings. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, or any newly enacted federal tax legislation. The impact of changes under the Tax Act, the CARES Act, or future reform legislation could increase our future U.S. tax expense and could have a material adverse impact on our business and financial condition.

The accounting treatment for certain of our warrants is complex and subject to judgments concerning the valuation of embedded derivative rights within the applicable securities. Fluctuations in the valuation of these rights could cause us to take charges to our statement of operations and make our financial results unpredictable.

Certain of our outstanding warrants contain or contained prior to being amended, or may be deemed to contain from time to time, embedded derivative rights in accordance with U.S. Generally Accepted Accounting Principles , or GAAP. There is a risk that questions could arise from investors or regulatory authorities concerning the appropriate accounting treatment of these instruments, which could require us to restate previous financial statements, which in turn could adversely affect our reputation, as well as our results of operations. These derivative rights, or similar rights in securities we may issue in the future, need to be, or may need to be, separately valued as of the end of each accounting period in accordance with GAAP. We record these embedded derivatives as liabilities at issuance, valued using the Black Scholes Option Pricing Model and are subject to revaluation at each reporting date. Any change in fair value between reporting periods is reported on our statement of operations. At December 31, 2020, the fair value of the derivative liability-warrants was $0. Changes in the valuations of these rights, the valuation methodology or the assumptions on which the valuations are based could cause us to take charges to our earnings, which would adversely impact our results of operations. Moreover, the methodologies, assumptions and related interpretations of accounting or regulatory authorities associated with these embedded derivatives are complex and, in some cases uncertain, which could cause our accounting for these derivatives, and as a result, our financial results, to fluctuate.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We do not own any real estate or other properties. We lease office space at 3200 Southwest Freeway, Suite 2500, Houston, Texas 77027 on a ten-year agreement set to expire in July 2030, which is our principal business office. We also lease office space at 5 West Forsyth Street, Suite 200, Jacksonville, Florida 32202 on a five-year agreement due to expire on June 30, 2022.

In April 2020, we entered into a lease for a research facility in Houston, Texas. The lease term is 71 months.

In June 2020, we entered into a lease for a manufacturing facility in Houston, Texas. The lease term is ten years from rent commencement date, which was in November 2020.

ITEM 3. LEGAL PROCEEDINGS

As of December 31, 2020, we were not a party to any material legal proceedings.

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 February 26, 2021, we had 412 stockholders of record whom are holding shares. The price of our common stock on February 26, 2021 was $2.42 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 2020.

ITEM 6. SELECTED FINANCIAL DATA

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 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 at December 31, 2020 and December 31, 2019 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 and innovative peptide-based vaccines 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 selective expansion of non-engineered, tumor-specific T cells that recognize tumor associated antigens, or TAAs, which are tumor targets, and then kill tumor cells expressing those targets. These T cells are designed to recognize multiple tumor targets to produce broad spectrum anti-tumor activity. We are advancing two pipelines of product candidates as part of our MultiTAA-specific T cell program: the autologous T cells for the treatment of lymphoma, multiple myeloma, or MM, and selected solid tumors and the allogeneic T cells for the treatment of acute myeloid leukemia, or AML, and acute lymphoblastic leukemia, or ALL. Because we do not genetically engineer the MultiTAA-specific T cell therapies, we believe that our product candidates are easier and less expensive to manufacture, have lower toxicities than current engineered chimeric antigen receptor, or CAR-T, and T cell receptor-based therapies and may provide patients with meaningful clinical benefit. We are also developing innovative peptide-based immunotherapeutic vaccines for the treatment of metastatic solid tumors.

We are pursuing post-transplant AML as the lead indication for our first company-sponsored MultiTAA-specific T cell program. In April 2020, the FDA granted orphan drug designation to MT-401 for the treatment of AML after receiving an allogeneic stem cell transplant. The 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 recent 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 hematopoietic stem cell transplant, or HSCT, never relapsed [median leukemia-free survival, or LFS, not reached at a median follow-up of 1.9 years], with 11 of 15 patients 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 submitted an investigational new drug, or IND, application to the United States Food and Drug Administration, or the FDA, to initiate a Phase 2 clinical trial of MultiTAA-specific T cell therapy, which we refer to as MT-401 (zedenoleucel), in post-allogeneic HSCT patients with AML in both the adjuvant and active disease setting. The dose administered in this multicenter trial is the approximate flat dose equivalent of the current maximum tolerated dose from the ongoing Phase 1 trial. In the adjuvant setting, patients will be randomized to either MultiTAA-specific T cell therapy at approximately 90 days post-transplant versus standard of care observation, while the active disease patients will receive MT-401 following relapse post-transplant as part of a single-arm group. We expect to complete the safety lead-in portion of the trial in the first half of 2021. We anticipate that we will initiate the remainder of the Phase 2 trial in the third quarter of 2021 and complete enrollment of 20 patients in that phase of the trial in the fourth quarter of 2021 in order to report results from the active disease arm of the trial in the first quarter of 2022. We expect to begin manufacturing MT-401 for the Phase 2 trial at our cGMP manufacturing facility in the third quarter of 2021.

We reported interim data for 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 this trial, we have observed a clinical benefit 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. These T cells exhibited activity against both targeted antigens and non-targeted TAAs, indicating induction of antigen spreading. To date, we have not observed any cytokine release syndrome or neurotoxicity in this trial.

We are also evaluating the MultiTAA-specific T cell therapies in a Phase 2 clinical trial for the treatment of breast cancer and in Phase 1 clinical trials for the treatment of ALL, lymphoma, MM and sarcoma, all of which are being conducted by BCM. As of December 2020, the MultiTAA-specific T cell therapies have been generally well tolerated by all of the patients enrolled in clinical trials in hematological and solid tumor indications with no incidents of cytokine release syndrome or neurotoxicity, which are frequently associated with CAR-T therapies. Our ongoing clinical trials may be also affected by the COVID-19 pandemic. 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. We may initiate additional Phase 2 clinical trials investigating other indications in addition to our planned Phase 2 trial in post-transplant AML patients.

Financial Overview

Critical Accounting Policies

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. We believe that the accounting estimates employed are appropriate and resulting balances are reasonable; however, due to inherent uncertainties in making estimates, actual results could differ from the original estimates, requiring adjustments to these balances in future periods. The critical accounting estimates that affect the consolidated financial statements and the judgments and assumptions used are consistent with those described under Note 3 in the Notes to Consolidated Financial Statements in this Form 10-K.

Research and Development Expenses

To date, our research and development expenses have related primarily to the development of our clinical platform and the identification and development of our product candidates. Clinical and research and development expenses consist of expenses incurred in performing research and development activities, cost of our clinical trials, including compensation, share-based compensation expense and benefits for research and development employees and consultants, facilities expenses, overhead expenses, cost of supplies, manufacturing expenses, fees paid to third parties and other outside expenses.

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 research and development 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 salaries and other related costs, including share-based compensation, for personnel in executive, finance, accounting, business development, legal and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters, insurance costs and professional fees for consultancy, accounting, audit and investor relations.

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities, and the potential commercialization of our product candidates.

