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, 2018

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

For the transition period from _____ to _____.

MARKER THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37939**	**45-4497941**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3200 Southwest Freeway, Suite 2240 **Houston, Texas** (Address of principal executive offices)	**77027** (Zip Code)

(713) 400-6400
(Registrant's telephone number, including area code)

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

Common Stock, Par Value $0.001
(Title of class)

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

☐ Large accelerated filer
☐ Non-accelerated filer
x Accelerated filer
x 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 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 was approximately $81,400,000 computed by reference to the price per share ($9.43) at which the registrant's common equity was last sold, as of June 30, 2018 (the last day of the registrant's most recently completed second fiscal quarter).

The registrant had 45,467,684 shares of common stock outstanding as of February 28, 2019.

Documents Incorporated By Reference

Portions of registrant's proxy statement relating to registrant's 2019 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.

TABLE OF CONTENTS

FORWARD LOOKING STATEMENTS

This annual report contains forward-looking statements that involve risks and uncertainties. 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. In evaluating these statements, you should consider various factors, including the assumptions, risks and uncertainties outlined in this annual report. Any of these items may cause our actual results to differ materially from any forward-looking statement made in this annual report. Forward-looking statements in this annual report include statements as to:

- the discovery, development, formulation, manufacturing and commercialization of our compounds, our drug candidates;
- conducting clinical trials internally, with collaborators, or with clinical research organizations;
- our collaboration and strategic relationship strategy; anticipated benefits and disadvantages of entering into such agreements;
- our licensing, investment and commercialization strategies;
- the regulatory approval process, including obtaining U.S. Food and Drug Administration and other international health authorities’ approval for our products in the United States and abroad;
- the safety, effectiveness and potential benefits and indications of our drug candidates and other compounds under development;
- the timing and size of our clinical trials; the compounds expected to enter clinical trials; the timing of clinical trial results;
- our ability to manage expansion of our drug discovery and development operations;
- future required expertise relating to clinical trials, manufacturing, sales and marketing;
- obtaining and terminating licenses to products, drug candidates or technology, or other intellectual property rights;
- the receipt from or payments pursuant to collaboration or license agreements resulting from milestones or royalties;
- plans to develop and commercialize products on our own;
- plans to use third party manufacturers;
- expected expenses and expenditure levels; expected uses of cash;
- the adequacy of our capital resources to continue operations;
- the need to raise additional capital;
- our expectations regarding competition;
- our investments, including anticipated expenditures, losses and expenses; and
- our patent prosecution and maintenance efforts.

While these forward-looking statements, and any assumptions upon which they are based, are made in good faith and reflect our current judgment regarding future events, our actual results will likely vary, sometimes materially, from any estimates, predictions, projections, assumptions or other future performance suggested herein. Some of the risks and assumptions include:

- our ability to obtain additional capital when needed;
- our history of operating losses;
- our ability to discover, develop, formulate, manufacture and commercialize our drug candidates;
- the risk of unanticipated delays in, or discontinuations of, research and development efforts;

- the risk that previous preclinical testing or clinical trial results are not necessarily indicative of future clinical trial results;
- risks relating to the conduct of our clinical trials;
- changing regulatory requirements and administrative practice;
- the risk of adverse safety findings;
- the risk that results of our clinical trials do not support submission of a marketing approval application for our drug candidates;
- the risk of significant delays or costs in obtaining regulatory approvals;
- risks relating to our reliance on third party manufacturers, collaborators, and clinical research organizations;
- risks relating to the development of new products and their use by us and our current and potential collaborators;
- risks relating to our inability to control the development of out-licensed compounds or drug candidates;
- risks relating to our collaborators' ability to develop and commercialize drug candidates;
- costs associated with prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights;
- our ability to maintain or obtain adequate product and clinical trial liability and other insurance coverage;
- the risk that our drug candidates may not obtain or maintain regulatory approval;
- the impact of technological advances and competition, including potential generic competition;
- our ability to compete against third parties with greater resources than ours;
- risks relating to changes in pricing and reimbursements in the markets in which we may compete;
- competition to develop and commercialize similar drug products;
- our ability to obtain and maintain patent protection and the freedom to operate for our discoveries and to continue to be effective in expanding our patent coverage;
- the impact of changing laws on our patent portfolio;
- developments in and expenses relating to litigation;
- our ability to in-license drug candidates or other technology;
- the competitive environment in which we operate;
- our dependence on key personnel;
- conflicts of interest of our directors and officers;
- our ability to fully implement our business plan;
- our ability to effectively manage our growth; and
- other regulatory, legislative and judicial developments.

Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by federal securities laws, we undertake no obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

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 cell-based immunotherapies and innovative peptide-based vaccines for the treatment of hematological malignancies and solid tumor indications. Our MultiTAA T cell technology is based on the selective expansion of non-engineered, tumor-specific T cells that recognize tumor associated antigens ("TAA" i.e. tumor targets) and kill tumor cells expressing those targets. Once infused into patients, this population of T cells recognizes multiple tumor targets to produce broad spectrum anti-tumor activity. Because we do not genetically engineer our T cells, when compared to current engineered chimeric antigen receptor ("CAR") and T cell receptor ("TCR")-based approaches, our products are significantly less expensive to manufacture and appear to be markedly less toxic, and yet are associated with meaningful clinical benefit. As a result, we believe our portfolio of T cell therapies has a compelling therapeutic product profile, as compared to current gene-modified CAR and TCR-based therapies. In addition, our Folate Receptor Alpha program (TPIV200) for breast and ovarian cancers and our HER2/neu program (TPIV100/110) are in Phase II clinical trials. In parallel, we are developing a proprietary nucleic acid-based antigen expression technology named PolyStart™ to improve the ability of the immune system to recognize and destroy diseased cells.

Immuno-oncology, which utilizes a patient's own immune system to combat cancer, is one of the most actively pursued areas of research by biotechnology and pharmaceutical companies today. Interest and excitement about immunotherapy are driven by compelling efficacy data in cancers with historically bleak outcomes, and the potential to achieve a cure or functional cure for some patients. Harnessing the power of the immune system is an important component of fighting cancerous cells in the body. Our MultiTAA T cell therapy platform identifies and selects effectively all T cells that are specific for any peptide from the antigens that we target (e.g., WT1, MAGE-A4, PRAME, Survivin, NY-ESO-1, and SSX2). Our in-vitro manufacturing process promotes proliferation of very rare cancer-killing T cells and augments their anti-tumor properties to provide benefit to patients following their infusion. By using the multi-antigen targeted approach, our proprietary technology can kill heterogeneous tumor cell populations more effectively than single-antigen targeted approaches, thereby reducing the likelihood of tumor escape and potentially increasing the durability of a patient's response to therapy.

We believe that our therapy presents a promising innovation in immuno-oncology. Our therapy has been developed through our collaboration with the Cell and Gene Therapy Center at Baylor College of Medicine ("BCM") founded by Malcolm K. Brenner, M.D., Ph.D., a recognized pioneer in immuno-oncology. Our cell therapy founders include Drs. Malcolm Brenner M.D., Ph.D., Ann Leen, Ph.D., Juan Vera, M.D., Helen Heslop, M.D., DSc (Hon) and Cliona Rooney, Ph.D., who all have significant experience in this field. Dr. James P. Allison, Dr. Malcom K. Brenner, Dr. Helen E. Heslop, Dr. Cliona M. Rooney and Dr. Padmanee Sharma serve on our Scientific Advisory Board.

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 will be developing a portfolio of highly-differentiated T cell therapies utilizing our MultiTAA platform that has the potential to significantly disrupt the current cell therapy landscape, while substantially improving survival and quality of life for patients with cancers.

Key elements of our strategy include:

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

Based on results in the Phase I clinical trials conducted at BCM, we plan to advance our lead product candidates into Phase II clinical trials and facilitate the initiation of company-sponsored clinical trials in post-transplant acute myeloid leukemia (AML) and in other tumor types based on emerging data. We expect to finalize our first clinical trial protocol by end of second quarter of 2019.

We plan to initiate a Phase II clinical trial in post-transplant AML in the second half of 2019 and in other tumor types based on emerging data in the future. We anticipate that product manufacturing in support of those clinical trials will be conducted at BCM's Good Manufacturing Practices ("GMP") cell manufacturing facility.

In 2019, we expect to begin the technology transfer process and begin the planning and implementation of additional GMP manufacturing capacity capable of supporting our manufacturing needs with respect to pivotal trials. If the results of our Phase II studies are positive, we will explore potential avenues to achieve regulatory approval for the use of our products in these indications, including any potential avenues for obtaining accelerated approval. The U.S. Food and Drug Administration ("FDA") may grant accelerated approval for product candidates used to treat serious conditions that fill an unmet medical need based on a surrogate or intermediate endpoint. We believe that an accelerated approval strategy may be warranted given the limited options available for patients with post-transplant AML. However, if the FDA grants accelerated approval, confirmatory trials will be required by the FDA.

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

We finalized a strategic alliance with BCM, in which we will sponsor selected research at the institution in support of our technology. In conjunction with this strategic alliance, BCM will conduct selected Phase I/II clinical trials using our technology. If data from these early clinical trials appear positive, we will consider the therapeutic and commercial potential for such therapies to be advanced as new products for us.

In addition, we plan to use BCM facilities to enable the process development and manufacturing required to support the Phase II clinical trials of our product candidates. Outside of our relationship with BCM, we will invest in our own research and development and chemistry, manufacturing and controls ("CMC") capabilities to enhance our ability to conduct process development to optimize our manufacturing process, product quality and commercial scalability.

We believe that the G-Rex® (G-Rex® is a registered trademark of Wilson Wolf Manufacturing Corporation ("Wilson Wolf:")) based manufacturing process we have in place is highly robust and scalable, and we will continue to invest resources in further refining the manufacturing process to create a product with highly attractive commercial attributes. We plan to engage Wilson Wolf (a company controlled by John Wilson, a director of the Company) to further customize the G-Rex® to optimally match our manufacturing requirements and to develop a scalability plan to drive efficiencies for a commercial product.

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

We plan to explore new product opportunities by expanding and/or customizing the antigens we target to expand the indications in which our products may be used, including solid tumors or other hematologic malignancies. Additionally, our research and development efforts may include the exploration of dosing and/or frequency of product administration and the relationship of these factors with potential therapeutic benefit.

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

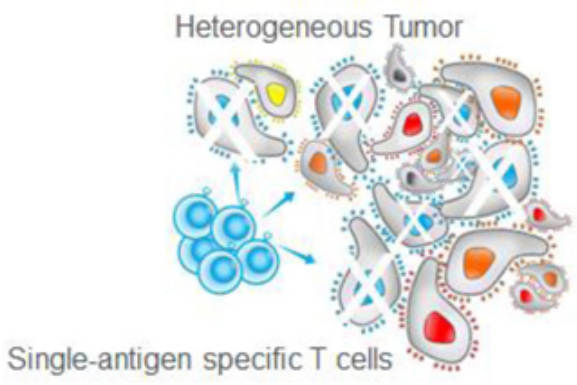
Our world-renowned scientific founders and scientific advisors have made seminal contributions to major discoveries in the field of immuno-oncology, and have significant experience in oncology, immunology and cell therapy. We intend to significantly leverage the knowledge, experience and advice of our 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 of our therapeutic products or programs. Such strategic review and evaluations are to be a priority and an important part of our ongoing operations.

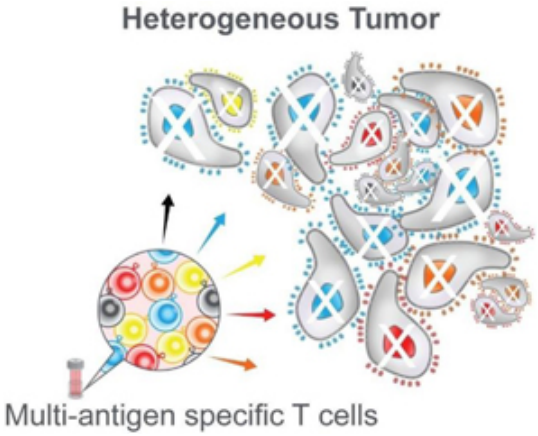
MultiTAA T Cell Products

Multi Tumor-Associated Antigen ("MultiTAA") Approach

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.



Even if the 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 immune escape. Our solution to the problem of tumor heterogeneity was to develop 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. Data suggest 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.



Our proprietary MultiTAA T cell platform may have meaningful advantages over CAR and TCR-engineered cell therapy approaches. Compared to current gene-modified T cell therapies, our programs are characterized by the following:

· **Demonstrated clinical benefit, without the need for lymphodepletion before infusion:** In BCM's Phase I lymphoma study, we saw complete responses ("CRs") in six of its evaluable patients, including three CRs in patients with diffuse large B-cell lymphoma ("DLBCL"). We believe it is significant that 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, observed therapeutic responses appear to be highly durable, with some patients being relapse-free beyond five years.

· **Non-gene-modified:** Unlike CAR-T and TCR approaches, our therapy requires no genetic modification of T cells, a costly and complex process that significantly complicates the manufacturing of a patient product. We believe our therapy can be manufactured at a fraction of the cost of a gene-modified T cell product.

· **Low incidence rate of adverse events:** In 78 patients treated to date, BCM has seen only one grade III adverse reaction possibly related to its therapy. This appears favorable compared to published CD19 CAR-T studies, wherein up to 95% of patients had associated grade III or higher adverse events during treatment. There have been no cases of cytokine-release syndrome ("CRS"), or related serious adverse events ("SAEs") in patients treated with our therapy to date.

· **Capable of addressing a broad repertoire of cancer cells:** While CAR-T and TCR therapies generally target a single epitope, our manufacturing process selects T cells that are specific for multiple peptides derived from several targeted antigens. Deep gene sequencing of the clinical products shows that a typical patient dose usually consists of approximately 4,000 unique T cell clonotypes targeting up to five different tumor-associated antigens. The five antigen targets can be recognized by a very wide range of T cells, facilitating robust killing of targeted cancer cells.

· **Appears to drive endogenous immune responses:** We see evidence of "epitope spreading" in the treated patients, meaning that the 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). BCM's correlative analyses show expansion of endogenous T cells, other than those present in our product, in the months following the infusion of our product. This phenomenon, also known as "antigen spreading," is potentially important in generating a durable response for a patient, because it enables the killing of tumors that do not express any of the antigens initially targeted by our product.

Peptide Vaccine Products and Technologies in Development

In contrast to standard therapies for cancer treatment including surgery, radiation therapy and chemotherapy that target both cancer cells and normal cells, we are also developing vaccines that precisely target breast and ovarian cancers. We are currently developing three core technology platforms:

1) an exclusively licensed peptide-based vaccine (composition and methods of use) for the treatment of breast cancers that overexpress Human Epidermal Growth Factor Receptor 2 (HER2/neu) (TPIV100/110),

(2) an exclusively licensed peptide-based vaccine (composition and methods of use) for treating breast and ovarian cancers that overexpress Folate Receptor Alpha (TPIV200), and

(3) a wholly-owned nucleic acid-based vaccine (composition and methods of use) technology (PolyStart™) for treatment of various cancers or infectious disease.

Our peptide vaccines are derived from naturally processed T cell antigens and are potentially effective standalone therapies but may also enhance the efficacy of other immunotherapy approaches such as CAR-T cell therapies and PD-1 inhibitors, for example, as well as our own MultiTAA T cell therapies.

The status of our development of other products and technologies is set forth in the table below:

Product/Candidate	Description	Application	Status
TPIV100/110 HER2/neu Breast Cancer Vaccine	Peptide Vaccine	Treatment of HER2/neu+ Breast Cancer	Phase I trial completed Phase I(b) trial to start in 2019 (TPIV100) Phase I/II to start in 2019 (TPIV110)
TPIV200 Folate Receptor Alpha Vaccine	Peptide Vaccine	Treatment of Folate Receptor Alpha+/Triple-Negative Breast and Ovarian Cancer	Phase I trial completed Multiple Phase II trials started in 2016 and 2017 and enrollment completed in 2018
PolyStart™	Nucleic acid expression technology	Broad Application to "Prime"- and- "Boost"	Preclinical

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 can 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 ("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" ("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 ("ACT") 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 immune 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 of time, 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 a major histocompatibility complex ("MHC"). 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 come with 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 ("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 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.

Process Development and Manufacturing

We are advancing two MultiTAA T cell products through clinical development:(a) Mixed Antigen Peptide Pool ("MAPP") T cells currently used for patients with lymphoma, multiple myeloma ("MM") and selected solid tumors, is an autologous product that targets the NY-ESO-1, PRAME, MAGE-A4, Survivin and SSX2 antigens; and (b) Leukemia Antigen Peptide Pool ("LAPP") T cells, currently used for patients with AML, is an allogeneic product targeting the WT1, NY-ESO-1, PRAME, and Survivin antigens using the blood of the stem cell donor as a source of the cells used for therapy. While the blood source and the antigens for stimulation differ between the LAPP and the MAPP products, the manufacturing process for each product is otherwise identical.