Income Taxes

We did not recognize any income tax expense for the years ended December 31, 2020 and 2019.

Other Income (Expense)

Other income (expense), net consists of interest income and change in fair value of warrant liabilities.

Results of Operations For the Years Ended December 31, 2020 and 2019

The following table summarizes the results of our operations (rounded to the thousand except for per share amounts) for the years ended December 31, 2020 and 2019, together with the changes to those items:

	For the Years Ended December 31,		Change	
	2020	2019		
Revenues:				
Grant income	$ 467,000	$ 213,000	$ 254,000	119 %
Total revenues	467,000	213,000	254,000	119 %
Operating expenses:				
Research and development	18,881,000	12,765,000	6,116,000	48 %
General and administrative	10,472,000	9,977,000	495,000	5 %
Total operating expenses	29,353,000	22,742,000	6,611,000	29 %
Loss from operations	(28,886,000)	(22,529,000)	(6,357,000)	28 %
Other income (expense):				
Change in fair value of warrant liabilities	31,000	18,000	13,000	72 %
Interest income	149,000	1,083,000	(934,000)	(86)%
Net loss	**$ (28,706,000)**	**$ (21,428,000)**	**$ (7,278,000)**	**34 %**
Net loss per share, basic and diluted	$ (0.61)	$ (0.47)	$ (0.14)	30 %
Weighted average number of common shares outstanding	47,040,000	45,588,000	1,452,000	3 %

Revenue

We did not generate any revenue during the years ended December 31, 2020 and 2019, respectively, from the sales or licensing of our product candidates. During the year ended December 31, 2020, we recognized $0.5 million of revenue associated with a grant awarded to Mayo Foundation from the US Department of Defense for the Phase 2 clinical trial of TPIV200 which Mayo paid to us for clinical supplies manufactured by us and provided for the clinical trial funded by the grant. We refer to this grant as the Mayo Grant. During the year ended December 31, 2019, we recognized $0.2 million of grant income from the Mayo Grant.

Operating Expenses

Operating expenses incurred during the fiscal year ended December 31, 2020 were $29.4 million compared to $22.7 million in the prior year. Significant changes and expenditures in operating expenses are outlined as follows:

Research and Development Expense

Research and development expenses increased by 48% to $18.9 million for the year ended December 31, 2020, compared to $12.8 million for the year ended December 31, 2019.

The increase of $6.1 million in 2020 was primarily attributable to the following:

- increase of $2.9 million in headcount-related expenses as we increased the number of research and development personnel,
- increase of $2.3 million in process development expenses,
- increase of $1.7 million in sponsored research and consulting expenses from BCM agreements,
- increase of $0.6 million in rent expenses,
- decrease of $1.3 million in our peptide vaccine clinical trial expenses due to the stages of ongoing clinical trials and the decreased number of active patients in such trials , and
- decrease of $0.1 million of other expenses.

Included in research and development expenses, are expenses related to agreements with BCM.

In November 2018 and February 2020, we entered in Sponsored Research Agreements with BCM, which provided for the conduct of research for us by credentialed personnel at BCM's Center for Cell and Gene Therapy. During the years ended December 31, 2020 and 2019, we incurred $0.3 million and $0.1 million of expenses related to these agreements, respectively.

In September 2019, we entered in a Clinical Supply Agreement with BCM, which provided for BCM to provide to us multi tumor antigen specific products. During the year ended December 31, 2020, we incurred $0.6 million related to this agreement.

In October 2019, we entered in a Workforce Grant Agreement with BCM, which provided for BCM to provide to us manpower costs of projects for manufacturing, quality control testing and validation run activities. During the year ended December 31, 2020, we incurred $0.6 million related to this agreement.

In August 2020, we entered in a Clinical Trial Agreement with BCM, which provided for BCM to provide to us investigator-initiated research studies. During the year ended December 31, 2020, we incurred $0.3 million related to this agreement.

General and Administrative Expenses

General and administrative expenses increased by 5% to $10.5 million for the year ended December 31, 2020 from $10.0 million during the prior period. The increase in general and administrative expenses of $0.5 million was mainly comprised of the following:

- increase of $1.0 million in headcount-related expenses as we increased the number of administrative personnel,
- increase of $0.2 million in rent expenses,
- increase of $0.4 million in insurance expenses,
- decrease of $0.3 million in other general and administrative expenses, and
- decrease of $0.8 million in legal and professional fees.

Other Income (Expense)

Change in Fair Value of Warrant Liabilities

Change in fair value of warrant liabilities for the year ended December 31, 2020 was $31,000 as compared to $18,000 for the fiscal year ended December 31, 2019.

Interest Income

Interest income was $0.1 million and $1.1 million for the years ended December 31, 2020 and 2019, 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. As part of the reaction to the COVID-19 pandemic, the Federal Reserve cut rates in mid-March 2020 to a range of 0.0%-0.25%. As such, we recorded lower interest income during the year ended December 31, 2020.

Net Loss

The increase in our net loss during the year ended December 31, 2020 compared to the year ended December 31, 2019 was due to the continued expansion of our research and development activities, increased expenses relating to future clinical trials, and the overall growth of our corporate infrastructure. 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. We have financed our operations primarily through public and private offerings of our stock and debt including warrants and the exercise thereof.

The following table sets forth our cash and cash equivalents and working capital as of December 31, 2020 and 2019:

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 21,352,000	$ 43,904,000
Working capital	$ 18,009,000	$ 43,494,000

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2020 and 2019:

	For the Years Ended December 31,	
	2020	2019
Net Cash provided by (used in):		
Operating activities	$ (18,860,000)	$ (18,284,000)
Investing activities	(10,428,000)	(375,000)
Financing activities	6,736,000	816,000
Net decrease in cash and cash equivalents	$ (22,552,000)	$ (17,843,000)

Operating Activities

Net cash used in operating activities during the year ended December 31, 2020 was $18.9 million. The use of cash primarily related to our net loss of $28.7 million, in addition to the effect of changes in asset and liability accounts, including an increase in prepaid expenses and deposits of $0.5 million, an increase in accounts payable and accrued liabilities of $4.3 million and an increase in lease liabilities of $0.2 million.

Net cash used in operating activities during the year ended December 31, 2019 was $18.3 million. The use of cash primarily related to our net loss of $21.4 million, in addition to the effect of changes in asset and liability accounts, including an increase in prepaid expenses and deposits of $1.4 million, a decrease in accounts payable and accrued liabilities of $1.0 million, a decrease in interest receivable of $52,000 and a net increase in lease liabilities of $0.2 million.

Investing Activities

Net cash used in investing activities was $10.4 million and $0.4 million for the purchase of property and equipment during the years ended December 31, 2020 and 2019, respectively. The increase relates to $6.8 million in construction in progress towards the new modular cleanrooms and the buildout of our manufacturing facility, an additional $2.2 million in laboratory equipment, $0.6 million in computers and equipment, $0.5 million in furniture and fixtures and $0.3 million in leasehold improvements at the new research facility.