In the manufacturing process, blood is drawn from either the individual patient (in the case of the autologous MAPP T cells) or from the allogeneic stem cell transplant donor (in the case of the allogeneic LAPP 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 (i) identify the T cells specific for the antigens that we intend to target, (ii) restore these T cells to functionality with respect to their anti-tumor capability and (iii) 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 cryopreserved. Sufficient numbers of cryopreserved PBMCs are taken to be used to manufacture a patient-specific product. These cells are placed inside a G-Rex® manufacturing device or standard plasticware 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.

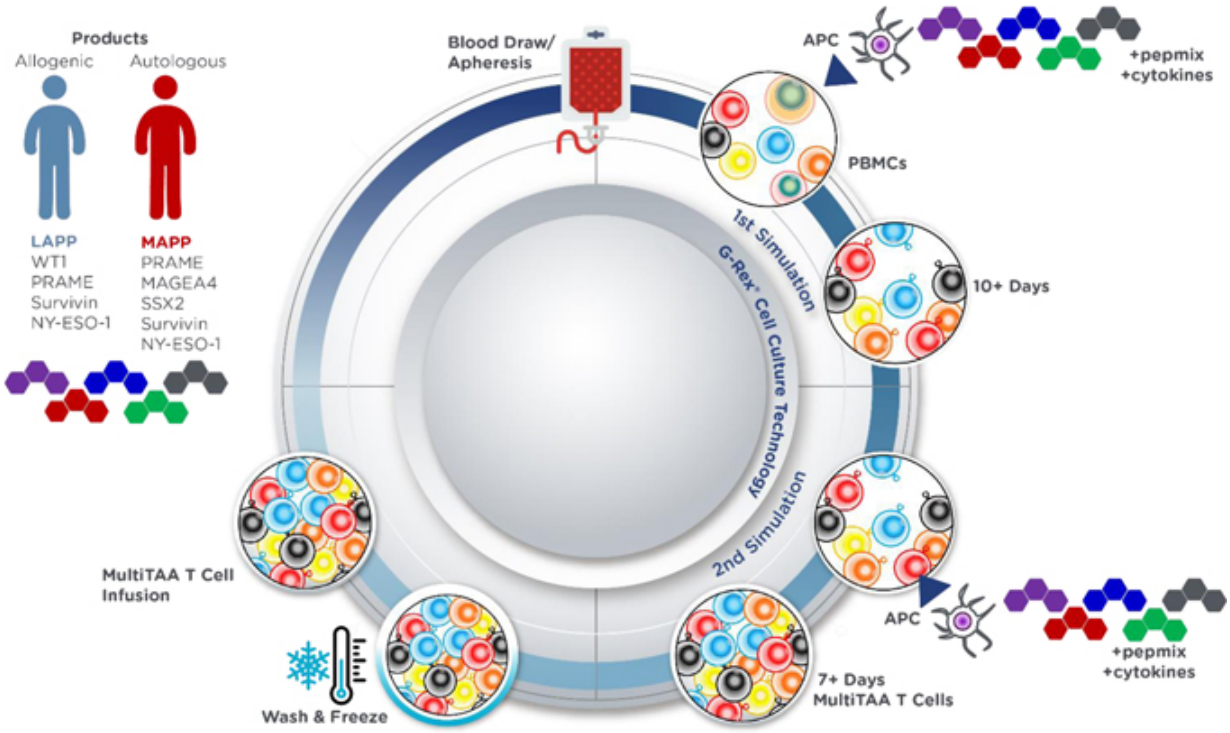
In addition, libraries of overlapping peptides ("pepmix") spanning the target antigens are combined and added to the cell culture. Each peptide within the pepmix represents a small segment of a target antigen, which a T cell might recognize. Each library represents the entire protein sequence of a target antigen, with each peptide in the pepmix 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, media 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® or the regular plasticware, PBMCs are co-cultured with antigen-presenting cells that have been exposed to the stimulating pepmixes. 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 antigens we are targeting.

Once cell manufacturing is complete, the product is tested for identity, sterility, phenotype, and safety 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 $5-20$ million cells per meter squared (compared to typical doses of $10-40$ 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.


Products
Allogenic
Autologous
LAPP
WT1
PRAME
Survivin
NY-ESO-1
MAPP
PRAME
MAGEA4
SSX2
Survivin
NY-ESO-1
Blood Draw/
Apheresis
APC
+pepmix
+cytokines
PBMCs
1st Simulation
G-Rex® Cell Culture Technology
10+ Days
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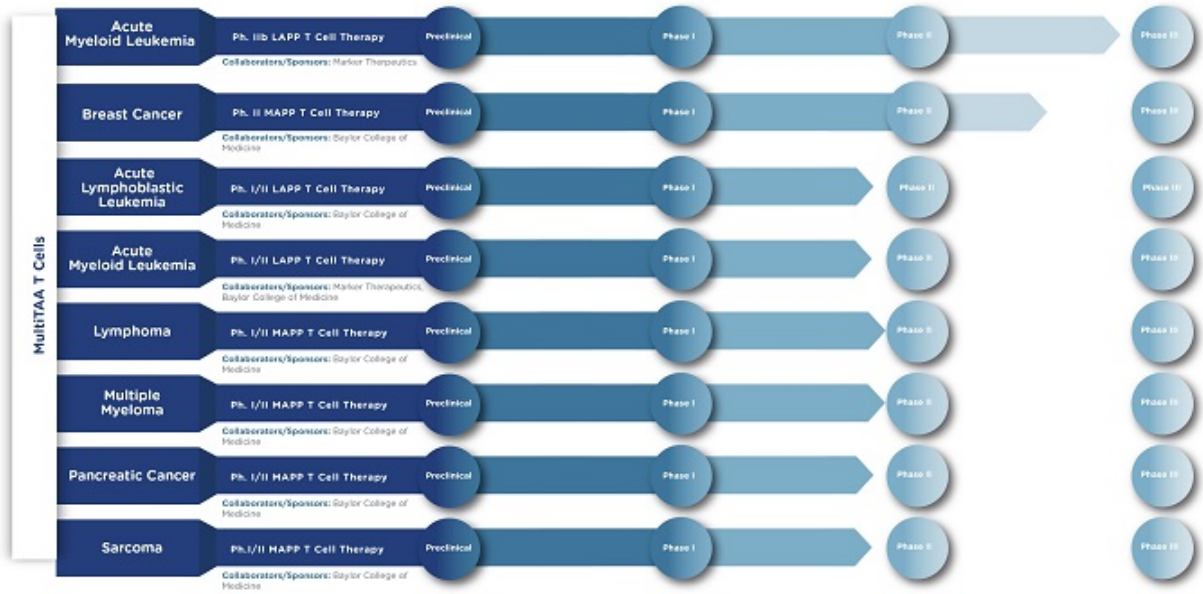
MultiTAA T Cells
MultiTAA T Cell
Infusion
Wash & Freeze

Clinical-stage MultiTAA T Cell Therapy



(1) Baylor College of Medicine

Our MAPP and LAPP product candidates identify and select for substantially all T cells that are specific for any peptide derived from the targeted antigens, thereby recognizing and killing heterogeneous tumors more effectively than single-antigen targeted approaches. These product candidates are currently in Phase I clinical trials for lymphoma, AML/myelodysplastic syndromes (“MDS”), and multiple myeloma (“MM”) at BCM and each of these programs is ready for initiation of Phase II. BCM has also initiated Phase I trials in acute lymphocytic leukemia (“ALL”), breast and pancreatic cancers.

In lymphoma, MAPP T cell therapy is currently in a Phase I trial that has treated 15 patients with active disease (“lymphoma active group”), of which all 15 patients had follow-up date beyond 3 months post-infusion, and 17 patients in remission (“lymphoma adjuvant group”). No SAEs or CRS have been observed in any of these patients.

Of the 15 patients in the lymphoma active group, 6 patients demonstrated a complete response, 3 patients had durable stable disease and 6 patients had transient disease stabilization (range 3 – 9 months). None of the complete responder patients has subsequently progressed after receiving MAPP T cells. The duration of response for the complete responder patients ranged from 5 months to over 5 years (ongoing). Of the 17 patients in the lymphoma adjuvant group, 15 patients were in a continuing complete response, at the time of data cutoff. The duration of response for these patients ranged from 3 to over 48 months.

In post-transplant AML, a setting where currently the only available alternative therapy is a donor lymphocyte infusion (“DLI”), we have seen significant therapeutic benefit for patients, without causing graft-versus-host disease (“GVHD”) — a frequent side effect of DLIs. LAPP T cell therapy is currently in a Phase I trial that has treated 6 patients with active disease (“AML/MDS active group”) after allogeneic hematopoietic stem cell transplant (“HSCT”), and 13 patients in remission after HSCT (“AML/MDS adjuvant group”), of which 11 patients were evaluable. One patient had a transient elevation in liver enzymes. Otherwise there were no possibly/probably related SAEs, nor episodes of CRS.

Of the 6 evaluable patients in the AML/MDS active group, 1 patient demonstrated a complete response which was durable for 13 months, 1 patient demonstrated a partial response that enabled that patient to receive a second allogeneic stem cell transplant, and 2 additional patients, who did not meet partial response criteria, experienced disease stabilization enabling a 2-month delay to next-line therapy. Two patients were non-responsive to MultiTAA therapy and progressed with relapsed/refractory disease. One patient demonstrated ongoing stable disease. The duration of response for the complete or partial response patients ranged from 7 to 11 months. Overall survival ranged from 4 to 21 months after T cell infusions. Of the 11 evaluable patients in the AML/MDS adjuvant group, 9 patients demonstrated a continued complete response. The duration of response for these patients ranged from 6 weeks to 2.5 years. Two patients saw local relapse in the central nervous system, but in both cases these patients were successfully treated with local therapy alone. One patient saw extramedullary relapse and was subsequently treated in the active disease arm of the trial, generating a CR that was durable for 13 months. One patient relapsed 8 months after receiving MultiTAA T cells but following a second allogeneic stem cell transplant this patient remains alive in relapse 1.5 years following his initial T cell infusion.

MAPP T cell therapy is also being evaluated at BCM in a Phase I/II trial for patients with MM. One arm of this trial assessed patients who received MAPP T cells more than 90 days after an autologous stem cell transplant ("ASCT"), while a second arm assessed patients who received MAPP T cells within 90 days of ASCT. 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 MAPP T cells immediately post ASCT.

Of the patients evaluated in the MM trial, there were 10 patients with residual active disease, 8 of whom were evaluable with greater than 3 months of available follow-up date. Of these evaluable patients, 1 patient demonstrated complete response and 3 patients demonstrated partial responses. The duration of response ranged from 6 to 29 months. Additionally, there were 8 patients treated in remission after ASCT and all were evaluable. Seven of the 8 patients remain in continuing complete remission. The duration of response for these patients ranged from 6 to 22 months.

BCM Exclusive License Agreement

On March 16, 2018, we entered into an exclusive license agreement (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 product candidates in exchange for an initial issuance of equity in the Company and future royalties and milestone payments.

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"

In partial consideration for the exclusive rights granted under the BCM License Agreement, prior to the Merger, Marker Cell issued shares of Marker Cell 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. 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 $500M, (2) $500M to $1.0B, (3) $1.0B and over, and (4) $2.0B 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 one-time 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 hitting certain net sales goals. Under the agreement, we may be obligated to make aggregate milestone payments of up to $64.85 million. We are also responsible for sublicensing fees. In addition, under the BCM License Agreement, we are responsible for reimbursing BCM for patent-related expenses. We will be responsible for filing, prosecuting and maintaining all patent applications and patents included in the licensed patent rights and 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) received by us or our stockholders in the liquidity event.

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 (i) 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 (ii) 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, (i) we have provided BCM with a written plan that is reasonably calculated to effect a cure, (ii) such plan is reasonably acceptable to BCM, in its sole but reasonable discretion, and (iii) 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 (i) become involved in insolvency, dissolution, bankruptcy or receivership proceedings affecting the operation of our business, (ii) make an assignment of all or substantially all of our assets for the benefit of creditors, or (iii) if a receiver or trustee is appointed for us and we shall, 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 its 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 and otherwise complies with the terms of the license agreement and sells all such licensed products within six months after the effective date of the termination.

On November 16, 2018, in furtherance of the BCM License Agreement and as contemplated by the terms thereof, we entered into a Sponsored Research Agreement ("SRA") with BCM, which provided for the conduct of research for us by credentialed personnel at BCM's Center for Cell and Gene Therapy. Each of Dr. Vera and Dr. Leen also serve as our Chief Development Officer and Chief Scientific Officer, respectively. The SRA has a four-year term and the research is to be supervised at BCM by co-investigators Dr. Vera and Dr. Leen. Pursuant to the SRA, we have agreed to pay BCM up to $256,272 for years one and two under the SRA with $76,882 paid up front and $153,764 paid in equal monthly installments over two years. Payments for years three and four are to be covered by an amendment

We will need to enter into additional agreements with BCM with respect to (i) a strategic alliance to advance pre-clinical research, early stage clinical trials, and Phase II 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.

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 (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.

On May 26, 2010, we signed a Technology Option Agreement with the Mayo Foundation in Rochester, Minnesota, for the evaluation of HER2/neu peptide epitopes as antigens for a breast cancer vaccine. The agreement grants us an exclusive worldwide option to become the exclusive licensee of the technology after completion of Phase I clinical trials.

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 acquired 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 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), and a $500,000 diligence fee had a Phase I clinical trial for a Licensed Product not been initiated prior to the fifth anniversary of the agreement and a $2,000,000 diligence fee if we fail to initiate a Phase II 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 (i) the practice or exercise of any rights and assignments granted by the agreement by or on behalf of us, any affiliate, or any sub-licensee; (ii) research, development, design, manufacture, distribution, use, sale, importation, exportation or other disposition of Licensed Products; (iii) our, any affiliates, or any sub-licensee's act or omission; and (iv) 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, (i) 45 days after providing us with notice of a material breach of this agreement, we fail to cure such breach, (ii) we fail to initiate a Phase III clinical trial for a Licensed Product prior to the tenth anniversary of the agreement, and (iii) 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 ("Mayo Foundation HER2/neu License") pursuant to which we acquired 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 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 and royalty fees (which will be subject to a minimum annual royalty fee once royalty fees are due).

We have agreed to indemnify and hold Mayo Foundation harmless from any damages caused as a result of (i) the practice or exercise of any rights and assignments granted by the agreement by or on behalf of us or any sub-licensee; (ii) research, development, design, manufacture, distribution, use, sale, importation, exportation or other disposition of Licensed Products; (iii) our or any sub-licensee's act or omission, including negligence or willful misconduct; and (iv) 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, (i) 30 days after providing us with notice of a material breach of this agreement, we fail to cure such breach, (ii) 90 days after providing us with written notice, we fail to meet either of the following diligence events (a) initiate a Phase II clinical trial for a Licensed Product prior to the second anniversary of the agreement and, once initiated, keep current on all of our Phase II funding obligations and (b) initiate a Phase IIB or III clinical trial for a Licensed Product prior to the fifth anniversary of the agreement, (iii) we fail to make a sale of a Licensed Product by May 4, 2026, and (iv) 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 ("Mayo Foundation FRa License") pursuant to which we acquired 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 ("Ayer") that was issued pursuant to a Technology Option Agreement that Ayer entered into with the Mayo Foundation on March 18, 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 express Folate Receptor Alpha. This license is an exclusive license for products that are based on the 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 and royalty fees (which will be subject to a minimum annual royalty fee once royalty fees are due).

We have agreed to indemnify and hold Mayo Foundation harmless from any damages caused as a result of (i) 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; (ii) research, development, design, manufacture, distribution, use, sale, importation, exportation or other disposition of Licensed Products; (iii) our or any sub-licensee's act or omission, including negligence or willful misconduct; and (iv) 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, (i) 30 days after providing us with notice of a material breach of this agreement, we fail to cure such breach, (ii) 90 days after providing us with written notice, we fail to meet either of the following diligence events (a) initiate a Phase II 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 II funding obligations and (b) initiate a Phase IIB or III clinical trial for a Licensed Product prior to the 5th anniversary of the Mayo Foundation FRa License, (iii) we fail to make a sale of a Licensed Product by July 21, 2025 and (iv) 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 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. The information provided in this section should be reviewed in the context of the information disclosed elsewhere in this annual report under "Risk Factors". 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 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 17, 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: (i) later-granted patents on processes and intermediates related to the most economical method of manufacture of the active ingredient of such product; (ii) patents relating to the use of such product; (iii) patents relating to novel compositions and formulations; and (iv) in the United States and certain other countries, 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 "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.

Manufacturing

Our manufacturing strategy is to contract with BCM and other third parties to manufacture our MultiTAA-specific T cells, as well as the raw materials, our active pharmaceutical ingredients ("API") and finished solid dose products for our peptide vaccines for clinical and ultimately commercial uses. We currently do not operate manufacturing facilities for clinical or commercial production of our drug candidates. In addition, we expect for the foreseeable future to continue to rely on third parties for the manufacture of our clinical and commercial supply of MultiTAA-specific T cells, and of the raw materials, API and finished drug product for our peptide vaccines. Of note, we anticipate that product manufacturing of MultiTAA-specific cells in support of Phase I/II clinical trials will be conducted at BCM within its GMP cell manufacturing facility.

In this manner, we expect to continue to build and maintain our supply chain and quality assurance resources.

Manufacturing of our Products

Our supply chain for manufacturing raw materials, API, peptide vaccines, as well as MultiTAA-specific T cell products 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.

We contract with third parties to manufacture our peptide vaccines and MultiTAA-specific T cells for clinical purposes. 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. Similarly, BCM is currently the sole manufacturer of our MultiTAA-specific T cells.

We may not be able to obtain sufficient quantities of any of our raw materials or peptide vaccine candidates if our designated manufacturers do not have the capacity or capability to manufacture our products according to our schedule and specifications. If any of these single source suppliers become unable or unwilling to supply us with API or finished product that complies with applicable regulatory requirements, we could incur significant delays in our clinical trials which could have a material adverse effect on our business. Similarly, if BCM become unable or unwilling to manufacture our MultiTAA-specific T cells that comply with applicable regulatory requirements, we could incur significant delays in our clinical trials which could have a material adverse effect on our business.

For our future products, we may continue contracting third-party suppliers to manufacture sufficient quantities of our peptide vaccine and MultiTAA-specific T cell candidates for clinical and commercial supply. If we are unable to contract for large scale manufacturing with third parties on acceptable terms for our future products or develop manufacturing capabilities internally, our ability to conduct large scale clinical trials and ultimately meet customer demand for commercial products will be adversely affected.

Third-party Manufacturers

Our third-party manufacturers are independent entities subject to their own unique operational and financial risks which are out of our control. If our third-party manufacturers fail to perform as required, this could impair our ability to deliver our products on a timely basis or cause delays in our clinical trials and applications for regulatory approval. To the extent that these risks materialize and affect their performance obligations to us, our financial results may be adversely affected.

While we believe there are multiple third-party suppliers available to provide most of the materials and services needed to manufacture our product candidates, and proper inventory planning is required for the materials that cannot be second-sourced, there is always a risk that we may underestimate demand and that our manufacturing capacity through third-party manufacturers may not be sufficient.

Access to Supplies and Materials

Our third-party manufacturers need access to certain supplies and products to manufacture our drug candidates. If delivery of material from their suppliers were interrupted for any reason or if they are unable to purchase sufficient quantities of raw materials used to manufacture our drug candidates, it could significantly delay our drug candidates in development for clinical trials.

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., Genzyme Molecular Oncology, Immune Design, Oncothyreon, Celldex, BN Immunotherapeutics, Immunocellular, SELLAS Life Sciences Group, Inc. (formerly) Galena BioPharma, 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, Torque Therapeutics, AdaptImmune, Mana 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.

Government Regulation

Our ongoing research and development activities and any manufacturing and marketing of our drug candidates are subject to extensive regulation by numerous governmental authorities in the United States and other countries. Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

The failure to comply with applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice ("DOJ"), or other governmental entities. The government regulations below may apply to any of our product candidates or anticipated pipeline of products.

FDA Review and Approval Process

The regulatory review and approval process is lengthy, expensive and uncertain. The steps generally required before a drug may be marketed in the United States include:

- preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice ("GLP") and Good Manufacturing Practice ("GMP") regulations;
- submission to the FDA of an Investigational New Drug application ("IND") for human clinical testing, which must become effective before human clinical trials may commence;
- performance of adequate and well-controlled clinical trials in three phases, as described below, to establish the safety and efficacy of the drug for each indication;
- submission of a New Drug Application ("NDA") or Biologics License Application ("BLA") to the FDA for review;
- random inspections of clinical sites to ensure validity of clinical safety and efficacy data;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices;
- FDA approval of the NDA or BLA; and
- payment of user and establishment fees, if applicable.

Similar requirements exist within foreign agencies as well. The time required to satisfy FDA requirements or similar requirements of foreign regulatory agencies may vary substantially based on the type, complexity and novelty of the product or the targeted disease.

Preclinical testing includes laboratory evaluation of product pharmacology, drug metabolism, and toxicity which includes animal studies, to assess potential safety and efficacy as well as product chemistry, stability, formulation, development, and testing. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time, the FDA raises safety concerns or questions about the conduct of the clinical trial(s) included in the IND, which are further parsed into hold and non-hold questions/issues. In the case of hold issues, the IND sponsor and the FDA must resolve all FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators and in accordance with good clinical practices regulations covering the protection of human subjects. These regulations require all research subjects to provide informed consent. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND and each trial must be reviewed and approved by an Institutional Review Board ("IRB") before it can begin.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase I usually involves the initial introduction of the investigational drug into healthy volunteers to evaluate its safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase II usually involves clinical trials in a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse effects and safety risks, and evaluate and gain preliminary evidence of the efficacy of the drug for specific indications. Phase III clinical trials usually further evaluate clinical efficacy and safety by testing the drug in its final form in an expanded patient population, providing statistical evidence of efficacy and safety, and providing an adequate basis for labeling. We cannot guarantee that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the IRB, or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

As a separate amendment to an IND, a clinical trial sponsor may submit to the FDA a request for a Special Protocol Assessment ("SPA"). Under the SPA procedure, a sponsor may seek the FDA's agreement on the design and size of a clinical trial intended to form the primary basis of an effectiveness claim. If the FDA agrees in writing, its agreement may not be changed after the trial begins, except when agreed by FDA or in limited circumstances, such as when a substantial scientific issue essential to determining the safety and effectiveness of a drug candidate is identified after a Phase III clinical trial is commenced and agreement is obtained with the FDA. If the outcome of the trial is successful, the sponsor will ordinarily be able to rely on it as the primary basis for approval with respect to effectiveness. However, additional trials could also be requested by the FDA to support approval, and the FDA may make an approval decision based on a number of factors, including the degree of clinical benefit as well as safety. The FDA is not obligated to approve an NDA or BLA as a result of a SPA agreement, even if the clinical outcome is positive.

Even after initial FDA approval has been obtained, post-approval trials or Phase IV studies, may be required to provide additional data, and will be required to obtain approval for the sale of a product as a treatment for a clinical indication other than that for which the product was initially tested and approved. Also, the FDA will require post-approval safety reporting to monitor the side effects of the drug. Results of post-approval programs may limit or expand the indication or indications for which the drug product may be marketed. Further, if there are any requests for modifications to the initial FDA approval for the drug, including changes in indication, manufacturing process, manufacturing facilities, or labeling, a supplemental NDA or BLA may be required to be submitted to the FDA.

The length of time and related costs necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or cause the costs of these clinical trials to increase, include:

- slow patient enrollment due to the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the study, competition with clinical trials for other drug candidates or other factors;
- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials;
- delays in approvals from a study site's IRB;
- longer than anticipated treatment time required to demonstrate effectiveness or determine the appropriate product dose;
- lack of sufficient supplies of the drug candidate for use in clinical trials;
- adverse medical events or side effects in treated patients; and

· lack of effectiveness of the drug candidate being tested.

Any drug is likely to produce some toxicities or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for sufficiently long periods of time. Unacceptable toxicities or side effects may occur at any dose level. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates and could ultimately prevent their marketing approval by the FDA or foreign regulatory authorities for any or all targeted indications.

Fast Track Designation and Accelerated Approval

The FDA's fast track and breakthrough therapy designation programs are intended to facilitate the development and expedite the review of drug candidates intended for the treatment of serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for these conditions. Under these programs, FDA can, for example, review portions of an NDA or BLA for a drug candidate before the entire application is complete, thus potentially beginning the review process at an earlier time.

We cannot guarantee that the FDA will grant any of our requests for fast track or breakthrough therapy designations, that any such designations would affect the time of review or that the FDA will approve the NDA or BLA submitted for any of our drug candidates, whether or not these designations are granted. Additionally, FDA approval of a fast track/breakthrough product can include restrictions on the product's use or distribution (such as permitting use only for specified medical conditions or limiting distribution to physicians or facilities with special training or experience). Approval of such designated products can be conditioned on additional clinical trials after approval.

The FDA is required to facilitate the development, and expedite the review, of biologics that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment, and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new biologic candidate may request that the FDA designate the candidate for a specific indication as a fast track biologic concurrent with, or after, the filing of the IND for the candidate. The FDA must determine if the biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

Under the fast track program and FDA's accelerated approval regulations, the FDA may approve a biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon 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.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A biologic candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval trials, or confirm a clinical benefit during post-marketing trials, will allow the FDA to withdraw the biologic from the market on an expedited basis. All promotional materials for biologic candidates approved under accelerated regulations are subject to prior review by the FDA.

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with the FDA, the FDA may initiate review of sections of a fast track product's BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the BLA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Breakthrough Therapy Designation

The FDA is also required to expedite the development and review of the application for approval of biological products that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

Under the breakthrough therapy program, the sponsor of a new biologic candidate may request that the FDA designate the candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the biologic candidate. The FDA must determine if the biological product qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request.

Sponsors submit the results of preclinical studies and clinical trials to the FDA as part of an NDA or BLA. NDAs and BLAs must also contain extensive product manufacturing information and proposed labeling. Upon receipt, the FDA initially reviews the NDA or BLA to determine whether it is sufficiently complete to initiate a substantive review. If the FDA identifies deficiencies that would preclude substantive review, the FDA will refuse to accept the NDA or BLA and will inform the sponsor of the deficiencies that must be corrected prior to resubmission. If the FDA accepts the submission for review (then deemed a "filing"), the FDA typically completes the NDA or BLA review within a pre-determined time frame. Under the Prescription Drug User Fee Act, the FDA agrees to review NDAs and BLAs under either a standard review or priority review. FDA procedures provide for priority review of NDAs and BLAs submitted for drugs that, compared to currently marketed products, if any, offer a significant improvement in the treatment, diagnosis or prevention of a disease. The FDA seeks to review NDAs and BLAs that are granted priority status more quickly than NDAs and BLAs given standard review status. The FDA's stated policy is to act on 90% of priority NDAs and BLAs within eight months of receipt (or six months after filing, which occurs 60 days after NDA or BLA submission). Although the FDA historically has not met these goals, the agency has made significant improvements in the timeliness of the review process. NDA and BLA review often extends beyond anticipated completion dates due to FDA requests for additional data or clarification, the FDA's decision to have an advisory committee review, and difficulties in scheduling an advisory committee meeting. The recommendations of an advisory committee are not binding on the FDA.

To obtain FDA approval to market a product, we must demonstrate that the product is safe and effective for the patient population that will be treated. If regulatory approval of a product is granted, the approval will be limited to those disease states and conditions for which the product is safe and effective, as demonstrated through clinical trials. Marketing or promoting a drug for an unapproved indication is prohibited. Furthermore, approval may entail requirements for post-marketing studies or risk evaluation and mitigation strategies, including the need for patient and/or physician education, patient registries, medication or similar guides, or other restrictions on the distribution of the product. If an NDA or BLA does not satisfy applicable regulatory criteria, the FDA may deny approval of an NDA or BLA or may issue a complete response, and require, among other things, additional clinical data or analyses.

In Canada, the Therapeutic Products Directorate and the Biologics and Genetic Therapies Directorate of Health Canada ("HC") ensure that clinical trials are properly designed and undertaken and that subjects are not exposed to undue risk. Regulations define specific Investigational New Drug submission ("IND") application requirements, which must be complied with before a new drug can be distributed for trial purposes. The directorates currently review the safety, efficacy and quality data submitted by the sponsor and approve the distribution of the drug to the investigator. The sponsor of the trial is required to maintain accurate records, report adverse drug reactions, and ensure that the investigator adheres to the approved protocol. Trials in humans should be conducted according to generally accepted principles of good clinical practice. Management believes that these standards provide assurance that the data and reported results are credible and accurate, and that the rights, integrity, and privacy of clinical trial subjects are protected.

Sponsors wishing to conduct clinical trials in Phases I through III of development must apply under a 30-day default system. Applications must contain the information described in the regulations, including: a clinical trial attestation; a protocol; statements to be contained in each informed consent form that set out the risks posed to the health of clinical trial subjects as a result of their participation in the clinical trial; an investigator's brochure; applicable information on excipients (delivery vehicles); and chemistry and manufacturing information.

The sponsor can proceed with the clinical trial if the directorates have not objected to the sale or importation of the drug within 30 days after the date of receipt of the clinical trial application and Research Ethics Board approval for the conduct of the trial at the site has been obtained. Additional information is available on Health Canada's website - *www.hc-sc.gc.ca*.

Outside the United States and Canada, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union ("EU"), registration procedures are available to companies wishing to market a product in more than one EU member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization may be granted. This foreign regulatory approval process involves all of the risks associated with FDA approval discussed above and may also include additional risks.

Orphan Drug Designation

The Orphan Drug Act provides incentives to manufacturers to develop and market drugs for rare diseases and conditions affecting fewer than 200,000 persons in the United States at the time of application for orphan drug designation. The first developer to receive FDA marketing approval for an orphan drug is entitled to a seven-year exclusive marketing period in the United States for the orphan drug indication. However, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven-year exclusive marketing period.

Under the FDA Modernization Act of 1997, designation as a Fast Track product for a new drug or biological product means that the FDA will take such actions as are appropriate to expedite the development and review of the application for approval of such product.

Legislation similar to the Orphan Drug Act has been enacted in other countries outside of the United States, including the EU. The orphan legislation in the EU is available for therapies addressing conditions that affect five or fewer out of 10,000 persons, are life-threatening or chronically debilitating conditions and for which no satisfactory treatment is authorized. The market exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product does not justify maintenance of market exclusivity.

Disclosure of Clinical Trial Information

Sponsors of human clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the Public Health Service Act ("PHSA") emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Regulation of Manufacturing Process

Even when NDA or BLA approval is obtained, a marketed product, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the FDA. The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product, manufacturer or facility, including costly recalls or withdrawal of the product from the market. Manufacturing facilities are always subject to inspection by the applicable regulatory authorities.

We and our third-party manufacturers are subject to current Good Manufacturing Practices ("GMP"), which are extensive regulations governing manufacturing processes, including but not limited to stability testing, record-keeping and quality standards as defined by the FDA and the European Medicines Agency. Similar regulations are in effect in other countries. Manufacturing facilities are subject to inspection by the applicable regulatory authorities. These facilities, whether our own or our contract manufacturers, must be inspected before we can use them in commercial manufacturing of our related products. We or our contract manufacturers may not be able to comply with applicable GMP and FDA or other regulatory requirements. If we or our contract manufacturers fail to comply, we or our contract manufacturers may be subject to legal or regulatory action, such as suspension of manufacturing, seizure of product, or voluntary recall of product. Furthermore, continued compliance with applicable Good Manufacturing Practices will require continual expenditure of time, money and effort on the part of us or our contract manufacturers in the areas of production and quality control and record keeping and reporting to ensure full compliance.

Post-Approval Regulation

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the drug and other reporting, advertising and promotion restrictions. The FDA's rules for advertising and promotion require, among other things, that our promotion be fairly balanced and adequately substantiated by clinical studies, and that we not promote our products for unapproved uses. We must also submit appropriate new and supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. On its own initiative, the FDA may require changes to the labeling of an approved drug if it becomes aware of new safety information that the agency believes should be included in the approved drug's labeling. The FDA also enforces the requirements of the Prescription Drug Marketing Act ("PDMA") which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

In addition to inspections related to manufacturing, we may be subject to periodic unannounced inspections by the FDA and other regulatory bodies related to the other regulatory requirements that apply to marketed drugs manufactured or distributed by us. The FDA also may conduct periodic inspections regarding our review and reporting of adverse events, or related to compliance with the requirements of the PDMA concerning the handling of drug samples. When the FDA conducts an inspection, the inspectors will identify any deficiencies they believe exist in the form of a notice of inspectional observations. The observations may be more or less significant. If we receive a notice of inspectional observations, we likely will be required to respond in writing, and may be required to undertake corrective and preventive actions in order to address the FDA's concerns.

There are a variety of state laws and regulations that apply in the states or localities where our drug candidates may be marketed. For example, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in that state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Any applicable state or local regulations may hinder our ability to market, or increase the cost of marketing, our products in those states or localities.

The FDA's policies may change and additional government regulations may be enacted which could impose additional burdens or limitations on our ability to market products after approval. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations which could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation which might arise from future legislative or administrative action, either in the United States or abroad.