Financing Activities

Net cash provided by financing activities was $6.7 million during the year ended December 31, 2020, mainly due to the sale of 4,113,440 shares of stock under the Purchase Agreement with Aspire Capital that provided proceeds to the Company of approximately $6.2 million, along with $0.6 million of proceeds from the exercise of stock warrants. Net cash provided by financing activities was $0.8 million during the year ended December 31, 2019, due to the exercise of stock warrants and stock options.

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.

As of December 31, 2020, we had working capital of $18.0 million, compared to working capital of $43.5 million as of December 31, 2019. Based on our revised clinical and research and development plans and our revised timing expectations related to the progress of our programs, we expect that our cash and cash equivalents as of December 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2021. 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;
- 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.

During fiscal 2020, we entered into agreements to buildout a manufacturing facility, to lease a research lab and to expand our corporate headquarters in Houston, Texas.

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. The extent to which the COVID-19 pandemic will impact our business and operations will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Aspire Common Stock Purchase Agreement

In February 2020, we entered into a common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $30.0 million of shares of our common stock over the 30-month term of the Purchase Agreement. As of December 31, 2020, Aspire Capital had purchased 4,113,440 shares under the Purchase Agreement, providing aggregate proceeds to the Company of approximately $6.2 million. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, the Company issued to Aspire Capital 345,357 shares of the Company's common stock.

The Purchase Agreement provides that we and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than $0.25. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us but is obligated to make purchases from us as directed by us on future funding, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at its discretion, without any cost to us. Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement. We expect to use any proceeds under the Purchase Agreement for working capital and general corporate purposes.

The Purchase Agreement provides that the number of shares that may be sold pursuant to the Purchase Agreement will be limited to 9,232,814 shares, including the Commitment Shares, or the Exchange Cap, which represents 19.99% of our outstanding shares of common stock as of the date of the Purchase Agreement, unless stockholder approval is obtained to issue more than 19.99%. This limitation will not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued under the Purchase Agreement is equal to or greater than $2.41, which was the closing price of our shares on The Nasdaq Global Market immediately preceding the execution of the Purchase Agreement. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of The Nasdaq Global Market.

Going Concern

We have no sources of revenue to provide incoming cash flows to sustain our future operations. As outlined above, our ability to pursue our planned business activities is dependent upon our successful efforts to raise additional capital.

While these factors raise substantial doubt regarding our ability to continue as a going concern. 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.

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, 2020, we have approximately $97.2 million of federal and $39.0 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 $41.6 million, if not utilized, will expire between 2029 and 2037. The federal net operating loss carryforwards of $55.6 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 $21.9 million, if not utilized, will begin to expire in 2035. The state net operating loss carryforwards of $17.1 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, 2020 and 2019, we recorded a 100% valuation allowance against our deferred tax assets of approximately $29.7 million and $24.6 million, respectively, as our management believes it is uncertain that they will be fully realized. 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.

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 F-1 to F-21 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, 2020 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, 2020. 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, 2020 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 Chief 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, financial and accounting officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2020 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, 2020.

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, 2020 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 Chief Financial 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

None.

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," "Management and Named Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for our 2020 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, 2020 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-Compensation Discussion and Analysis" 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 "Equity Compensation Plan Information" and "Security Ownership of Management and Certain Beneficial Owners" 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-Compensation Discussion and Analysis" and "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 "Certain Relationships and Related Transactions" and "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 "Independent Auditors' 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 on pages F-1 through F-21.

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

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
3.1	Certificate of Incorporation	8-K	001-37939	3.4	10/17/18	
3.2	Bylaws of Marker Therapeutics, Inc.	8-K	000-37939	3.6	10/17/18	
4.0	Form of Common Stock Certificate of Marker Therapeutics, Inc.	8-A/A	000-37939	4.1	10/17/18	
4.1	Form of Common Stock Purchase Warrant	8-K	000-27239	4.1	8/14/14	
4.2	Form of Placement Agent Warrant Common Stock Purchase Warrants-Series A	8-K	000-27239	4.6	1/12/15	
4.3	Form of Placement Agent Warrant Common Stock Purchase Warrants-Series C	8-K	000-27239	4.8	1/12/15	
4.4	Form of Placement Agent Warrant Common Stock Purchase Warrants-Series D	8-K	000-27239	4.9	1/12/15	
4.5	Form of Placement Agent Warrant Common Stock Purchase Warrants-Series E	8-K	000-27239	4.10	1/12/15	
4.6	Form of Placement Agent Warrant Common Stock Purchase Warrants-Series A-1	8-K	000-27239	4.6	3/10/15	
4.7	Form of Placement Agent Warrant Common Stock Purchase Warrants-Series E-1	8-K	000-27239	4.10	3/10/15	
4.8	Form of Amended Series A Warrant	8-K	000-27239	4.2	8/11/16	
4.9	Form of Amended Series C Warrant	8-K	000-27239	4.3	8/11/16	
4.10	Form of Amended Series D Warrant	8-K	000-27239	4.4	8/11/16	
4.11	Form of Amended Series E Warrant	8-K	000-27239	4.5	8/11/16	

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
4.12	Form of Amended Series A-1 Warrant	8-K	000-27239	4.6	8/11/16	
4.13	Form of Amended Series D-1 Warrant	8-K	000-27239	4.7	8/11/16	
4.14	Form of Series F Warrant	8-K	000-27239	4.9	8/11/16	
4.15	Form of Series F-1 Warrant	8-K	000-27239	4.10	8/11/16	
4.16	Form of August 2016 Private Placement Warrant	8-K	000-27239	4.1	8/11/16	
4.17	Form of 2016 Private Placement Agent Warrant	8-K	000-27239	4.11	8/11/16	
4.18	Form of June 2017 Private Placement Warrant	8-K	001-37939	4.1	6/22/17	
4.19	Form of 2017 Private Placement Agent Warrant	8-K	001-37939	4.2	6/22/17	
4.20	Form of Warrant Amendment Agreement August 2016 Private Placement	8-K	000-27239	10.3	8/11/16	
4.21	Form of Warrant Exercise Agreement	8-K	001-37939	10.3	6/22/17	
4.22	Form of Private Placement Warrant	8-K	001-37939	4.1	6/8/18	
4.23	Form of Private Placement Warrant	8-K	001-37393	4.2	6/8/18	
4.24	Form of Marker Warrant	8-K	001-37939	2.1	5/15/18	
4.25	Description of Common Stock of Marker Therapeutics, Inc.	10-K	001-37939	4.25	3/12/20	
10.1	Form of Restructuring Agreement dated May 28, 2015	8-K	000-27239	10.1	6/3/15	
10.2	Amended and Restated Restructuring Agreement, dated as of June 2, 2015	8-K	000-27239	10.1	6/5/15	
10.3	Form of Securities Purchase Agreement (including registration rights)	8-K	001-37939	10.1	6/8/18	
10.4	Registration Rights Agreement	8-K	001-37939	2.1	5/15/18	
10.5	License and Assignment Agreement, dated July 21, 2015, with The Mayo Foundation for Medical Education and Research**	10-Q	000-27239	10.1	8/14/15	
10.6	License and Assignment Agreement with Mayo Foundation for Medical Education and Research dated May 19, 2016**	10-Q	000-27239	10.1	8/15/16	
10.7	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	
10.8	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	
10.9	2009 Stock Incentive Plan*	DEF14-C	000-27239	B	1/29/10	

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
10.10	2014 Omnibus Stock Ownership Plan, as amended through August 29, 2017*	8-K	001-37939	10.1	9/5/17	
10.11	Amendment to 2014 Omnibus Stock Ownership Plan, as amended *	8-K	001-37939	4.4	10/17/18	
10.12	Form of Stock Option Award Agreement –Employee*	8-K	001-37939	10.3	10/23/18	
10.13	Form of Stock Option Award Agreement – Non-Employee Director*	S-8	333-228056	10.1	10/30/18	
10.14	Form of Stock Option Award Agreement – Consultant*	8-K	001-37939	10.2	10/23/18	
10.15	Form of Restricted Stock Award Agreement – Consultant*	10-Q	000-27239	10.7	11/16/15	
10.16	Employment Agreement between TapImmune Inc. and Peter Hoang dated as of September 22, 2017*	8-K	001-37939	10.1	9/25/17	
10.17	Employment Agreement by and between TapImmune Inc. and Michael J. Loiacono dated as of August 25, 2016*	8-K	000-27239	10.1	8/25/16	
10.18	Amendment to Employment Agreement between Marker Therapeutics, Inc. and Michael J. Loiacono dated as of November 27, 2018*	8-K	001-37939	10.2	12/3/18	
10.19	Employment Agreement between Marker Therapeutics, Inc. and Anthony Kim dated as of November 27, 2018*	8-K	001-37939	10.3	12/3/18	
10.20	Consulting Agreement between Dr. Juan Vera and Marker Therapeutics, Inc. dated October 19, 2018*	8-K	001-37939	10.1	10/23/18	
10.21	Form of Director and Officer Indemnification Agreement*	10-K	001-37939	10.39	3/15/19	
10.22	Amendment to Employment Agreement between Marker Therapeutics, Inc. and Peter Hoang, dated March 14, 2019*	10-K	001-37939	10.40	3/15/19	
10.23	Employment Agreement between Marker Therapeutics, Inc. and Mythili Koneru, dated February 6, 2019.*	10-Q	001-37939	10.3	5/10/19	
10.24	Marker Therapeutics, Inc. 2020 Equity Incentive Plan	S-8	333-239136	99.1	6/12/20	

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
10.25	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	
10.26	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	
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-14(a).					X
31.2	Certification of Chief Financial Officer pursuant to Securities Exchange Act of 1934 Rule 13a-14(a) or 15d-14(a).					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
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

* 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 9, 2021

Marker Therapeutics, Inc.

By: /s/ Peter Hoang
Peter Hoang
Chief Executive Officer (Principal Executive Officer)

By: /s/ Anthony Kim
Anthony Kim
Chief Financial Officer (Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each of the undersigned officers and directors of Marker Therapeutics, Inc., hereby constitutes and appoints Peter Hoang and Anthony Kim, 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 9, 2021 on behalf of the registrant and in the capacities indicated.

Signature	Title	Date
/s/ Peter Hoang Peter Hoang	President, Chief Executive Officer and Director (Principal Executive Officer)	March 9, 2021
/s/ Frederick Wasserman Frederick Wasserman	Director	March 9, 2021
/s/ David Laskow-Pooley David Laskow-Pooley	Director	March 9, 2021
/s/ John Wilson John Wilson	Director	March 9, 2021
/s/ Juan Vera Juan Vera	Director	March 9, 2021
/s/ N. David Eansor N. David Eansor	Director	March 9, 2021
/s/ Steve Elms Steve Elms	Director	March 9, 2021
/s/ Anthony Kim Anthony Kim	Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2021

MARKER THERAPEUTICS, INC.
CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2020 AND DECEMBER 31, 2019

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 sheet of Marker Therapeutics, Inc. (the “Company”) as of December 31, 2020 and 2019, the related consolidated statements of operations, stockholders’ equity (deficit) and cash flows for each of the two years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph - Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matters

Critical Audit Matters 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. We determined that there are no critical audit matters.

/s/ Marcum LLP

Marcum LLP

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

New York, NY
March 9, 2021

MARKER THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,352,382	$ 43,903,949
Prepaid expenses and deposits	2,057,924	1,526,442
Interest receivable	559	56,189
Other receivable	1,000,000	—
Total current assets	24,410,865	45,486,580
Non-current assets:		
Property, plant and equipment, net	3,570,736	417,528
Construction in progress	6,789,098	—
Right-of-use assets, net	10,844,116	455,174
Total non-current assets	21,203,950	872,702
Total assets	**$ 45,614,815**	**$ 46,359,282**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 6,013,010	$ 1,757,680
Lease liability	388,792	204,132
Warrant liability	-	31,000
Total current liabilities	6,401,802	1,992,812
Non-current liabilities:		
Lease liability, net of current portion	11,868,440	280,247
Total non-current liabilities	11,868,440	280,247
Total liabilities	18,270,242	2,273,059
Commitments and contingencies (see Note 15)	—	—
Stockholders' equity:		
Preferred stock - $0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	—
Common stock, $0.001 par value, 150 million shares authorized, 50.7 million and 45.7 million shares issued and outstanding as of December 31, 2020 and 2019, respectively	50,731	45,728
Additional paid-in capital	383,533,326	371,573,909
Accumulated deficit	(356,239,484)	(327,533,414)
Total stockholders' equity	27,344,573	44,086,223
Total liabilities and stockholders' equity	**$ 45,614,815**	**$ 46,359,282**

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,	
	2020	2019
Revenues:		
Grant income	$ 466,785	$ 213,194
Total revenues	466,785	213,194
Operating expenses:		
Research and development	18,880,751	12,764,804
General and administrative	10,471,846	9,977,196
Total operating expenses	29,352,597	22,742,000
Loss from operations	(28,885,812)	(22,528,806)
Other income (expense):		
Change in fair value of warrant liabilities	31,000	18,000
Interest income	148,742	1,082,842
Net loss	**$ (28,706,070)**	**$ (21,427,964)**
Net loss per share, basic and diluted	$ (0.61)	$ (0.47)
Weighted average number of common shares outstanding	47,039,862	45,587,734

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

MARKER THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par value			
Balance at January 1, 2019	**45,440,704**	**$ 45,440**	**$ 365,400,748**	**$ (306,105,450)**	**$ 59,340,738**
Stock options exercised for cash	11,980	12	57,732	—	57,744
Warrants exercised for cash	190,258	190	758,543	—	758,733
Stock warrants cashless exercised	9,449	9	(9)	—	—
Stock-based compensation	76,440	77	5,356,895	—	5,356,972
Net loss	—	—	—	(21,427,964)	(21,427,964)
Balance at December 31, 2019	**45,728,831**	**45,728**	**371,573,909**	**(327,533,414)**	**44,086,223**
Issuance common stock for cash	4,113,440	4,114	6,181,897	—	6,186,011
Warrants exercised for cash	458,334	459	549,541	—	550,000
Issuance of common stock as commitment fee for future financing	345,357	345	(345)	—	—
Stock-based compensation	85,110	85	5,228,324	—	5,228,409
Net loss	—	—	—	(28,706,070)	(28,706,070)
Balance at December 31, 2020	**50,731,072**	**$ 50,731**	**$ 383,533,326**	**$ (356,239,484)**	**$ 27,344,573**