Marketing Exclusivity

The FDA may grant five years of exclusivity in the United States for the approval of NDAs for new chemical entities, and three years of exclusivity for supplemental NDAs, for among other things, new indications, dosages or dosage forms of an existing drug if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the supplemental application. Additionally, six months of marketing exclusivity in the United States is available if, in response to a written request from the FDA, a sponsor submits and the agency accepts requested information relating to the use of the approved drug in the pediatric population. The six-month pediatric exclusivity is added to any existing patent or non-patent exclusivity period for which the drug is eligible. Orphan drug products are also eligible for pediatric exclusivity if the FDA requests and the company completes pediatric clinical trials. Under the Biologics Price Competition and Innovation Act, the FDA may grant 12 years of data exclusivity for innovative biological products.

Health Law Compliance

In addition to FDA laws and regulations, we must also comply with various federal and state laws and regulations pertaining to healthcare "fraud and abuse" laws which govern, among other things, our relationships with healthcare providers, and organizations such as specialty pharmacies, wholesalers and group purchasing organizations relating to the marketing and pricing of prescription drug products. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, and physician payment sunshine laws.

The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated.

Federal false claims and false statement laws, including the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. Entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, or for providing medically unnecessary services or items.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, require certain types of individuals and entities to protect the privacy, security, and electronic exchange of certain patient data.

The federal Physician Payments Sunshine Act 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 the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members.

Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Additionally, we may be subject to 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. Further, we may be subject to 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, as well as 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. If our operations are found to be in violation of any of these federal, state or foreign laws or regulations, we may be subject to penalties, including without limitation, administrative or civil penalties, imprisonment, damages, fines, disgorgement, exclusion from participation in government healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, or the curtailment or restructuring of our operations.

There are also an increasing number of state laws that require manufacturers to make reports to those states on certain pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the state authorities.

Healthcare Reform and Reimbursement and Pricing Controls

There has been an increased focus on drug pricing in recent years in the United States. Although there are no direct government price controls over private sector purchases in the United States, there are rebates and other financial requirements for federal and state health care programs. The Medicare Modernization Act, enacted in December 2003, established the Medicare Part D outpatient prescription drug benefit, which is provided primarily through private entities that attempt to negotiate price concessions from pharmaceutical manufacturers. The health care reform legislation enacted in 2010, known as the Affordable Care Act, requires drug manufacturers to pay 50% of the Medicare Part D coverage gap, also known as the "donut hole," on prescriptions for branded products filled when the beneficiary reaches this coverage. The Deficit Reduction Act of 2005 resulted in changes to the way drug prices are reported to the government and the formula using such information to calculate the required Medicaid rebates. The Affordable Care Act increased the minimum basic Medicaid rebate for branded prescription drugs from 15.1% to 23.1% and requires pharmaceutical manufacturers to pay states rebates on prescription drugs dispensed to Medicaid managed care enrollees. In addition, the Affordable Care Act increased the additional Medicaid rebate on "line extensions" (such as extended release formulations) of solid oral dosage forms of branded products, revised the definition of average manufacturer price by changing the classes of purchasers included in the calculation, and expanded the entities eligible for discounted pricing under the federal 340B drug pricing program. Current orphan drugs are excluded from the expanded 340B hospitals eligible for discounts.

The Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. The fee (which is not deductible for federal income tax purposes) is based on the manufacturer's market share of sales of branded drugs and biologics (excluding orphan drugs) to, or pursuant to coverage under, specified U.S. government programs. The Affordable Care Act also contains a number of provisions, including provisions governing the way that health care is financed by both governmental and private insurers, enrollment in federal health care programs, reimbursement changes, the increased use of comparative effectiveness research in health care decision-making, and enhancements to fraud and abuse requirements and enforcement, that are affecting existing government health care programs and will result in the development of new programs. The Affordable Care Act also contains requirements for manufacturers to publicly report certain payments or other transfers of value made to physicians and teaching hospitals. We are unable to predict the future course of federal or state health care legislation and regulations, including regulations that will be issued to implement provisions of the Affordable Care Act. The Affordable Care Act and further changes in the law or regulatory framework that reduce our revenues or increase our costs could also have a material adverse effect on our business, financial condition and results of operations and cash flows.

Public and private health care payors control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. Payors may require physicians to seek approval from them before a product will be reimbursed or covered, commonly referred to as prior authorization. In particular, many public and private health care payors limit reimbursement and coverage to the uses of a drug that is either approved by the FDA or appears in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA. For example, in the case of Medicare Part D coverage for oncology drugs, the Medicare Modernization Act, with certain exceptions, provides for Medicare coverage of unapproved uses of an FDA-approved drug if the unapproved use is reasonable and necessary and is supported by one or more citations in CMS-approved compendia, such as the National Comprehensive Cancer Network Drugs and Biologics Compendium. Different pricing and reimbursement schemes exist in other countries. For example, in the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines but monitor and control company profits and may limit or restrict reimbursement. The downward pressure on health care costs in general, and prescription drugs in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the actions of the National Institute for Clinical Excellence in the United Kingdom, which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries, cross-border imports from low-priced markets (parallel imports) exert a commercial pressure on pricing within a country.

Other Federal and State Regulatory Requirements

The Centers for Medicare & Medicaid Services, or CMS, has issued a final rule that implements a statutory requirement under the Healthcare Reform Act that requires applicable manufacturers of drugs, devices, biologicals, or medical supplies that are covered under Medicare, Medicaid, or the Children's Health Insurance Program, or CHIP, to begin collecting and reporting annually information on payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members. Manufacturers had to begin collecting information in 2013, with the first reports due in 2014. On September 30, 2014, CMS posted the first round of data in searchable form on a public website. Failure to submit required information may result in civil monetary penalties.

In addition, several states now require prescription drug companies to report expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual physicians in these states. Other states prohibit various other marketing-related activities. Still other states require the posting of information relating to clinical trials and their outcomes. In addition, California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

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, 2018, we had 11 full-time employees. Three were in research and development and eight 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.

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 Related to our Business and Intellectual Property

We are a development stage company with a history of operating losses.

We are a clinical-stage immunotherapy company with a history of losses, and it 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 products. We anticipate that our ongoing operational costs will increase significantly as we continue conducting our clinical development program. Our deficit will continue to grow during our drug development period. 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 depends upon our successful efforts to raise additional financing.

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. As of December 31, 2018, we had an accumulated deficit of approximately $306.1 million since inception. We expect to spend substantial additional sums on the continued administration and research and development of licensed and proprietary products 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 does 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.

Our future success is highly dependent upon our key personnel, and our ability to attract, retain, and motivate additional qualified personnel.

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, Ann Leen, Ph.D., our Chief Scientific Officer, Juan Vera, M.D., our Chief Development Officer, and Mythili Koneru, M.D., Ph.D. our Senior Vice President, Clinical Development, 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 other products, and unable to adequately address our management needs.

Our strategic relationship with Baylor College of Medicine, or BCM, is dependent, in part, upon our relationship with key medical and scientific personnel and advisors.

Our MultiTAA 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. In addition to Dr. Brenner, Marker Cell's founders include Ann Leen, Ph.D., Juan Vera, M.D., Helen Heslop, M.D., DSc (Hon) and Cliona Rooney, Ph.D., who all have significant experience in this field and are all affiliated with the Center for Cell and Gene Therapy at BCM. Dr. Leen and Dr. Vera are our Chief Scientific Officer and Chief Development Officer, respectively. In addition, Dr. Brenner, Dr. Heslop and Dr. Rooney have joined our newly-formed Scientific Advisory Board.

Our strategic relationship with BCM is dependent, in part, on our relationship with these key employees and advisors, and in particular Dr. Leen and Dr. Vera, who are also employed with the Center for Cell and Gene Therapy at BCM. If we lose Dr. Leen or Dr. Vera, or if either leaves their position at BCM, our relationship with BCM may deteriorate, and our business could be harmed.

We, and certain of our key medical and scientific personnel, will need additional agreements in place with BCM to expand our development, manufacture, and clinical trial efforts.

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 product candidates, we will need to enter into additional agreements with BCM with respect to (i) a strategic alliance to advance pre-clinical research, early stage clinical trials, and Phase II 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.

The multiple roles of certain of our officers and directors could limit their time and availability to us, and create, or appear to create, conflicts of interest.

Dr. Leen and Dr. Vera are employees of BCM and are contractually obligated to spend a significant portion of their time with BCM. In addition, Dr. Leen and Dr. Vera are co-founders and members of ViraCyte and perform services from time to time for ViraCyte LLC ("ViraCyte"). ViraCyte is owned by the same principal stockholder group as Marker Cell prior to the Merger and has technology which is being developed under a license agreement with BCM by the same research group at BCM. ViraCyte is a clinical-stage biopharmaceutical company, which is investigating and developing virus-specific T cell therapy technology for the prevention and/or treatment of viral infections. Accordingly, Dr. Leen and Dr. Vera may have other commitments that would, at times, limit their availability to us. Other research being conducted by Dr. Leen and 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 member, director and officer of ViraCyte and is a director of the Company. Dr. Leen and Dr. Vera are also co-founders and members of ViraCyte, and perform services for ViraCyte from time to time, and Dr. Vera is a director of the Company. All of these individuals have certain fiduciary or other obligations to us and certain fiduciary or other obligations to ViraCyte and, in the case of Dr. Leen and 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 ViraCyte. A conflict of interest also may arise concerning the timing of the parties' planned and ongoing clinical trials, investigational new drug application filings and the parties' opportunities for marketing their respective product candidates. In addition, they may be faced with decisions that could have different implications for us than for ViraCyte. 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.

We have not yet sold any products or received regulatory approval to sell our products.

We have no approved products or products 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. Without revenue, we can only finance our operations through debt and equity financings.

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

Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical 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 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 products, such as with respect to lack of toxicity and manufacturing cost estimates, are based on early limited clinical trials and current manufacturing processes at BCM and may prove to be incorrect. 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. A number of 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 II, Phase III, 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.

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.

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.

We are subject to numerous risks inherent in conducting clinical trials.

We outsource some of the management of our clinical trials to third parties. Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services, place substantial responsibilities on these parties that, if unmet, could result in delays in, or termination of, our clinical trials. If any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, agents. We cannot be certain that we will successfully recruit enough patients to complete our clinical trials nor that we will reach our primary endpoints. Delays in recruitment, lack of clinical benefit or unacceptable side effects would delay our clinical trials.

We, or our regulators, may suspend or terminate our clinical trials for a variety of reasons. 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. 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 successful development of immunotherapies is highly uncertain.

Successful development of biopharmaceuticals is highly uncertain and depends on numerous factors, many of which are beyond our control. Immunotherapies that appear promising in the early phases of development may fail to reach the market for several reasons including:

- clinical study results that may show the immunotherapy to be less effective than expected (e.g., the study failed to meet its primary endpoint) or to have unacceptable side effects;

- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis, or Biologics License Application ("BLA") preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues;

- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the immunotherapy uneconomical; and

- the proprietary rights of others and their competing products and technologies that may prevent the immunotherapy from being commercialized.

Success in preclinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one immunotherapy to the next and may be difficult to predict.

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 once approved, market acceptance and commercial success would be reduced.

In addition, if one of our products is approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with current Good Manufacturing Practices ("cGMPs") and current Good Clinical Practices ("cGCPs") for any clinical trials that we conduct post-approval. In addition, there is always the risk that we or a regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates' post-market approval could have a material adverse effect on our business, financial condition and results of operations.

It may take longer and cost more to complete our clinical trials than we project, or we may not be able to complete them at all.

For budgeting and planning purposes, we have projected the dates for the commencement, continuation, and completion of our various clinical trials. However, a number of factors, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, and competition for such eligible patents from other clinical trials, may cause significant delays. We may not commence or complete clinical trials involving any of our products as projected or may not conduct them successfully.

During the second half of 2012, BCM began enrollment of the investigator-sponsored, Phase 1 clinical trial to establish the feasibility of one of our lead products, MAPP, and to assess its overall safety, inclusion of multiple antigens, and dosage tolerance in patients with lymphoma. During the second quarter of 2016, BCM began enrollment of the investigator-sponsored Phase 1 clinical trial to establish the feasibility of one of our lead products, LAPP, and to assess its overall safety, inclusion of multiple antigens, and dosage tolerance in patients with acute myeloid leukemia ("AML")/myelodysplastic syndromes ("MDS"). However, 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.

We rely on medical institutions, academic institutions, and clinical research organizations to conduct, supervise, or monitor some or all aspects of clinical trials involving our products. We may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. If we fail to commence or complete, or experiences delays in, any of our planned clinical trials, we may experience delays in our clinical development and/or commercialization plans.

In particular, while BCM will continue to support our trials with production of MAPP and LAPP T cells under contract, we anticipate that we will have to rely on third parties (contract manufacturing organizations or "CMOs") or internal facilities yet to be developed for the commercial manufacture of our multi-antigen specific T cell therapy products for clinical trials and eventual licensure. If they fail to commence or complete, or experience delays in, manufacturing our multi-antigen specific T cell therapy products, our planned clinical trials with respect to such products will be delayed, and we may experience delays in our clinical development and/or commercialization plans.

Clinical trials are expensive, time-consuming, and difficult to design and implement, and our clinical trial costs may be higher than for more conventional therapeutic technologies or drug products.

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 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.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.

The clinical trials of our product candidates are, and the manufacturing and marketing of our products 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 drug 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. The risk/benefit profile required for product licensure will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also adequate duration of response, a delay in the progression of the disease, and/or an improvement in survival. For example, response rates from the use of our product candidates may not be sufficient to obtain regulatory approval unless we can also show an adequate duration of response. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of studies in one set of patients or line of treatment may not be predictive of those obtained in another. In addition, we expect that there may be greater variability in results for products processed and administered on a patient-by-patient basis, as anticipated for our MultiTAA T cell product candidates, than for “off-the-shelf” products, like many other drugs. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

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 trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial’s primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;

- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics not involving cell-based immunotherapy;
- clinicians' and patients' perceptions of the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete a clinical trial.

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. 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. Because the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods of cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and approved immunotherapies, rather than enroll patients in any future clinical trial. In addition, potential enrollees in our MultiTAA T cell product clinical trials may opt to participate in alternate clinical trials because of the length of time between the time that the patient's or the donor's blood is drawn and the time when the product is infused back into the patient.

Even if we can enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If unacceptable toxicities arise in the development of our product candidates, we or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. 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 T cell therapy products, are not normally encountered in the general patient population and by medical personnel. Any of these occurrences may harm our business, financial condition and prospects significantly.

Our MultiTAA T cell therapy research and development efforts are to a large extent dependent upon BCM's investigators.

It will take time to fully develop our research and development infrastructure. We currently depend upon and will continue to depend upon independent investigators and collaborators, such as BCM, and which in the future may include other universities, medical institutions, and strategic partners, to conduct our preclinical studies and clinical trials. If we need to enter into alternative arrangements, our product development activities would be delayed. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties.

We expect to use the results of BCM's research to support the filing with the FDA of IND applications to conduct more advanced clinical trials of our products. However, we have limited control over the nature or timing of BCM's clinical trials and limited visibility into their day-to-day activities. The research we are funding constitutes only a small portion of BCM's overall research. Other research being conducted by Dr. Ann Leen and Dr. Juan Vera may at times receive higher priority than research on our programs. These factors could adversely affect the timing of our IND filings and our ability to conduct future planned clinical trials.

We will be unable to commercialize our products if our trials are not successful.

Our research and development programs are at an early stage. We must demonstrate our products' safety and efficacy in humans through extensive clinical testing. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of our products, including but not limited to the following:

- safety and efficacy results in various human clinical trials reported in scientific and medical literature may not be indicative of results we obtain in our clinical trials;
- after reviewing trial results, we or our collaborators may abandon products that we might previously have believed to be promising;
- we, our collaborators or regulators, may suspend or terminate clinical trials if the participating subjects or patients are being exposed to unacceptable health risks; and
- the effects our potential products have may not be the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

Clinical testing is very expensive, can take many years, and the outcome is uncertain. For example, it can take as much as 12 months or more before we learn the results from any clinical trial using our MultiTAA T cell therapy. The data collected from our clinical trials may not be sufficient to support approval by the FDA of our MultiTAA T cell therapy-based product candidates for the treatment of hematological malignancies, or our Folate Receptor Alpha (TPIV200) product for breast and ovarian cancers, HER2/neu peptide antigen product (TPIV100/110) or possible future clinical trials utilizing our DNA expression PolyStart™ product. The clinical trials for our products under development may not be completed on schedule and the FDA may not ultimately approve any of our product candidates for commercial sale. If we fail to adequately demonstrate the safety and efficacy of any product candidate under development, we may not receive regulatory approval for those products, which would prevent us from generating revenues or achieving profitability.

We may not be able to expand our manufacturing processes to other third-party manufacturing facilities or successfully create our own manufacturing infrastructure for supply of our requirements of product candidates for use in clinical trials and for commercial sale.

We do not own any 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 vaccine products. We anticipate we will initially rely solely on the Good Manufacturing Practices ("cGMP") manufacturing facility within BCM for the manufacturing of our MultiTAA T cell therapy-based product candidates. If the cGMP manufacturing facility of BCM, which does manufacture for itself and other parties, experiences capacity constraints, disruptions, or delays in manufacturing our MultiTAA T cell therapy-based product candidate products, our planned clinical trials and necessary manufacturing capabilities will be disrupted or delayed, which will adversely affect our ability to conduct and further develop our business as currently planned. Further, the cGMP manufacturing facility is most likely too small to conduct the pivotal clinical studies being planned by us, so we will need to develop our own cGMP manufacturing capacity that will be adequate for such clinical trials with respect to our MultiTAA T cell therapy-based product candidates.

In 2019 or in 2020, we intend to begin developing additional cGMP manufacturing capacity of our own that would be capable of supporting our manufacturing needs with respect to our clinical trials, particularly with respect to pivotal studies. Our manufacturing strategy going forward will involve the use of one or more CMOs or we will establish our own capabilities and infrastructure, including a manufacturing facility. Establishment of our own manufacturing facility is subject to many risks. For example, the establishment of a cell-therapy manufacturing facility is a complex endeavor requiring knowledgeable individuals. Creating an internal manufacturing infrastructure will rely upon building out a complex facility and finding personnel with an appropriate background and training to staff and operate the facility. Should we be unable to find these individuals, we may need to rely on external contractors or train additional personnel to fill needed roles. There are a small number of individuals with experience in cell therapy, and the competition for these individuals is high.

We expect that development of our own manufacturing facility could 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. However, we do not have any experience in developing a manufacturing facility and may never be successful in developing our own manufacturing facility or capability. We may establish multiple manufacturing facilities as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we are successful, 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 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 products 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 such 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. 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.

Regardless of whether we engage additional CMOs to manufacture our products or establish our own manufacturing facility, in order to transfer our MultiTAA T cell manufacturing from or expand our manufacturing capabilities beyond BCM pursuant to our development plans, whether through additional third parties or by developing our own manufacturing capabilities, we will need access to the Standard Operating Procedures (“SOPs”) and the specific Batch Production Records that are used to manufacture the product candidates. If BCM fails to transfer our manufacturing processes or impedes our ability to transfer the manufacturing processes of its products to us or third-party manufacturers, 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.

We will be dependent on third-party vendors to design, build, maintain and support our manufacturing and cell processing facilities.

As a result of our strategy to outsource our manufacturing, we will rely very heavily on BCM and other third-party manufacturers to perform the manufacturing of our products for our clinical trials. We license our technology from others. We intend to rely on our contract manufacturers to produce large quantities of materials needed for clinical trials and potential product commercialization. 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 products for regulatory approval or the market introduction and subsequent sales of our 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 products under development 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 products, 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.

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 products.

We will depend on a limited number of vendors for supply of certain materials and equipment used in the manufacture of our MultiTAA 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 John Wilson, who is a director of the Company), 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.

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 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. We do not own any exclusive rights to the G-Rex® that could be used to prevent third parties from developing similar and competing processes. 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 manufacturers encounter such difficulties, our ability to supply our product candidates for clinical trials, or our products 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 products is complex, highly regulated and subject to multiple risks. For example, the manufacture of our MultiTAA 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 differences 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 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 products 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 an effort 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 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 products is dependent.

In cooperation with our potential contract manufacturers, we intend to develop 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 products in a cGMP facility is subject to many uncertainties and difficulties. We have never manufactured our adoptive T cell therapy product candidate on any scale, commercially or otherwise. As a result, we cannot give any assurance that we will be able to establish a manufacturing process that can produce our products at a cost or in quantities necessary to make them commercially viable. Moreover, our third-party manufacturers will have to continually adhere to current cGMP regulations enforced by the FDA through its facilities inspection program. If the facilities of these manufacturers cannot pass a pre-approval plant inspection, the FDA premarket approval of our products 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 products 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.

The deviations in our proposed new MultiTAA-based products from existing products may require us to perform additional testing, which will increase the cost, and extend the time for obtaining approval.

Our MultiTAA T cell therapy platform is based on the adoptive T cell therapy technology that we licensed from BCM and that is presently available as a physician-sponsored investigational therapy at BCM for the treatment of lymphoma, AML/MDS, multiple myeloma and select solid tumors in the U.S. The current method of treatment is labor intensive and expensive. We are performing process optimization that we anticipate will enable more efficient manufacturing of our products. We may have difficulty demonstrating that the products 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 the 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 products 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.

We may enter into one or more transactions with entities controlled by one of our directors, which could pose a conflict of interest.

John Wilson, a director of the Company, is also CEO and co-founder of Wilson Wolf, which is the sole source vendor that provides us with the G-Rex® cell culture device for the large-scale production of T cells used in our manufacturing process. We do not currently have a supply contract with Wilson Wolf for the G-Rex®. We plan to negotiate a supply contract with Wilson Wolf for the purchase of G-Rex® devices. We have engaged Wilson Wolf in discussions to customize the G-Rex® further to optimally match our manufacturing requirements, as well as to develop a scalability plan to drive efficiencies for a commercial product. There may be conflicts of interest between us and Wilson Wolf. There can be no assurance that Wilson Wolf will agree to enter into any contract with us, or that the terms of any such agreements will be in the best interests of us or will have terms no less favorable to us than could have been obtained from unaffiliated third parties.

We may not be able to develop products successfully or develop them on a timely basis.

Our immunotherapy product candidates are at various stages of research and development. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. We will need to complete significant additional clinical trials demonstrating that our product candidates are safe and effective to the satisfaction of the FDA and other non-U.S. regulatory authorities. The drug approval process is time-consuming, which involves substantial expenditures of resources, and depends upon a number of factors, including the severity of the disease indication in question, the availability of alternative treatments, and the risks and benefits demonstrated in the clinical trials. Our success depends on our ability to achieve scientific and technological advances and to translate such advances into licensable, FDA-approvable, commercially-competitive products on a timely basis. Failure can occur at any stage of the process. If such programs are not successful, we may be unable to develop revenue-producing products. As we enter a more extensive clinical program for our product candidates, the data generated in these studies may not be as compelling as the earlier results.

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. For example, the FDA or non-U.S. regulatory authorities may disagree with the design or implementation of our clinical trials or study endpoints; or we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks. In addition, the FDA or non-U.S. regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application ("NDA") or other submission or to obtain regulatory approval in the United States or elsewhere. The FDA or non-U.S. regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA or non-U.S. regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. The proposed development schedules for our immunotherapy product candidates may be affected by a variety of other factors, including technological difficulties, clinical trial failures, regulatory hurdles, competitive products, intellectual property challenges and/or changes in governmental regulation, many of which will not be within our control.

Any delay in the development, approval, introduction or marketing of our products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects, the unproven technology involved and the other factors described elsewhere in this section, we might not be able to successfully complete the development or marketing of any new products, and as a result, our business, prospects, financial condition and results of operations could be materially and adversely affected. We may be required to reduce our staff, discontinue certain research or development programs of our future products and cease to operate.

We may encounter substantial delays in our clinical trials or may not be able to conduct our trials on the timelines we expect.

Clinical testing is expensive, time-consuming, and subject to uncertainty. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. BCM has submitted INDs to the FDA, which allow the use of MAPP T cells and LAPP T cells for human clinical testing. BCM initiated its first clinical trials for our product candidate, MAPP, in 2012, and clinical trials for LAPP in 2016. Issues may yet arise that could suspend or terminate such clinical trials. We intend to file one or more new INDs to advance these products into Phase II clinical trials, and any delay in filing these INDs may have a material adverse impact on our ability to advance clinical studies in accordance with management's plans. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design;
- the FDA may not allow us to use the clinical trial data from a research institution to support an IND, if we cannot demonstrate the comparability of our product candidates with the product candidate used by the relevant research institution in our clinical studies;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board ("IRB") approval at each clinical study site;
- the departure of a principal investigator from a clinical site, which could cause delays in conducting the clinical trial at a particular clinical site;
- imposition of a temporary or permanent clinical hold by regulatory agencies;
- delays in recruiting suitable patients to participate in our clinical studies;
- failure by our CROs, other third parties, or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's current good clinical practices ("cGCPs") requirements, or applicable regulatory guidelines in other countries;
- patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs;
- delays in transfer of manufacturing processes for MultiTAA T cells from BCM to our contract manufacturers or other larger-scale facilities operated by a CMO, delays or failure by our CMOs or us to make any necessary changes to such manufacturing process, and any inability to obtain all necessary reagents for manufacturing the product;

- any shutdown of our sole manufacturing site at BCM for MultiTAA T cells, which would render us unable to produce such products for clinical trials;

- disruptions in transportation between the clinical site and manufacturing facility; and

- delays in manufacturing, testing, release, validating, or import/export of sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing, including any quality issues associated with the contract manufacturer.

We also may conduct clinical and preclinical research in collaboration with other biotechnology and biologics entities in which we combine our technologies with those of our collaborators. Such collaborations may be subject to additional delays because of the management of the trials and the necessity of obtaining additional approvals for therapeutics used in the combination trials. These combination therapies will require additional testing and clinical trials will require additional FDA regulatory approval and will increase our future expenses.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required, or may elect, to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to commercialize our product candidates successfully and may harm our business and the results of our operations.

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;

- availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;

- relative convenience and ease of administration; and

- effectiveness of any sales and marketing efforts.

Moreover, 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.

We may not be able to establish or maintain the third-party relationships that are necessary to develop or potentially commercialize 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.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or with the USPTO.

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.

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 products, 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 these activities, 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.

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 products, 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 us 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 products 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 products. 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 products. 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 products.

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.

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 products.

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 product candidates. 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.

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. 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.

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 products. 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 products 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 products 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.

We may face legal claims; litigation is expensive and we may not be able to afford the costs.

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. We may initiate or become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or we may become subject to proceedings initiated by our competitors or other third parties or the USPTO or applicable foreign bodies to reexamine the patentability of our licensed or owned patents. 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.

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 law suit 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.

Our research and development programs are subject to uncertainty.

Factors affecting our research and development programs include, but are not limited to:

- limited financial resources from which to budget and allocate among our product candidates;
- competition from companies that are substantially and financially stronger than us;
- the need for acceptance of our immunotherapies;
- our ability to anticipate and adapt to a competitive market and rapid technological developments;
- the amount and timing of operating costs and capital expenditures relating to expansion of our business, operations and infrastructure;
- the need to rely on multiple levels of outside funding due to the length of drug development cycles and governmental approved protocols associated with the pharmaceutical industry; and
- the dependence upon key personnel including key independent consultants and advisors.

Our research and development expenses may not be consistent from time to time. We may be required to accelerate or delay incurring certain expenses depending on the results of our studies and the availability of adequate funding.

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

We do not currently have an organization for the sale, marketing and distribution of 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.

If we are unable to establish or manage strategic collaborations in the future, our revenue and drug development may be limited.

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 our 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 it directly marketed and sold any products that we may develop.

Management of our relationships with our collaborators 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 its research and development programs or the commercialization, marketing or distribution of its 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.

We may not be able to license newly developed MultiTAA T cell technology from BCM and others.

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 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 products or to develop additional products. 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 products.

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 products 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. 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, LAPP, 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.

We are required to pay substantial royalties and lump sum milestone payments under our license agreement with BCM, and we must meet certain milestones to maintain our license rights.

Under our license agreement with BCM for our MultiTAA 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 our 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. There is no assurance that we will be successful in meeting all of the milestones 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, but shall not include the “Merger”) 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.

Because our current products represent, and our other potential product candidates will represent novel approaches to the treatment of disease, there are many uncertainties regarding the development, the market acceptance, third-party reimbursement coverage and the commercial potential of our product candidates.

There is no assurance that the approaches offered by our products will gain broad acceptance among doctors or patients or that governmental agencies or third-party medical insurers will be willing to provide reimbursement coverage for proposed product candidates. Moreover, 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. Since our current product candidates and any future product candidates will represent new approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these product candidates. Accordingly, we may spend large amounts of money trying to obtain approval for product candidates that have an uncertain commercial market. 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.

Our MultiTAA 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 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.

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.

We face significant competition from other biotechnology and pharmaceutical companies and from non-profit institutions.

Competition in the field of cancer therapy is intense and is accentuated by the rapid pace of technological development. Research and discoveries by others may result in breakthroughs that may render our products obsolete even before they generate any revenue. There are products currently under development by others that could compete with the products that we are developing. Many of our potential competitors have substantially greater research and development capabilities and manufacturing, marketing, financial and managerial resources than we have. Our competitors may:

- develop safer or more effective immunotherapies and other therapeutic products;
- reach the market more rapidly, reducing the potential sales of our products; or
- establish superior proprietary positions.

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 and AdaptImmune, which are focused on genetically engineered T cell technologies to treat cancer, may also be competitors. Furthermore, companies such as Iovance, Immatics, WindMIL Therapeutics, Mana Therapeutics and Torque Therapeutics are developing non-genetically modified T cell therapies such as Tumor Infiltrating Lymphocytes (“TIL”) and Marrow Infiltrating Lymphocytes (“MIL”) therapies that may compete with our products. All of 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 products.

Our lead product candidate, LAPP, is a therapy for the treatment of refractory AML. Currently, there are numerous companies that are developing various alternate treatments for AML. Accordingly, LAPP faces significant competition in the AML treatment space from multiple companies. Even if we obtain regulatory approval for LAPP, 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 products 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 products for use in limited circumstances.

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

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.

We maintain cybersecurity insurance, however, an incident may exceed our coverage premiums.

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.

We may incur costs of addressing a cybersecurity incident.

Cybersecurity incidents have increased in number and severity recently and it is expected that these trends will continue. 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.

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 obtain regulatory approval for some of our products, those products may still face regulatory difficulties.

All of our potential products, 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 products, which may lengthen the regulatory review process, increase our development costs and delay or prevent their commercialization.

No adoptive T cell therapy using MultiTAA 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 products 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. 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.

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.

We have not previously submitted a Biologics License Application ("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 CMC 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. 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 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 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.

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.

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 receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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.

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.

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 ("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 has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, two 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, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress may consider other legislation to repeal or replace elements of the ACA. These executive orders and legislative actions may result in increased health insurance premiums and reduce the number of people with health insurance in the United States and have other effects that could adversely affect U.S. health insurance markets and the ability of patients to have access to therapies that our product candidates can provide.

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, providers are subject to Medicare payment reductions of 2% per fiscal year through 2027 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 also introduced a quality payment program under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. Payment adjustments for the Medicare quality payment program will begin in 2019. At this time, it is 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. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics.

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.

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 civil, criminal and administrative penalties, damages, disgorgement, monetary fines, 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.

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

On December 9, 2015, we announced that we received Orphan Drug Designation from the FDA's Office of Orphan Products Development ("OOPD") for our cancer vaccine TPIV200 in the treatment of ovarian cancer. The TPIV200 ovarian cancer clinical program will now receive benefits including tax credits on clinical research and seven-year market exclusivity upon receiving marketing approval. Even though we were granted orphan drug designation, we may not receive the benefits associated with orphan drug designation. This may result from a failure to maintain orphan drug status or result from a competing product reaching the market that has an orphan designation for the same disease indication. Under U.S. regulations for orphan drugs, if such a competing product reaches the market before ours does, the competing product could potentially obtain a scope of market exclusivity that limits or precludes our product from being sold in the United States for seven years. Even if we obtain exclusivity, the FDA could subsequently approve a drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. A competitor also may receive approval of different products for the same indication for which our orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

In addition, if and when we request orphan drug designation in Europe, the European exclusivity period is ten years but can be reduced to six years if the drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or European Medicines Evaluation Agency ("EMEA") 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.

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

Under the federal Patient Protection and Affordable Care Act ("PPACA") 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 PPACA 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.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

As described above, the PPACA 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.

The current U.S. administration and Congress could carry out significant changes in legislation, regulation, and government policy (including with respect to the possible repeal of all or portions of the PPACA, possible changes in the existing treaty and trade relationships with other countries, and tax reform). While it is not possible to predict whether and when any such changes will occur, changes in the laws, regulations, and policies governing the development and approval of our product candidates and the commercialization, importation, and reimbursement of our product candidates could adversely affect our business.

Risks Related to our Securities

The price of our stock may be volatile.

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 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;
- 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;
- announcements of new collaboration agreements with strategic partners or developments by our existing collaboration partners;
- announcements of acquisitions, mergers or business combinations;
- announcements of technological innovations, new commercial products, failures of products, or progress toward commercialization by our competitors or peers;
- general economic conditions and trends;
- positive and negative events relating to healthcare and the overall pharmaceutical and biotechnology sectors;

- major catastrophic events;
- sales of large blocks of our stock and sales by insiders and our institutional investors;
- departures of key personnel;
- changes in the regulatory status of our immunotherapies, including results of our clinical trials;
- events affecting BCM, Mayo Clinic, Mayo Foundation for Medical Education and Research or any future collaborators;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;
- regulatory developments in the United States and other countries;
- failure of our common stock to maintain listing requirements on the Nasdaq Capital Market;
- changes in accounting principles; and
- discussion of the Company or our stock price by the financial and scientific press and in online investor communities.