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,	
	2020	2019
Cash Flows from Operating Activities:		
Net loss	$ (28,706,070)	$ (21,427,964)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	485,641	105,123
Changes in fair value of warrant liabilities	(31,000)	(18,000)
Stock-based compensation	5,228,409	5,356,972
Amortization on right-of-use assets	590,039	181,459
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(531,482)	(1,384,725)
Interest receivable	55,630	51,988
Accounts payable and accrued expenses	4,222,470	(963,967)
Lease liability	(173,268)	(185,179)
Net cash used in operating activities	(18,859,631)	(18,284,293)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(3,638,849)	(374,983)
Purchase of construction in progress	(6,789,098)	—
Net cash used in investing activities	(10,427,947)	(374,983)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock	6,186,011	—
Proceeds from exercise of stock options	—	57,744
Proceeds from exercise of warrants	550,000	758,733
Net cash provided by financing activities	6,736,011	816,477
Net decrease in cash	(22,551,567)	(17,842,799)
Cash and cash equivalents at beginning of the period	43,903,949	61,746,748
Cash and cash equivalents at end of the period	$ 21,352,382	$ 43,903,949

	For the Years Ended December 31,	
	2020	2019
Supplemental schedule of non-cash financing activities:		
Issuance of common stock as commitment fee for future financing	$ 345	$ —
Recognition of right-of-use assets and lease liability from new operating lease agreements	$ 11,114,300	$ —
Stock warrants cashless exercised	$ —	$ 9

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, 2020 AND 2019

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 and innovative peptide-based vaccines 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.

NOTE 2: FINANCIAL CONDITION, GOING CONCERN AND MANAGEMENT PLANS

As of December 31, 2020, the Company had cash and cash equivalents of approximately $21.4 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 and debt financings.

The Company expects to continue to incur substantial losses over the next several years during its development phase. To fully execute its business plan, the Company will need to complete certain research and development activities and clinical trials. Further, the Company's product candidates will require regulatory approval prior to commercialization. These activities will span many years and require substantial expenditures to complete and may ultimately be unsuccessful. Any delays in completing these activities could adversely impact the Company. The Company plans to meet its capital requirements primarily through issuances of debt and equity securities and, in the longer term, revenue from sales of its product candidates, if approved.

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, 2020 will enable the Company to fund its operating expenses and capital expenditure requirements into the third quarter of 2021, as such these factors raise substantial doubt regarding the Company's ability to continue as a going concern. 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;
- 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.

These factors raise substantial doubt regarding the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis, which implies that the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The consolidated 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 the Company be unable to continue as a going concern.

In addition to the foregoing, based on the Company's current assessment, the Company does not expect any material impact on its long-term liquidity due to the COVID-19 pandemic. However, the Company will continue to assess the effect of the pandemic on its operations, including its clinical programs. The extent to which the COVID-19 pandemic will impact the Company's business and operations will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, 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 resulting from the spread of COVID-19 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. 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 certain reported amounts and disclosures. Accordingly, actual results could differ materially from those estimates. Significant areas requiring management's estimates and assumptions include valuation allowance on deferred tax assets, determining the fair value of stock-based compensation and stock-based transactions, the fair value of the components of the warrant liabilities and accrued liabilities.

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, 2020 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, 2020, approximately $2.7 million in cash was uninsured based upon the FDIC insurance coverage limits.

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.

Property and equipment - Construction in Progress

In June 2020, the Company entered into a lease for a manufacturing facility in Houston, Texas. In connection with the manufacturing facility, the Company has incurred costs pursuant to an agreement with a vendor to design, engineer, build and install modular cleanrooms in a manufacturing facility. The facility's construction was completed during December 2020, and a certificate of occupancy was delivered to the Company in January 2021, and as such was placed into service in January 2021. All costs associated with the buildout will be recorded as either manufacturing equipment and/or leasehold improvements and amortized over the estimated useful life of the asset and/or leasehold lease.

Fair Value Measurements

The Company follows Accounting Standards Codification (“ASC”) 820, “Fair Value Measurements and Disclosures,” (“ASC 820”) for the Company’s financial assets and liabilities that are re-measured and reported at fair value at each reporting period and are re-measured and reported at fair value at least annually using a fair value hierarchy that is broken down into three levels. Level inputs are defined as follows:

- Level 1 - Quoted prices (unadjusted) in active markets for identical assets and liabilities.
- Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as unadjusted quoted prices for similar assets and liabilities, unadjusted quoted prices in the markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, financial instruments and concentration of credit risk.

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 expenses incurred in performing research and development activities, including compensation and benefits for research and development employees and consultants, facilities expenses, overhead expenses, cost of laboratory supplies, manufacturing expenses, fees paid to third parties and other outside expenses.

Research and development costs are expensed as incurred. Clinical trial and other development 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, 2020 and 2019, 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, 2020 and 2019.

Warrant Liability

The Company evaluates options, warrants or other contracts to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for. This accounting treatment requires that the carrying amounts of embedded derivatives be marked-to-market at each balance sheet date and carried at fair value. If the fair value is recorded as a liability, the change in fair value during the period is recorded in the Statement of Operations as either income or expense. Upon conversion, exercise or modification to the terms of a derivative instrument, the instrument is marked to fair value at the conversion date and then the related fair value is reclassified to equity.

In circumstances where the embedded conversion option in a convertible instrument is required to be bifurcated and there are also other embedded derivative instruments in the convertible instrument that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument.

The classification of financial instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period. Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities will be classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is expected within 12 months of the balance sheet date.

Management must determine whether an instrument (or an embedded feature) is indexed to the Company's own stock. An entity should use a two-step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. This exercise affects the accounting for (i) certain freestanding warrants that contain exercise price adjustment features and (ii) convertible notes containing full-ratchet and anti-dilution protections (iii) certain free-standing warrants that contain contingently putable cash settlement.

Grant Income

The Company recognizes grant income in accordance with the terms stipulated under the grant awarded to the Company's collaborators at the Mayo Foundation from the U. S. Department of Defense. In various situations, the Company receives certain payments from the U.S. Department of Defense for reimbursement of clinical supplies. These payments are non-refundable and are not dependent on the Company's ongoing future performance. The Company has adopted a policy of recognizing these payments when received and as revenue in accordance with Accounting Standards Update No. 2014-09, "Revenue from Contracts with Customers (Topic 606)" issued by the Financial Accounting Standards Board.

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 Financial Accounting Standards Board ("FASB") or other standard setting bodies that we adopt 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.