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.

A limited public trading market may cause volatility in the price of our common stock.

The listing of our common stock on the Nasdaq Capital Market does not assure that a meaningful, consistent and liquid trading market currently exists or will exist in the future. In recent years, the stock market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility. Sales of substantial amounts of common stock, or the perception that such sales might occur, could adversely affect prevailing market prices of our common stock and our stock price may decline substantially in a short time and our stockholders could suffer losses or be unable to liquidate their holdings. Our stock is thinly traded due to the limited number of shares available for trading thus causing large swings in price. There is no established trading market for our warrants.

The market prices for our common stock may be adversely impacted by future events.

Market prices for our common stock will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering, including issuances of shares upon the exercise of outstanding warrants or the issuance of preferred stock;
- changes in interest rates;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- variations in quarterly operating results;
- change in financial estimates by securities analysts;

- the depth and liquidity of the market for our common stock and warrants;
- investor perceptions of us and the pharmaceutical and biotech industries generally; and
- general economic and other national conditions.

If we fail to remain current with our listing requirements, we could be removed from the Nasdaq Capital Market which would limit the ability of broker-dealers to sell its securities and the ability of stockholders to sell its securities in the secondary market.

Companies listed for trading on the Nasdaq Capital Market must be reporting issuers under Section 12 of the Exchange Act. If we fail to file such reports in a timely manner, or if we fail to meet any other listing requirements, the shares of our common stock would eventually cease to be listed on the Nasdaq Capital Market, and the market liquidity for our securities could be severely adversely affected by limiting the ability of broker-dealers to sell its securities and the ability of stockholders to sell their securities in the secondary market.

Sales of additional equity securities may adversely affect the market price of our common stock and your rights may be reduced.

We expect to continue to incur drug development and sale, general and administrative costs, and to satisfy our funding requirements, we will need to sell additional equity securities, which may be subject to registration rights and warrants with anti-dilutive protective provisions. 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 and our stock price may decline substantially. Our stockholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, new equity securities issued may have greater rights, preferences or privileges than our existing common stock.

Because we have a significant number of additional authorized shares of common stock available for issuance and outstanding warrants to purchase our common stock, our stockholders may experience dilution in the future and it may adversely affect the market price of our securities.

We are currently authorized to issue 150 million shares of our common stock. As of December 31, 2018, we had 45,440,704 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, 2018, there were outstanding warrants to purchase up to approximately 23.0 million shares of our common stock at a weighted average exercise price of $4.78 per share, and options exercisable for an aggregate of approximately 4.1 million shares of common stock at a weighted average exercise price of $8.69 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.

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 (“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, 2018, the fair value of the derivative liability-warrants was $49,000. 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.

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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We do not own any real estate or other properties. We lease office space at 5 West Forsyth Street, Suite 200, Jacksonville, Florida 32202, for our principal business office on a five-year agreement due to expire on June 30, 2022. The base rent is approximately $8,600 per month.

In November 2018, we leased office space at 3200 Southwest Freeway, Suite 2240, Houston, Texas 77027 on a three-year agreement set to expire in November 2021 (the "Houston Office").

On February 15, 2019, we announced the relocation of our corporate headquarters from the Jacksonville location to the Houston Office. Base rent is approximately $10,000 per month.

We also rent an office at the Florida Atlantic Research and Development Authority at 3651 FAU Blvd, Boca Raton, Florida on a month by month agreement. The monthly rent for the Boca Raton space is approximately $800 per month.

In January 2019, we leased a dedicated portion of an existing laboratory located at the Texas Medical Center in Houston for the purpose of conducting laboratory research and other laboratory related activities. The laboratory, referred to as JLABS, was established by Johnson & Johnson at the Texas Medical Center to provide space for research and development stage entities. We signed an 11-month license, which automatically renews for 3-month successive periods for two dedicated suites and access to common space of approximately 20,000 square feet of the JLABS premises located at the Texas Medical Center. The base rent is $6,000 per month.

ITEM 3. LEGAL PROCEEDINGS

As of December 31, 2018, 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 28, 2019, we had 492 stockholders of record whom are holding shares. The price of our common stock on February 28, 2019 was $6.22 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 recorded the issuances of the following unregistered securities during the fourth quarter of 2018 pursuant to exemptions under the Securities Act of 1933, including Section 4(2):

During the fourth quarter of 2018, 65,000 shares of common stock were issued pursuant to third parties consisting of (i) 50,000 shares to Caro Capital for services pursuant to a vendor agreement and (ii) 15,000 shares to Omnicor Media for services pursuant to a vendor agreement.

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, 2018 and December 31, 2017 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 cell-based immunotherapies and innovative peptide-based vaccines for the treatment of hematological malignancies and solid tumor indications. Our MultiTAA T cell technology is based on the selective expansion of non-engineered, tumor-specific T cells that recognize tumor associated antigens ("TAA" i.e. tumor targets) and kill tumor cells expressing those targets. Once infused into patients, this population of T cells recognizes multiple tumor targets to produce broad spectrum anti-tumor activity. Because we do not genetically engineer our T cells, when compared to current engineered chimeric antigen receptor ("CAR") and T cell receptor ("TCR")-based approaches, our products are significantly less expensive to manufacture and appear to be markedly less toxic, and yet are associated with meaningful clinical benefit. As a result, we believe our portfolio of T cell therapies has a compelling therapeutic product profile, as compared to current gene-modified CAR and TCR-based therapies. In addition, our Folate Receptor Alpha program (TPIV200) for breast and ovarian cancers and our HER2/neu program (TPIV100/110) are in Phase II clinical trials. In parallel, we are developing a proprietary nucleic acid-based antigen expression technology named PolyStart™ to improve the ability of the immune system to recognize and destroy diseased cells.

Immuno-oncology, which utilizes a patient's own immune system to combat cancer, is one of the most actively pursued areas of research by biotechnology and pharmaceutical companies today. Interest and excitement about immunotherapy are driven by compelling efficacy data in cancers with historically bleak outcomes, and the potential to achieve a cure or functional cure for some patients. Harnessing the power of the immune system is an important component of fighting cancerous cells in the body. Our MultiTAA T cell therapy platform identifies and selects effectively all T cells that are specific for any peptide from the antigens that we target (e.g., WT1, MAGE-A4, PRAME, Survivin, NY-ESO-1, and SSX2). Our in-vitro manufacturing process promotes proliferation of very rare cancer-killing T cells and augments their anti-tumor properties to provide benefit to patients following their infusion. By using the multi-antigen targeted approach, our proprietary technology can kill heterogeneous tumor cell populations more effectively than single-antigen targeted approaches, thereby reducing the likelihood of tumor escape and potentially increasing the durability of a patient's response to therapy.

Recent Developments

Change in Headquarters. On February 15, 2019 we announced a change in our corporate headquarters from Jacksonville, Florida to Houston, Texas.

Presentations at American Society for Blood and Marrow Transplantation and the *Center for International Blood and Marrow Transplant Research* (ASBMT and CIBMTR). Between February 20-23, 2019, four abstracts, including three oral presentations, were presented at the Transplantation & Cellular Therapy (TCT) Meetings of the American Society for Blood and Marrow Transplantation and the *Center for International Blood and Marrow Transplant Research* (ASBMT and CIBMTR). The studies summarize data achieved using multi-tumor antigen specific T cells that were developed at Baylor College of Medicine in the laboratories of Dr. Swati Naik, Dr. Ann Leen, Dr. Premal Lulla and Dr. Juan Vera, and exclusively licensed to us.

Presentations at 60th American Society of Hematology Annual Meeting (ASH 2018). Between December 1-3, 2018 three presentations, including one oral presentation were presented at 60th American Society of Hematology Annual Meeting. The studies describe results achieved using multi-tumor antigen specific T cells that were developed at the Baylor College of Medicine in the laboratories of Dr. Swati Naik, Dr. Premal Lulla, Dr. Ann Leen and Dr. Juan Vera, and exclusively licensed to Marker.

Merger Agreement. On October 17, 2018, the Company completed its previously announced acquisition with Marker Cell Therapy, Inc., formerly known as Marker Therapeutics, Inc., a privately-held Delaware corporation ("Marker Cell"), in accordance with the terms of an Agreement and Plan of Merger and Reorganization dated as of May 15, 2018 (the "Merger Agreement") by and among the Company, Timberwolf Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of the Company ("Merger Sub"), and Marker. On October 17, 2018, pursuant to the Merger Agreement, Merger Sub was merged with and into Marker Cell (the "Merger"), with Marker Cell being the surviving corporation and becoming a wholly-owned subsidiary of the Company. In connection with the Merger, the Company changed its name to Marker Therapeutics, Inc. and Marker Cell changed its name to Marker Cell Therapy, Inc. At the effective time of the Merger, the former Marker Cell stockholders received (i) an aggregate of 13,914,255 shares of the Company's common stock which equaled the number of shares of the Company's common stock issued and outstanding immediately prior to the effective time of the Merger, and (ii) an aggregate of 5,046,003 warrants which equaled the number of the Company's warrants and stock options issued and outstanding immediately prior to the effective time of the Merger.

The issuance of the shares of Company common stock to the former stockholders of Marker Cell in connection with the Merger and related transactions was approved by the Company's stockholders at the 2018 annual meeting of stockholders (the "2018 Annual Meeting") held on October 16, 2018.

In connection with the Merger, the Company filed an amendment to its articles of incorporation in Nevada to increase the authorized shares of common stock from 41,666,667 shares to 150,000,000 shares and to change the Company's name to Marker Therapeutics, Inc. ("Certificate of Amendment"). The Company then reincorporated from a Nevada corporation to a Delaware corporation and filed its certificate of incorporation in Delaware. Finally, a certificate of merger was filed in Delaware to merge Marker Cell Therapy, Inc. (f/k/a Marker Therapeutics, Inc.) with and into Merger Sub, with Marker Cell Therapy, Inc. being the surviving corporation and wholly owned subsidiary of the Company. The name change, reincorporation and Merger were all effective as of October 17, 2018. Beginning as of the market open on October 18, 2018, shares of the Company's common stock commenced trading on The Nasdaq Capital Market under its new ticker symbol "MRKR".

Securities Purchase Agreements. On October 17, 2018, concurrent with the completion of the Merger, the Company issued to certain accredited investors in a private placement transaction (the "Financing"), an aggregate of 17,500,000 shares of its common stock, and warrants to purchase 13,437,500 shares of common stock at an exercise price of $5.00 per share with a five-year term, for aggregate proceeds of $70 million pursuant to the terms of the Securities Purchase Agreements, dated June 8, 2018, by and among the Company and certain accredited investors.

After taking into account the issuance of shares in the Financing described above, immediately following the effective time of the Merger, the pro forma ownership of the issued and outstanding shares of Company common stock on a fully diluted basis (assuming all issued and outstanding warrants and options are exercised) was approximately as follows: Marker Cell's former stockholders 27.5%, Company stockholders prior to the Merger 27.5%, and the private placement stockholders 45%. Following the completion of the Merger and the Financing, there were 45,328,510 issued and outstanding shares of the Company's common stock.

Products and Technology in Development

The following chart sets forth our products and technologies under development.

Our MultiTAA T Cell Products

We are advancing two MultiTAA T cell products through clinical development:

1) Mixed Antigen Peptide Pool (“MAPP”) T cells is a product currently being studied for patients with lymphoma, multiple myeloma and selected solid tumors in Phase 1. MAPP is an autologous product that targets the NY-ESO-1, PRAME, MAGE-A4, Survivin and SSX2 antigens, and
2) Leukemia Antigen Peptide Pool (“LAPP”) T cells is a product currently being studied for patients with AML and MDS in Phase 1. LAPP is an allogeneic product targeting the WT1, NY-ESO-1, PRAME, and Survivin antigens and the stem cell donor is used as the source of the cells manufactured for therapy.

While the blood source and the antigens for stimulation differ between the LAPP and the MAPP products, the manufacturing process for each product is otherwise identical.

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 was to develop 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 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.

Our proprietary MultiTAA T cell platform may have meaningful advantages over current CAR-T and TCR cell therapy approaches. Compared to current gene-modified T cell therapies, our programs are characterized by the following:

· **Demonstrated clinical benefit, without the need for lymphodepletion before infusion:** In BCM's Phase I lymphoma study, we saw complete responses ("CRs") in 50 – 60% of its evaluable patients. We believe it is significant that 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, observed therapeutic responses appear to be highly durable, with some patients being relapse-free beyond five years.

· **Non-gene-modified**: Unlike CAR-T and TCR approaches, our therapy requires no genetic modification of T cells, a costly and complex process that significantly complicates the manufacturing of a patient product. We believe our therapy can be manufactured at a fraction of the cost of a gene-modified T cell product, with substantially reduced complexity of manufacturing.

· **Low incidence rate of adverse events**: In 78 patients treated to date, we have seen only one grade III adverse reaction considered possibly related to our therapy. This appears to compare favorably with published CD19 CAR-T studies, wherein up to 95% of patients had associated grade III or higher adverse events during treatment. We believe that it is notable that there have been no cases of cytokine-release syndrome ("CRS"), or related serious adverse events ("SAEs") in patients treated with MAPP or LAPP therapy to date.

· **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 targeting up to five different tumor-associated antigens. In layman's terms, the five antigen targets can be recognized by a very wide range of T cells, facilitating robust killing of targeted cancer cells.

· **Appears to drive endogenous immune responses**: We see evidence of "epitope spreading" in our patients, meaning that our 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 our infused product). Our correlative analyses show expansion of endogenous T cells, other than those present in our product, in the months following the infusion of our product. This phenomenon, also known as "antigen spreading," is potentially important in generating a durable response for a patient, because it enables the killing of tumors that do not express any of the antigens initially targeted by our product.

Our Folate Receptor Products

Folate Receptor alpha ("FRa") is overexpressed in over 80% of breast cancers and in addition, over 90% of ovarian cancers, for which the only treatment options 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, there are approximately 30,000 ovarian cancer patients and 40,000 triple-negative breast cancer patients newly diagnosed every year. The FRa vaccine (now called TPIV200) intended to treat these conditions is composed of a mixture of five FRa immunogenic peptides adjuvanted with low-dose granulocyte-macrophage colony-stimulating factor ("GM-CSF").

GMP Manufacturing Scale Up of TPIV200 and Production to Supply Additional Phase II Clinical Trials

We have developed a commercial-quality lyophilized formulation of the TPIV200 peptides in a single vial for reconstitution and injection. Multi-gram peptide production scale-up has been successfully concluded, and so has the GMP manufacturing of a recent clinical lot of the TPIV200 peptides. The supply will be used in the company's ongoing Phase II study in platinum-sensitive ovarian cancer, as well as the 280-patient Phase II study sponsored by the Mayo Foundation and funded by the U.S. Department of Defense ("DoD") for treating triple-negative breast cancer. We also made various improvements to the vaccine manufacturing process, resulting in what we believe to be a superior formulation of the vaccine that is more amenable to large-scale manufacturing and commercialization. Thus, Good Manufacturing Practice ("GMP") manufacturing development for the Phase II trials has been completed.

***Phase I Human Clinical Trial* – Folate Receptor Alpha Breast and Ovarian Cancers – Mayo Foundation**

On July 27, 2015, we exercised our option agreement with Mayo Foundation with the signing of a worldwide exclusive license agreement to commercialize the proprietary FRa vaccine technology for all cancer indications. As part of this agreement, the IND for the Folate Receptor alpha Phase I trial was transferred from Mayo Foundation to the Company for Phase II clinical trials as our lead peptide vaccine product.

The results from the initial 21-patient Phase I clinical trial for the FRa vaccine have now been reported. Twenty-one patients with breast or ovarian cancer, who had undergone standard surgery and adjuvant treatment, were treated with one cycle of cyclophosphamide. Following this, patients were vaccinated intradermally with TPIV200 on day one of a 28-day cycle for a maximum of six vaccination cycles. On March 15, 2018, we announced the publication of the clinical data from this trial. The results show that 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. TPIV200 vaccine was safe and well-tolerated; 20 out of 21 evaluable patients showed positive immune responses, providing a strong rationale for progressing to Phase II trials. Further, the data showed that 16 out of 16 patients in the observation stage showed persistent immune responses (Source: published online 15Mar2018; DOI: 10.1158/1078-0432.CCR-17-2499).

Phase II Development of TPIV200 for Triple-negative Breast Cancer

Triple-negative breast cancer ("TNBC") is one of the most difficult cancers to treat and represents a clear unmet medical need. On September 15, 2015, we announced that our collaborators at the Mayo Foundation had been awarded a grant of $13.3 million from the DoD. This grant led by Dr. Keith Knutson of the Mayo Clinic in Jacksonville, Florida covers the costs for a 280-patient Phase II clinical trial of the FRa vaccine in patients with TNBC. We are working closely with Mayo Foundation on this clinical trial by providing clinical and manufacturing expertise, as well as providing GMP vaccine formulations under contract. This Phase II study of TPIV200 in the treatment of triple-negative breast cancer began enrolling patients in late 2017 and enrollment continues. Details regarding this trial can be found at www.clinicaltrials.gov under identifier numbers NCT03012100 and RU011501I.