Recent Accounting Standards Not Yet Adopted

Income Taxes

In December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company has adopted the new standard effective January 1, 2021 and is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

NOTE 4: NET LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDERS

Net Loss per Share Applicable to Common Stockholders

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 loss per share for the years ended December 31, 2020 and 2019, respectively:

	For the Years Ended December 31,	
	2020	2019
Numerator:		
Net loss	$ (28,706,070)	$ (21,427,964)
Denominator:		
Weighted average common shares outstanding	47,039,862	45,587,734
Net loss per share data:		
Basic and diluted	$ (0.61)	$ (0.47)

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,	
	2020	2019
Common stock options	6,002,000	4,983,000
Common stock purchase warrants	20,830,000	22,605,000
Common stock warrants - liability treatment	—	59,000
Potentially dilutive securities	26,832,000	27,647,000

NOTE 5: OTHER RECEIVABLE

Pursuant to the Company's lease agreement for its manufacturing facility, the Company incurred and paid for the construction invoices directly for both the structural improvements of the facility and the building of the manufacturing modular cleanroom (i.e. leasehold improvements and manufacturing equipment). At the time the construction invoices are received by the Company, a fixed asset is recorded in construction-in-progress. In accordance with the agreement, upon completion of the facility's construction, the Company is owed up to $1.0 million as reimbursement, and as such a landlord receivable is recorded, which provides for a legal right to receive construction reimbursements from the landlord for tenant improvement allowances. The construction of the facility was completed during December 2020, and a certificate was occupancy was delivered to the Company in January 2021. During the fiscal year ended 2020, the Company recorded a $1.0 million receivable in its consolidated financial statements. The Company expects to receive the $1.0 million in the first half of 2021.

NOTE 6: PROPERTY AND EQUIPMENT

Property and equipment consist of the following as of December 31, 2020 and 2019, respectively:

	Estimated Useful Lives	December 31, 2020	December 31, 2019
Lab equipment	5 Years	$ 2,360,000	$ 111,000
Computers, equipment and software	3-5 Years	835,000	211,000
Office furniture	5 Years	678,000	178,000
Leasehold improvements	Lesser of lease term or estimated useful life	289,000	23,000
Total		4,162,000	523,000
Less: accumulated depreciation		(591,000)	(105,000)
Construction in progress		6,789,000	—
Total fixed assets, net		$ 10,360,000	$ 418,000

Depreciation expense for the years ended December 31, 2020 and 2019 was approximately $0.5 million and $0.1 million, respectively.

In June 2020, the Company entered into a lease for a manufacturing facility in Houston, Texas. In connection with the manufacturing facility, the Company has incurred costs pursuant to an agreement with a vendor to design, engineer, build and eventually install modular cleanrooms in a manufacturing facility. $6.8 million is recorded in fixed assets – construction in progress on the balance sheet as of December 31, 2020. The completion of the facility's construction occurred during December 2020 and the Company received its certificate of occupancy in January 2021, and as such was placed into service in January 2021. During January 2021, all costs associated with the buildout will be recorded as either manufacturing equipment and/or leasehold improvements and amortized over the estimated useful life of the asset and/or leasehold lease.

In connection with the research facility that the Company opened during the second quarter of 2020, the Company incurred approximately $2.2 million of costs acquiring necessary lab equipment to carry out its experiments. The $2.2 million is included in Lab equipment within fixed assets and is being depreciated over five years. Additionally, the Company incurred $0.3 million in leasehold improvements relating to the research facility.

NOTE 7: LEASES

The Company entered into a new agreement for its corporate headquarters in Houston, Texas, which commenced in August of 2020. The initial lease term is ten years with two five-year renewal options. Fixed rent payments under the initial term are approximately $5.6 million. Additionally, the Company is also responsible for its share of operating expenses. As of December 31, 2020, the Company had remaining $4.1 million from the lease liability and $4.0 million of the related right-of-use asset resulting from the lease of its corporate headquarters.

In April 2020, the Company entered into a lease for a research facility in Houston, Texas. The lease term is 71 months. Fixed rent payments under the initial term are approximately $1.1 million. As of December 31, 2020, the Company had remaining $0.8 million from the lease liability and $0.8 million of the related right-of-use asset resulting from the lease of its research facility.

In June 2020, the Company entered into a lease for a manufacturing facility in Houston, Texas. The initial lease term is ten years from the rent commencement date in the fourth quarter of 2020 with two five-year renewal options. Fixed rent payments under the initial term are approximately $9.8 million. Additionally, the Company is also responsible for its share of operating expenses. In accordance with the agreement, upon completion of the facility's construction, the Company is owed up to $1.0 million as reimbursement, and as such a landlord receivable is recorded, which provides for a legal right to receive construction reimbursements from the landlord for tenant improvement allowances. As of December 31, 2020, the Company had remaining $7.2 million from the lease liability and $5.8 million of the related right-of-use asset resulting from the lease of its manufacturing facility.

The Company also leases office space under agreements classified as operating leases that expire in 2022. As of December 31, 2020, the Company had remaining $0.2 million from the lease liability and $0.2 million of the related right-of-use asset resulting from the lease of its Jacksonville, Florida office space, which expires in 2022.

Such leases do not require any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees. Certain of the Company's leases include renewal options and escalation clauses; renewal options have not been included in the calculation of the lease liabilities and right-of-use assets as the Company is not reasonably certain to exercise the options. Variable expenses generally represent the Company's share of the landlord's operating expenses. The Company does not act as a lessor or have any leases classified as financing leases.

At December 31, 2020, the Company had operating lease liabilities of approximately $12.3 million and right-of-use assets of approximately $10.8 million, which were included in the consolidated balance sheet.

The following summarizes quantitative information about the Company's operating leases:

	For the Years Ended December 31, 2020	2019
Operating lease expense summary:		
Operating lease expense	$ 960,000	$ 220,000
Short-term lease expense	22,000	100,000
Variable lease expense	167,000	90,000
Total	$ 1,149,000	$ 410,000
Other information:		
Operating cash flows - operating leases	$ 544,000	$ 225,000
Weighted-average remaining lease term – operating leases	9.3	1.6
Weighted-average discount rate as of adoption date – operating leases	5.7 %	6.8 %

Maturities of the Company's operating leases, excluding short-term leases, are as follows:

Year ended December 31, 2021	$ 1,077,000
Year ended December 31, 2022	1,278,000
Year ended December 31, 2023	1,542,000
Year ended December 31, 2024	1,826,000
Year ended December 31, 2025	1,874,000
Thereafter	8,772,000
Total	16,369,000
Less present value discount	(4,112,000)
Operating lease liabilities included in the Condensed Consolidated Balance Sheet at December 31, 2020	$ 12,257,000

NOTE 8: ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities consist of the following as of December 31, 2020 and 2019, respectively:

	December 31, 2020	December 31, 2019
Accounts payable	$ 2,935,000	$ 993,000
Compensation and benefits	1,694,000	323,000
Professional fees	875,000	94,000
Technology license fees	105,000	105,000
Other	404,000	243,000
Total accounts payable and accrued liabilities	$ 6,013,000	$ 1,758,000

NOTE 9: WARRANT LIABILITY

A weighted average summary of quantitative information with respect to valuation methodology and significant unobservable inputs used for the Company's common stock purchase warrants that are categorized within Level 3 of the fair value hierarchy for the years ended 2020 and 2019, respectively:

	Weighted Average Inputs For the Years Ended December 31,	
	2020	2019
Exercise price	$ —	$ 6.92
Contractual term (years)	—	0.05
Volatility (annual)	—	83 %
Risk-free rate	—	2 %
Dividend yield (per share)	—	0 %

The foregoing assumptions are recalculated every reporting period and are subject to change based primarily on management's assessment of the probability of the events described occurring. Accordingly, changes to these assessments could materially affect the valuations.