On June 21, 2016, we announced the initiation of a randomized four-arm Phase II trial of TNBC that is sponsored and conducted by the Company (FRV-002), enrolling women with stage I-III disease 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. The study is evaluating two doses of TPIV200 (a high dose and a low dose), each of which will be tested both with and without cyclophosphamide prior to vaccination. Key data from the trial are expected to be included in a future Biologics License Application submission to the FDA for marketing clearance. We completed enrollment in late 2017 and are now treating and following the patients. An independent Data Safety Monitoring Board ("DSMB") reviews the safety in this ongoing Phase II study; no safety issues have been identified to date. Details regarding this trial can be found at www.clinicaltrials.gov under the identifier number NCT02593227.

Phase II Development of TPIV200 for Ovarian Cancer

On December 9, 2015, we announced that we received Orphan Drug Designation from the U.S. Food & Drug Administration's Office of Orphan Products Development ("OOPD") for our cancer vaccine TPIV200 in the treatment of ovarian cancer. The TPIV200 ovarian cancer clinical program will now receive benefits including tax credits on clinical research and seven-year market exclusivity upon receiving marketing approval. TPIV200 is a multi-epitope peptide vaccine that targets Folate Receptor alpha which is overexpressed in multiple cancers including over 90% of ovarian cancers. On February 3, 2016, we announced that the U.S. FDA designated the investigation of the multiple-epitope TPIV200 vaccine for maintenance therapy in subjects with platinum-sensitive advanced ovarian cancer who achieved stable disease or partial response following completion of standard-of-care chemotherapy, as a Fast Track Development Program.

On April 21, 2016, we announced our participation in an ovarian cancer study sponsored by Memorial Sloan Kettering Cancer Center ("MSKCC") in New York City in collaboration with AstraZeneca Pharmaceuticals in ovarian cancer patients who are not responsive to platinum, a commonly used chemotherapy for ovarian cancer. This study, an open-label Phase II study of TPIV200 in 40 patients is designed to look at 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 established in these heavily-pretreated patients and a subset of patients exhibited durable disease stabilization. ORR and PFS with combination treatment was not superior from the expected efficacy of single-agent PD-1/PD-L1 blockade. 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 are paying for one-half of the costs of the clinical study, in addition to providing our TPIV200 for the study. Details regarding this trial can be found at www.clinicaltrials.gov under identifier numbers NCT02764333.

On January 10, 2017, we announced the initiation of a Company-sponsored Phase II study in platinum-sensitive ovarian cancer patients (FRV-004). This multi-center, double-blind efficacy study is designed to evaluate TPIV200 compared to GM-CSF alone in a randomized, placebo-controlled fashion during the first maintenance period after primary surgery and chemotherapy. We have opened multiple clinical sites and enrollment of the 120 patients has been completed ahead of schedule. The 120^{th} subject was given the study drug on December 10, 2018. Safety is reviewed by an independent DSMB quarterly and an interim efficacy analysis is planned in 2019, once 50 patients have progressed. Details regarding this trial can be found at www.clinicaltrials.gov under the identifier number NCT02978222.

TPIV 100/110 – HER2/neu peptides with GM-CSF

Human epidermal growth factor receptor 2 ("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 still 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 Class I-restricted peptide, also licensed from the Mayo Foundation on April 16, 2012, to the four Class II-restricted peptides in TPIV100, resulting in TPIV 110 after the five peptides are mixed with GM-CSF. Management believes that the combination of Class I and Class II HER2/neu antigens, gives us the leading HER2/neu vaccine platform. We have amended the IND to incorporate the fifth peptide and will use TPIV110 in subsequent studies with the goal of producing an even more robust vaccine activating both $CD4^+$ (helper) and $CD8^+$ (killer) T cells.

Transition of the HER2/neu Vaccine

On June 7, 2016, we announced that the Company had exercised its option agreement with Mayo Foundation and signed a worldwide license agreement to the proprietary HER2/neu vaccine technology. The license gives the Company 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 I Trial was transferred from Mayo Foundation to the Company for Phase II clinical trials as TPIV100, our second product.

***Phase I Human Clinical Trial* – HER2/neu+ Breast Cancer – Mayo Foundation**

A Phase I study using a vaccine containing four HER2/neu peptides in combination with GM-CSF (now called TPIV100) was initiated in 2012 at the Mayo Clinic and the primary readout was completed in 2015. Final safety analysis on all the patients treated showed that the vaccine was safe in that context. In addition, 19 out of 20 evaluable patients showed robust T-cell immune responses to the antigens in the vaccine composition providing a case for advancement to Phase II. Data from the study was presented at the San Antonio Breast Cancer Symposium on December 10, 2015. An additional secondary endpoint incorporated into this Phase I Trial was a two-year follow-on recording the time to disease recurrence in the participating breast cancer patients. Details regarding this trial can be found at www.clinicaltrials.gov under the identifier number NCT01632332.

On March 14, 2017, we announced that our partners at the Mayo Clinic received a $3.8 million grant from the DoD to conduct a Phase Ib study of the HER2-targeted vaccine candidate (TPIV100) in an early form of breast cancer called ductal carcinoma in situ ("DCIS"). This is the second Company vaccine to be tested in a fully-funded study sponsored by the Mayo Foundation. We are working closely with Mayo Foundation on this clinical trial by providing clinical and manufacturing expertise, as well as providing GMP vaccine formulations under contract. If the study is successful, our HER2/neu vaccine 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. The study is expected to enroll 40 – 45 women with DCIS and commence such enrollment during the first quarter of 2019.

Phase II Development of the HER2/neu TPIV110 Vaccine

On October 10, 2018, we announced that Mayo Clinic had been awarded a grant of $11 million from the DoD. This grant is intended to cover the costs of a large randomized, double-blind Phase II study of the Company's HER2/neu-targeted breast cancer vaccine, TPIV110 with maintenance ado-trastuzumab emtansine (T-DM1) compared to GM-CSF alone, in combination with standard one year of T-DM1 maintenance therapy, for treating up to 190 women with HER2/neu-positive breast cancer. We are working closely with Mayo Foundation on this clinical trial by providing clinical and manufacturing expertise, as well as providing GMP vaccine formulations under contract. The study will ask 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.

Products and Technology – Pre-clinical

Polystart

In addition to the clinical developments, our peptide vaccine technology can be coupled with our PolyStart™ nucleic acid-based technology, which is designed to make vaccines significantly more effective by producing four times the required peptides for the immune systems to recognize and act on.

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.

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, 2018 and 2017.

Other Income (Expense)

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

Results of Operations For the Years Ended December 31, 2018 and 2017

The following table summarizes the results of our operations (rounded to the thousand except for per share amounts) for the years ended December 31, 2018 and 2017, together with the changes to those items:

	For the Years Ended December 31,			
	2018	2017	Increase / (decrease)	
Revenues:				
Grant income	$ 206,000	$ 183,000	$ 23,000	13%
Total revenues	206,000	183,000	23,000	13%
Operating expenses:				
Research and development - intellectual property acquired	116,045,000	-	116,045,000	-
Research and development	7,953,000	5,251,000	2,702,000	51%
General and administrative	24,380,000	6,412,000	17,968,000	280%
Total operating expenses	148,378,000	11,663,000	136,715,000	1172%
Loss from operations	(148,172,000)	(11,480,000)	(136,692,000)	1191%
Other income (expense):				
Change in fair value of warrant liabilities	(40,000)	6,000	(46,000)	(767)%
Interest income	254,000	-	254,000	-
Debt extinguishment gain	-	492,000	(492,000)	(100)%
Net loss	**$ (147,958,000)**	**$ (10,982,000)**	**$ (136,976,000)**	**1247%**
Net loss per share, Basic and Diluted	$ (7.75)	$ (1.16)	$ (6.59)	568%
Weighted average number of common shares outstanding	19,092,000	9,453,000	9,639,000	102%

Revenue

We did not generate any revenue during the years ended December 31, 2018 and 2017, respectively from the sales or licensing of our product candidates. During the year ended December 31, 2018, we recognized $206,000 of revenue associated with a grant awarded to Mayo Foundation from the US Department of Defense for the Phase II Clinical Trial of TPIV200 which Mayo paid to us for clinical supplies manufactured by us and provided for the clinical study funded by the grant. During the year ended December 31, 2017, we also recognized $183,000 of grant income.

Operating Expenses

Operating expenses incurred during the fiscal year ended December 31, 2018 were $148.4 million compared to $11.7 million in the prior year. Significant changes and expenditures are outlined as follows:

Research and Development Expense-Intellectual Property Acquired

Research and development – Intellectual Property Acquired, increased $116.0 million in the year ended December 31, 2018 and represented the fair market value of assets acquired by us in connection with the Merger. Because the Merger was accounted for as an asset acquisition and the assets acquired consisted of intellectual property that has not received regulatory approval, the total purchase price was immediately expensed as in process research and development or intellectual property acquired.

Research and Development Expense

Research and development expenses increased by 51% to $8.0 million for the year ended December 31, 2018 from $5.3 million for the year ended December 31, 2017.

Our research and development expenses are highly dependent on the phases of our research projects and therefore fluctuate from period to period.

The increase in our research and development expenses of $2.7 million for the year ended December 31, 2018 compared to the same period in 2017 was primarily due to our increases from prior period for expenses relating to our planned clinical trials.

General and Administrative Expenses

General and administrative expenses increased by 280% to $24.4 million for the year ended December 31, 2018 from $6.4 million during the prior period. The increase of $18.0 million was primarily attributable to the following:

- $12.5 million of stock-based compensation expenses for employees and outside consultants,
- $0.7 million of headcount-related expenses,
- $4.0 million of legal, accounting and professional expenses relating to the merger agreement inclusive of $0.2 million to settle shareholder litigation filed in connection with our proxy statement,
- $0.2 million of investor relations expenses, and
- $0.2 million of costs associated with Sarbanes Oxley and cybersecurity initiatives.

Other Income (Expense)

Change in fair value of warrant liabilities

The change in fair value of warrant liabilities for fiscal year ended December 31, 2018 was $40,000 as compared to ($6,000) for the fiscal year ended December 31, 2017. This increase by $40,000 for the fiscal year ended December 31, 2018 is reflected by a corresponding loss in other income (expense) in the consolidated statement of operations.

Interest income

Interest income was approximately $0.3 million for the year ended December 31, 2018 and was attributable to interest income relating to a significant portion of the net proceeds received from our equity financing in October which are held in U.S. Treasury notes and U.S. government agency-backed securities.

Debt extinguishment gain

Debt extinguishment gain was approximately $0.5 million for the year ended December 31, 2017 due to the extinguishment of liabilities we recorded in the prior period.

Net Loss

We recorded a net loss of $148.0 million or ($7.75) basic and diluted per share during the year ended December 31, 2018 compared to a net loss of $11.0 million or ($1.16) basic and diluted per share during the year ended December 31, 2017. The weighted average number of shares outstanding was 19.1 million basic and diluted for the year ended December 31, 2018 compared to 9.5 million basic and diluted for the year ended December 31, 2017. The increase in our net losses in 2018, as compared to 2017, was due to the research and development intellectual property acquired, continued expansion of our research and development activities, increased clinical trials and manufacturing activities, and the overall growth of our corporate infrastructure. We anticipate that we will continue to incur net losses in the future as we further invest in our research and development activities, including our clinical development. In addition, our general and administrative expenses increased in 2018 due to the increase in headcount and stock-based equity awards related to existing and new executives and key consultants.

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, 2018 and 2017:

	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 61,747,000	$ 5,129,000
Working Capital	$ 59,193,000	$ 3,658,000

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2018 and 2017:

	For the Years Ended December 31,	
	2018	2017
Net Cash provided by (used in):		
Operating activities	$ (14,480,000)	$ (8,439,000)
Investing activities	(148,000)	-
Financing activities	71,245,000	5,717,000
Net increase/(decrease) in cash	$ 56,617,000	$ (2,722,000)

Financings

May 2018 Private Placement Transaction Common Stock Purchase Agreement

On May 18, 2018, we closed on the sale of 1,300,000 shares of common stock for $2.40 per share pursuant to a Common Stock Purchase Agreement with an existing accredited investor in a private placement under Rule 506 of Regulation D pursuant to the terms of a Common Stock Purchase Agreement. Aggregate gross proceeds were approximately $3.1 million.

May 2018 Exercise of Warrants Held by Existing Institutional Investors

Also on May 18, 2018, we and certain existing institutional investors, who are holders of various warrants to purchase shares of Company common stock, closed on Warrant Exercise Agreements in which we agreed to reduce the exercise price for a portion of the investors' previously purchased Series C, Series D, Series E and Series F warrants from $6.00, $9.00, $15.00 and $7.20, respectively per share to $2.50 per share, provided that the investors exercise such warrants for cash immediately, which they did, for 782,506 shares and aggregate proceeds of approximately $2.0 million.

June 2017 Private Placement Transaction

On June 26, 2017, we completed private placements of units with certain accredited investors. In the private placement transaction, we sold 1,503,567 shares of common stock for $3.97 per share and five-year warrants to purchase an equal number of shares of common stock, at an exercise price of $3.97 per share, for $0.125 per warrant, with one common share and one warrant being sold together as a unit for a total of $4.095 per unit. We issued and sold an aggregate of 1,503,567 million units for aggregate gross proceeds of $6.2 million. We incurred $0.8 million in agency fees and legal costs. In connection with the offering, we reduced the exercise price for the warrants to purchase an aggregate of 653,187 shares of common stock issued to investors in the private placement that closed in August 2016 from $6.00 per share to $3.97 per share.

October 2018 Private Placement Transaction

On October 17, 2018, concurrent with the completion of the Merger, we issued to certain accredited investors in a private placement transaction an aggregate of 17,500,000 shares of its common stock, and warrants to purchase 13,437,500 shares of common stock at an exercise price of $5.00 per share with a five-year term, for aggregate proceeds of $70.0 million pursuant to the terms of the Securities Purchase Agreements, dated June 8, 2018, by and among us and certain accredited investors.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical and research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses, facility costs and general overhead costs.

The successful development of any of our product candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of product candidates. This is due to the numerous risks and uncertainties associated with developing medical treatments, including, but not limited to, the uncertainty of:

- successful enrollment in, and successful completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- launching commercial sales of our products, if and when approved, whether alone or in collaboration with others; and market acceptance of our products, if and when approved;
- successfully negotiating reimbursement for our products from various third-party payors; and
- the ability to successfully manufacture patient doses.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of our product candidates.

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

We plan to continue to fund our operations and capital funding needs through equity and/or debt financing. We may also consider new collaborations or selectively partnering 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. 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. Any of these actions could harm our business, results of operations and future prospects.

Outlook

Based on our clinical and research and development plans and our timing expectations related to the progress of our programs, we expect that our cash, cash equivalents and investment securities as of December 31, 2018 will enable us to fund our operating expenses and capital expenditure requirements through at least the second quarter of 2020. 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 to meet operational needs and capital requirements for product development and commercialization sooner than planned. 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; 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;
- 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.

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, 2018, we have approximately $57.0 million of federal and $37.3 million of state Net Operating Loss (“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 $15.4 million generated in 2018 are subject to an 80% limitation on taxable income, do not expire and will carry forward indefinitely. The state net operating loss carryforwards of $21.8 million, if not utilized, will begin to expire in 2035. The state net operating loss carryforwards of $15.4 million generated in 2018 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, or the “Code”, places significant annual limitations on the use of such net operating loss carryforwards.

At December 31, 2018 and 2017, we recorded a 100% valuation allowance against our deferred tax assets of approximately $20.0 million and $11.9 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-27 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, 2018 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, 2018. 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, 2018.

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, 2018 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, 2018.

The independent registered public accounting firm, Marcum LLP, has issued an attestation report on our internal control over financial reporting. The report on the audit of internal control over financial reporting is included in this Annual Report on Form 10-K.

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 has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

Opinion on Internal Control over Financial Reporting

We have audited Marker Therapeutics, Inc.'s (the "Company") internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets as of December 31, 2018 and 2017 and the related consolidated statements of operations, shareholders' equity (deficit), and cash flows and the related notes for each of the two years in the period ended December 31, 2018 of the Company, and our report dated March 15, 2019 expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management Annual Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that degree of compliance with the policies or procedures may deteriorate.

/s/ Marcum LLP

Marcum LLP
New York, NY
March 15, 2019

ITEM 9B. OTHER INFORMATION

The disclosure set forth below is filed in lieu of a Form 8-K that otherwise would have been required with respect to Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers, particularly 5.02 (e) Compensatory Arrangements of Certain Officers.