The following table presents changes in Level 3 warrant liabilities, reflected in accrued expenses measured at fair value for the years ended December 31, 2020 and 2019, respectively:

	Warrant Liability
Balance - January 1, 2019	49,000
Change in fair value of warrant liability	(18,000)
Balance – December 31, 2019	31,000
Change in fair value of warrant liability	(31,000)
Balance – December 31, 2020	$ —

NOTE 10: FAIR VALUE MEASUREMENTS

Financial assets and liabilities measured at fair value on a recurring basis are summarized below and disclosed on the balance sheet under Warrant liability:

	Fair value measured at December 31, 2020			
	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Fair value at December 31, 2020
Warrant liability	$ —	$ —	$ —	$ —

	Fair value measured at December 31, 2019			
	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Fair value at December 31, 2019
Warrant liability	$ —	$ —	$ 31,000	$ 31,000

There were no transfers between Level 1, 2 or 3 during the years ended December 31, 2020 and 2019, respectively.

The valuation of warrants is subjective and is affected by changes in inputs to the valuation model including the price per share of common stock, the historical volatility of the stock price, risk-free rates based on U. S. Treasury security yields, the expected term of the warrants and dividend yield. Changes in these assumptions can materially affect the fair value estimate. The Company could ultimately incur amounts to settle the warrant at a cash settlement value that is significantly different than the carrying value of the liability on the financial statements. The Company will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire, or are amended in a way that would no longer require these warrants to be classified as a liability. Changes in the fair value of the common stock warrants liability are recognized as a component of other income (expense) in the Statements of Operations.

The net cash settlement value at the time of any future transactions, where the Company consolidates or merges with another entity, will depend upon the value of the following inputs at that time: the consideration value per share of the Company's common stock, the volatility of the Company's common stock, the remaining term of the warrant from announcement date, the risk-free interest rate based on U. S. Treasury security yields, and the Company's dividend yield. The warrant requires use of a volatility assumption equal to the greater of 100% and the 100-day volatility function determined as of the trading day immediately following announcement of a Fundamental Transaction.

NOTE 11: STOCKHOLDERS' EQUITY

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 150,000,000 shares of common stock, $0.001 par value per share, for issuance. Significant 2020 and 2019 common stock transactions were as follows:

2020 Common Stock Transactions

Exercise of Stock Warrants

During the year ended December 31, 2020, certain outstanding warrants were exercised for 0.5 million shares of common stock providing aggregate proceeds to the Company of approximately $0.6 million.

Board Compensation

During the year ended December 31, 2020, the Company issued an aggregate of 0.1 million shares of common stock to its non-employee directors. The fair value of the common stock of approximately $0.2 million was recognized as a component of stock-based compensation expense in general and administrative expenses.

Aspire Capital

On February 28, 2020, the Company entered into a common stock purchase agreement (the "Purchase Agreement") with Aspire Capital Fund, LLC ("Aspire Capital") which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $30.0 million of shares of the Company's common stock over the 30-month term of the purchase agreement. In consideration for entering into the purchase agreement, the Company issued to Aspire Capital 0.3 million shares of the Company's common stock as a commitment fee. The Company recorded the commitment fee to additional paid in capital. As of December 31, 2020, Aspire Capital had purchased 4.1 million shares under the Purchase Agreement, providing aggregate proceeds to the Company of approximately $6.2 million.

2019 Common Stock Transactions

Consulting Arrangements

During the year ended December 31, 2019, the Company issued 0.05 million shares of common stock in connection with consulting agreements. The fair value of the common stock of approximately $0.3 million was recognized as stock-based compensation expense in general and administrative expenses.

Board Compensation

During the year ended December 31, 2019, the Company issued an aggregate of 0.03 million shares of common stock to its non-employee directors. The fair value of the common stock of approximately $0.2 million was recognized as stock-based compensation expense in general and administrative expenses.

NOTE 12: WARRANTS

Share Purchase Warrants

A summary of the Company's share purchase warrants as of December 31, 2020 and 2019, 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, 2019	**23,016,000**	**4.78**	**4.29**	**$ 26,066,000**
Warrants granted	45,000	4.26	—	—
Exercised for cash	(190,000)	3.99	—	—
Cashless exercise	(17,000)	2.38	—	—
Expired or cancelled	(190,000)	13.63	—	—
Balance - December 31, 2019	**22,664,000**	**4.71**	**3.33**	**954,000**
Exercised for cash	(458,000)	1.20	—	—
Expired or cancelled	(1,376,000)	9.46	—	—
Balance - December 31, 2020	**20,830,000**	**$ 4.47**	**2.60**	**$ —**

2020 Warrant Transactions

Exercise of Stock Warrants

During the year ended December 31, 2020, certain outstanding warrants were exercised for 0.5 million shares of common stock providing aggregate proceeds to the Company of approximately $0.6 million.

2019 Warrant Transactions

Exercise of Stock Warrants

During the year ended December 31, 2019, certain outstanding warrants were exercised for 0.2 million shares of common stock providing aggregate proceeds to the Company of approximately $0.8 million.

NOTE 13: STOCK OPTION PLANS

Options to Purchase Shares of Common Stock

2020 Equity Incentive Plan

On May 19, 2020, the Board adopted the 2020 Equity Incentive Plan ("2020 Plan") which replaced the 2014 Omnibus Stock Option Plan ("2014 Plan"). 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 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 New York Stock Exchange.

Options granted under the 2020 Plan have a maximum term of ten years from the date of grant. Options granted in 2020 and 2019 generally vest over four years.

As of December 31, 2020, approximately 4.7 million options are available to be issued from the 2020 Plan.

2014 Omnibus Stock Ownership Plan

The 2014 Plan, which the Board adopted on May 19, 2020 and subsequently amended from time to time, allowed for grants of stock options, restricted shares, stock bonuses and other equity-based awards to employees and non-employee directors of the Company. The terms of the 2014 plan are substantially identical to the terms of the 2020 Plan described above.

Stock Options

A summary of the Company's stock option activity is as follows for stock options:

	Number of Shares	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding as of January 1, 2020	4,983,314	$ 7.79	$ 18,000	8.9
Granted	1,531,000	2.08	—	9.2
Canceled	(512,500)	—	—	—
Outstanding as of December 31, 2020	6,001,814	$ 6.22	$ —	8.3
Options vested and exercisable	2,598,981	$ 7.29	$ —	8.0

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, 2020 and 2019, respectively, were as follows:

	For the Years Ended December 31,	
	2020	2019
Exercise price	$ 2.08	$ 4.70
Expected term (years)	6.0	6.0
Expected stock price volatility	108 %	126 %
Risk-free rate of interest	1 %	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,	
	2020	2019
Stock Compensation expenses:		
Research and development	$ 2,588,000	$ 2,574,000
General and administrative	2,640,000	2,783,000
Total stock compensation expenses	$ 5,228,000	$ 5,357,000

At December 31, 2020, the total stock-based compensation cost related to unvested awards not yet recognized was $10.6 million. The expected weighted average period compensation costs to be recognized was 2.2 years. Future option grants will impact the compensation expense recognized.

NOTE 14: GRANT INCOME

During the years ended December 31, 2020 and 2019, the Company received $0.5 million and $0.2 million, respectively, of a grant awarded to Mayo Foundation from the U.S. Department of Defense for the Phase II Clinical Trial of TPIV200. The grant compensated the Company for clinical supplies manufactured and provided by the Company for the clinical study. In accordance with Accounting Standards Update No. 2014-09, “Revenue from Contracts with Customers (Topic 606)” issued by the Financial Accounting Standards Board, the Company recorded the $0.5 million and $0.2 million, respectively, of grant income as revenue.

NOTE 15: COMMITMENTS AND CONTINGENCIES

An arbitration proceeding was brought against the Company before the Financial Industry Regulatory Authority, Inc. by a broker seeking to be paid approximately $1.0 million as compensation for two financing transactions that occurred in 2018, a warrant conversion and a private placement brokered by another broker. The broker’s claims are based on a placement agent agreement for a private placement it brokered in 2017, under which it alleges it is entitled to compensation for the 2018 transactions. The Company believes it has defenses to all of the allegations and intends to vigorously defend itself in this matter.

NOTE 16: 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 17: RELATED PARTY TRANSACTIONS

The following table sets forth related party transaction expenses recorded for the years ended December 31, 2020 and 2019, respectively.

	For the Years Ended December 31,	
	2020	2019
Baylor College of Medicine	$ 1,818,000	$ 69,000
Bio-Techne Corporation	152,000	51,000
Dr Juan Vera	$ —	$ 233,000
Total Research and development	$ 1,970,000	$ 353,000

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

In November 2018 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, the Company entered in a Clinical Supply Agreement 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.

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 is serving as the President of the Protein Sciences Segment of Bio-Techne Corporation.

Consulting Agreement with Dr. Juan Vera. On October 19, 2018, after the closing of the Company's merger, the Company entered into a consulting agreement with Dr. Juan Vera, a member of the Company's board of directors, to serve as the Company's Chief Development Officer. On September 1, 2019, Dr. Vera became an employee of the Company and his consulting agreement was terminated.

NOTE 18: INCOME TAXES

The Company has no income tax expense due to operating losses incurred for the years ended December 31, 2020 and 2019.

The effects of temporary differences that give rise to significant portions of the deferred tax assets as of December 31, 2020 and 2019 are as follows:

	For the Years Ended December 31,	
	2020	2019
Deferred Tax Assets		
Net Operating Loss Carryforward	21,783,000	17,166,000
Stock Compensation	6,775,000	6,538,000
License Agreements	144,000	177,000
Research and Development	733,000	733,000
Charitable Contributions	8,000	9,000
Operating Lease Liability	2,626,000	115,000
	32,069,000	24,738,000
Less: Valuation Allowance	(29,689,000)	(24,632,000)
Total Deferred Tax Assets	2,380,000	106,000
Deferred Tax Liabilities		
Fixed Assets	—	(106,000)
Right-of-Use Assets	(2,380,000)	—
Total Deferred Tax Liabilities	(2,380,000)	(106,000)
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, 2020 and 2019. The valuation allowance increased by $5.1 million as of December 31, 2020. The Company has research and development tax credit carryforwards of $0.7 million available to offset future federal income taxes. The research and development tax credit carryforwards begin to expire in 2030.

The Company has approximately $97.2 million of federal and $39.0 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 $41.6 million, if not utilized, will expire between 2029 and 2037. The federal net operating loss carryforwards of $55.6 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 $21.9 million, if not utilized, will begin to expire in 2035. The state net operating loss carryforwards of $17.1 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.

The Company's income tax returns for 2016 to 2019 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, 2020 and 2019, the expected tax expense (benefit) based on the U. S. federal statutory rate is reconciled with the actual tax provision (benefit) as follows:

	For the Years Ended December 31,			
	2020		2019	
	Amount	Percent of Pre-Tax Loss	Amount	Percent of Pre-Tax Loss
U.S. federal statutory rate	(6,028,000)	21.00 %	(4,500,000)	21.00 %
State taxes, net of federal benefit	(118,000)	0.41 %	(600,000)	2.80 %
Tax rate change	677,000	(2.36)%	665,000	(3.10)%
Permanent Differences				
- Change in fair value of derivative liabilities	(7,000)	0.02 %	(4,000)	0.02 %
- Other permanent differences	182,000	(0.63)%	32,000	(0.15)%
Change in valuation allowance	5,057,000	(17.62)%	4,681,000	(21.85)%
Deferred true-up	237,000	(0.83)%	(274,000)	1.28 %
Income tax provision/(benefit)	—	0.00 %	—	0.00 %

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, 2020, and 2019, 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, 2020 and 2019. 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.

On March 27, 2020, the CARES Act was enabled in response to COVID-19 pandemic. Under ASC 740, the effects of changes in tax rates and laws are recognized in the period which the new legislation is enacted. The CARES Act made various tax law changes including among other things (i) increasing the limitation under Section 163(j) of the Internal Revenue Code of 1986, as amended (the "IRC") for 2019 and 2020 to permit additional expensing of interest, (ii) enacting a technical correction so that qualified improvement property can be immediately expensed under IRC Section 168(k),(iii) making modifications to the federal net operating loss rules including permitting federal net operating losses incurred in 2018, 2019 and 2020 to be carried back to the five preceding taxable years in order to generate a refund of previously paid income taxes and (iv) enhancing the recoverability of alternative minimum tax credits. Given the Company's full valuation allowance position, the CARES Act did not have an impact on the financial statements.

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 File No. 333-215258, No. 333-220538, No. 333-228059 and No. 333-232122 and on Form S-8 File No. 333-223900, No. 333-228056 and 333-239136 of our report dated March 9, 2021, 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, 2020 and 2019 and for each of the two years in the period ended December 31, 2020, which report is included in this Annual Report on Form 10-K of Marker Therapeutics, Inc. for the year ended December 31, 2020.

/s/ Marcum LLP

Marcum LLP
New York, NY
March 9, 2021

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Peter L. Hoang, 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 assurances regarding the reliability of financial reporting in 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 9, 2021

/s/ Peter L. Hoang
By: **Peter L Hoang**
Title: Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Anthony Kim, 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 assurances regarding the reliability of financial reporting in 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 9, 2021

/s/ Anthony Kim
By: **Anthony Kim**
Title: Chief Financial 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, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Peter L. Hoang, 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 9, 2021

/s/ Peter L. Hoang

Peter L. Hoang
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, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Anthony Kim, 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 9, 2021

/s/ Anthony Kim

Anthony Kim
Chief Financial Officer