Bonus Awards 2018

On March 14, 2019 the Board of Directors approved a discretionary bonus to Mr. Hoang, the Company's President and Chief Executive Officer, of $181,250 to be paid in cash and determined that no other discretionary cash bonuses would be paid for 2018 to any of our other named executive officers.

Amendment to Mr. Hoang's Option Award Agreement.

On March 14, 2019, the Company and Mr. Hoang entered into an amendment to Mr. Hoang's stock option award agreement (the "Amended Option Agreement"). Pursuant to the terms of the Amended Option Agreement, Mr. Hoang's prior grant of 1,359,855 options to purchase common stock, which previously vested immediately was revised to add a vesting requirement over four years. The Amended Option Agreement provides for the 1,359,855 options to vest monthly over four years through September 2022. All other terms of the original award relating to the exercise price and grant date remained unchanged from the initial award.

Amendment to Mr. Hoang's Employment Agreement.

On March 14, 2019, the Company and Mr. Hoang entered into an amendment to Mr. Hoang's employment agreement to make the following changes:

- To reflect an increase of Mr. Hoang's annual base salary from $362,500 to $380,000 per year effective January 1, 2019;
- To eliminate references to future equity awards in the second and third anniversary of the Employment Agreement of one percent (1%) of outstanding shares and to eliminate references to the initial equity award Mr. Hoang already received and to eliminate the first anniversary equity award that was not paid by the Company to Mr. Hoang;
- To revise the Company's products and services applicable to the non-compete provision; and
- To change the notice provision to the new headquarter location in Texas and the governing law to Texas.

All other terms of Mr. Hoang's employment agreement not modified by the Amendment remain unchanged and in place. The description of the Amendment is qualified in its entirety by reference to the Amendment filed hereto as Exhibit 10.40.

2019 Bonus Program

On March 14, 2019, the Board of Directors approved the 2019 bonus program for Mr. Peter Hoang, our Chief Executive Officer and President, Mr. Anthony Kim, our Chief Financial Officer and Mr. Michael J. Loiacono, our Chief Accounting Officer, as recommended by the Compensation Committee of the Board of Directors. Under such bonus program, Mr. Hoang, Mr. Kim and Mr. Loiacono are eligible for bonuses of up to $190,000 $150,000 and $96,250, respectively, equaling up to 50%, 40% and 35%, of their respective base salaries (each a "Bonus Target").

The bonuses payable to Mr. Hoang are to be based upon the achievement of the following objectives:

(i) up to 40% of the Bonus Target for meeting regulatory and clinical objectives associated with the Company's AML product candidate;

(ii) up to 35% of the Bonus Target for financial performance and corporate objectives including related to capital management and partnership outreach undertakings;

(iii) up to 15% of the Bonus Target for meeting scientific and technical objectives relating to the manufacturing processes and laboratory development; and

(iv) up to 10% of the Bonus Target for product manufacturing objectives.

The bonuses payable to Mr. Kim are to be based upon the achievement of the following objectives:

(i) up to 40% of the Bonus Target related to capital management activities;

(ii) up to 20% of the Bonus Target related to the Company's operating budget;

(iii) up to 20% of the Bonus Target related to investor relations; and

(iv) up to 20% of the Bonus Target related to partnership outreach undertakings.

The bonuses payable to Mr. Loiacono are to be based upon the achievement of the following objectives:

(i) up to 40% of the Bonus Target related to compliance matters;

(ii) up to 30% of the Bonus Target related to the Company's operating budget;

(iii) up to 20% of the Bonus Target related to implementation of cybersecurity matters; and

(iv) up to 10% of the Bonus Target related to capital management activities.

The payments of any bonuses pursuant to the above are qualified and subject to (i) the Company having sufficient capital to operate its business for the ensuing twelve months, and (ii) the successful attainment of at least 85% of each person's objectives. The bonuses are able to be paid in a combination of cash and common stock at the discretion of the Compensation Committee.

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 2018 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, 2018, 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 AND 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-27.

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 exhibits required to be filed by this report or able to be incorporated by reference are listed in the "Exhibit Index" following the financial statements.

(b) Other Exhibits
Exhibits required by Item 601 of Regulation S-K are submitted (or incorporated by reference) and listed in a separate section herein immediately following the "Exhibit Index" and are incorporated herein by reference.

(c) Not Applicable.

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 15, 2019

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 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 15, 2019 on behalf of the registrant and in the capacities indicated.

Signature	Title	Date
/s/ Peter Hoang Peter Hoang	President, Chief Executive Officer and Director	March 15, 2019
/s/ Frederick Wasserman Frederick Wasserman	Director	March 15, 2019
/s/ David Laskow-Pooley David Laskow-Pooley	Director	March 15, 2019
/s/ John Wilson John Wilson	Director	March 15, 2019
/s/ Juan Vera Juan Vera	Director	March 15, 2019
/s/ N. David Eansor N. David Eansor	Director	March 15, 2019
/s/ Anthony Kim Anthony Kim	Chief Financial Officer	March 15, 2019

MARKER THERAPEUTICS, INC.

CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2018

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Marker Therapeutics, Inc. (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2018, based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013 and our report dated March 15, 2019, expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

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 audit**s**. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit**s** in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit**s** to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit**s** provide a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

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

New York, NY
March 15, 2019

MARKER THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,746,748	$ 5,129,289
Prepaid expenses and deposits	141,717	51,150
Interest receivable	108,177	-
Total current assets	61,996,642	5,180,439
Property, plant and equipment, net	147,668	-
Total assets	$ 62,144,310	$ 5,180,439
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 2,754,572	$ 1,513,312
Warrant liability	49,000	9,000
Total current liabilities	2,803,572	1,522,312
Total liabilities	2,803,572	1,522,312
COMMITMENTS AND CONTINGENCIES		
Stockholders' equity:		
Preferred stock - $0.001 par value, 5 million shares authorized at December 31, 2018 and 2017, respectively		
Series A, $0.001 par value, 1.25 million shares designated, 0 shares issued and outstanding as of December 31, 2018 and 2017, respectively	-	-
Series B, $0.001 par value, 1.5 million shares designated, 0 shares issued and outstanding as of December 31, 2018 and 2017, respectively	-	-
Common stock, $0.001 par value, 150 million shares authorized, 45.4 million and 10.6 million shares issued and outstanding as of December 31, 2018 and 2017, respectively	45,440	10,616
Additional paid-in capital	365,400,748	161,067,538
Accumulated deficit	(306,105,450)	(157,420,027)
Total stockholders' equity	59,340,738	3,658,127
Total liabilities and stockholders' equity	$ 62,144,310	$ 5,180,439

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,	
	2018	**2017**
Revenues:		
Grant income	$ 205,994	$ 183,064
Total revenues	205,994	183,064
Operating expenses:		
Research and development - intellectual property acquired	116,044,886	-
Research and development	7,952,870	5,250,985
General and administrative	24,379,871	6,412,121
Total operating expenses	148,377,627	11,663,106
Loss from operations	(148,171,633)	(11,480,042)
Other income (expense):		
Change in fair value of warrant liabilities	(40,000)	5,500
Interest income	253,723	-
Debt extinguishment gain	-	492,365
Net loss	**$ (147,957,910)**	**$ (10,982,177)**
Net loss per share, Basic and Diluted	$ (7.75)	$ (1.16)
Weighted average number of common shares outstanding	19,091,926	9,453,483

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par value			
Balance at January 1, 2017	**8,421,185**	**$ 8,421**	**$ 151,991,974**	**$ (145,815,808)**	**$ 6,184,587**
Issuance of common stock and warrants in private placement	1,503,567	1,504	6,188,499	-	6,190,003
Fees and legal costs relating to private placement	-	-	(781,660)	-	(781,660)
Exercise of warrants	167,926	168	666,498	-	666,666
Legal costs relating to exercise of warrants	-	-	(47,043)	-	(47,043)
Fair value of repriced warrants as inducement	-	-	622,042	(622,042)	-
Stock-based compensation	620,685	621	2,737,623	-	2,738,244
Repurchase of common stock to pay for employee withholding taxes	(97,639)	(98)	(310,395)	-	(310,493)
Net loss	-	-	-	(10,982,177)	(10,982,177)
Balance at December 31, 2017	**10,615,724**	**10,616**	**161,067,538**	**(157,420,027)**	**3,658,127**
Issuance of common stock for research and development intellectual property	13,914,255	13,914	116,030,972	-	116,044,886
Issuance of common stock and warrants in private placement	18,800,000	18,800	73,101,200	-	73,120,000
Fees and legal costs relating to private placement	-	-	(6,175,000)	-	(6,175,000)
Stock options exercised for cash	10,416	10	18,115	-	18,125
Stock warrants exercised for cash	1,499,324	1,499	4,352,129	-	4,353,628
Stock warrants cashless exercised	280,760	280	(280)	-	-
Stock-based compensation	327,786	329	16,350,263	-	16,350,592
Repurchase of common stock to pay for employee withholding taxes	(7,561)	(8)	(71,702)	-	(71,710)
Fair value of repriced warrants as inducement	-	-	727,513	(727,513)	-
Net loss	-	-	-	(147,957,910)	(147,957,910)
Balance, December 31, 2018	**45,440,704**	**$ 45,440**	**$ 365,400,748**	**$ (306,105,450)**	**$ 59,340,738**

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,	
	2018	**2017**
Cash Flows from Operating Activities:		
Net loss	$ (147,957,910)	$ (10,982,177)
Reconciliation of net loss to net cash used in operating activities:		
Changes in fair value of warrant liabilities	40,000	(5,500)
Stock-based compensation	16,350,592	2,738,244
Debt extinguishment gain	-	(492,365)
Research and development - intellectual property acquired	116,044,886	-
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(90,567)	18,999
Interest receivable	(108,177)	
Accounts payable and accrued expenses	1,241,260	283,372
Net cash used in operating activities	(14,479,916)	(8,439,427)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(147,668)	-
Net cash used in investing activities	(147,668)	-
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock and warrants in private placement, net of offering costs	66,945,000	5,408,343
Proceeds from exercise of stock warrants, net of offering costs	4,353,628	619,623
Proceeds from exercise of stock options	18,125	-
Repurchase of common stock to pay for employee withholding taxes	(71,710)	(310,493)
Net cash provided by financing activities	71,245,043	5,717,473
Net increase (decrease) in cash	56,617,459	(2,721,954)
Cash at beginning of year	5,129,289	7,851,243
Cash and cash equivalents at end of year	$ 61,746,748	$ 5,129,289

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,	
	2018	**2017**
Supplemental schedule of non-cash financing activities:		
Fair value of repriced warrants as inducement	$ 727,513	$ 622,042
Stock warrants cashless exercised	$ 280	$ -

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

NOTE 1: NATURE OF OPERATIONS

Marker Therapeutics, Inc., a Delaware corporation formerly known as TapImmune, Inc. (the "Company" or "we"), is a clinical-stage immuno-oncology company specializing in the development and commercialization of innovative cell-based immunotherapies for the treatment of hematological malignancies and solid tumor indications, and novel peptide-based vaccines for the treatment of breast and ovarian cancers. The Company's cell-based immunotherapy technology is based on the selective expansion of non-engineered, tumor-specific T cells that recognize tumor associated antigens (i.e. tumor targets) and kill tumor cells expressing those targets. Once infused into patients, this population of T cells recognizes multiple tumor targets to produce broad spectrum anti-tumor activity. Because the Company does not genetically engineer its T cells, when compared to current engineered CAR-T and TCR-based approaches, its products (i) are significantly less expensive to manufacture, (ii) appear to be markedly less toxic, and (iii) are associated with potentially meaningful clinical benefit. As a result, the Company believes its portfolio of T cell therapies has a potentially compelling therapeutic product profile, as compared to current gene-modified CAR-T and TCR-based therapies. In addition, the Company's Folate Receptor Alpha program (TPIV200) for breast and ovarian cancers and our HER2/neu program (TPIV100/110) are in five Phase II clinical trials. In parallel, the Company has been working on a proprietary nucleic acid-based antigen expression technology named PolyStart™ to improve the ability of the immune system to recognize and destroy diseased cells. The Company was incorporated in Nevada in 1992 and reincorporated in Delaware in October 2018 in connection with the Marker Transaction.

On October 17, 2018, the Company completed its previously announced acquisition with Marker Cell Therapy, Inc., formerly known as Marker Therapeutics, Inc., a privately-held Delaware corporation ("Marker Cell"), in accordance with the terms of an Agreement and Plan of Merger and Reorganization dated as of May 15, 2018 (the "Merger Agreement") by and among the Company, Timberwolf Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of the Company ("Merger Sub"), and Marker. On October 17, 2018, pursuant to the Merger Agreement, Merger Sub was merged with and into Marker Cell (the "Merger"), with Marker Cell being the surviving corporation and becoming a wholly-owned subsidiary of the Company. In connection with the Merger, the Company changed its name to Marker Therapeutics, Inc. and Marker Cell changed its name to Marker Cell Therapy, Inc. At the effective time of the Merger, the former Marker Cell stockholders received (i) an aggregate of 13,914,255 shares of the Company's common stock which equaled the number of shares of the Company's common stock issued and outstanding immediately prior to the effective time of the Merger, and (ii) an aggregate of 5,046,003 warrants which equaled the number of the Company's warrants and stock options issued and outstanding immediately prior to the effective time of the Merger.

NOTE 2: BASIS OF PRESENTATION AND MANAGEMENT PLANS

The accompanying 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").

The Company has not generated any revenue from product sales to date and, if the Company does not successfully obtain regulatory approval and commercialize any of its product candidates, the Company will not be able to generate product revenue or achieve profitability.

The Company is subject to risks common to companies in the biotechnology industry and the future success of the Company is dependent on its ability to successfully complete the development of, and obtain regulatory approval for its product candidates, manage the growth of the organization, obtain additional financing necessary in order to develop, launch and commercialize its product candidates, and compete successfully with other companies in its industry. These financial statements are presented in United States dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). In the opinion of management, the accompanying audited consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of such annual results.

NOTE 3: SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

These 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 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.

Prior Period Reclassification

Prior period grant income that was included in other income (expense) in the December 31, 2017 consolidated statement of operations has been reclassified to revenues for comparability with the December 31, 2018 presentation. This reclassification had no effect on previously reported net loss.

Research and Development – Intellectual Property Acquired

The Company concluded that its acquisition with Marker Cell Therapy, Inc. completed on October 17, 2018 should be accounted for as an asset acquisition rather than a business combination under Accounting Standards Codification (ASC) 805, Business Combinations. The merger was accounted for as an asset acquisition because substantially all the fair value of the assets being acquired are concentrated in a group of similar assets. Furthermore, the acquired assets did not have outputs or employees. The assets acquired by the Company under the merger included a license, other associated intellectual property, documentation and records, and related materials. Because Marker's intellectual property had not received regulatory approval, the $116.0 million purchase price paid for these assets was immediately expensed in the Company's statement of operations as research and development – intellectual property acquired.

Revenue Recognition

The Company has not yet generated any revenue from product sales. The Company's source of revenue in 2018 and 2017 has been from grants. When grant funds are received after costs have been incurred, the Company records grant revenue upon the receipt of cash.

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, 2018 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, 2018, and 2017, approximately $3.4 million and $4.9 million, respectively, 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.

Rent and Deferred Rent

The Company recognizes rent expense for leases with increasing annual rents on a straight-line basis over the term of the lease. The amount of rent expense in excess of cash payments is classified as deferred rent. Any lease incentives received are deferred and amortized over the term of the 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 restricted stock units and stock options. The fair value of restricted stock is determined by the closing market price of the Company's common stock on the date of grant. 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. 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. Expected volatility is based on historical volatility. The expected life of options granted is based on historical expected life. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant. The forfeiture rate is based on historical data, and the Company records stock-based compensation expense only for those awards that are expected to vest. The dividend yield is based on the fact that no dividends have been paid historically and none are currently expected to be paid in the foreseeable future:

Expected Term — The expected term of options represents the period that the Company's stock-based awards are expected to be outstanding based on the simplified method, which is the half-life from vesting to the end of its contractual term.

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 recognizes fair value of stock options granted to nonemployees as stock-based compensation expense over the period in which the related services are received.

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, 2018, and 2017, 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, 2018 and 2017.

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 include only the weighted average common shares outstanding, without consideration of potentially dilutive securities. Diluted loss per share include 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, we do not believe that the impact of recently issued standards that are not yet effective will have a material impact on our financial position or results of operations upon adoption.

Recent Accounting Standards Adopted in the Year

Revenue from Contracts with Customers

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers (Topic 606)" (ASU 2014-09) as modified by ASU No. 2015-14, "Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date," ASU 2016-08, "Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)," ASU No. 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing," and ASU No. 2016-12, "Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients." The revenue recognition principle in ASU 2014-09 is that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, new and enhanced disclosures will be required. Companies may adopt the new standard either using the full retrospective approach, a modified retrospective approach with practical expedients, or a cumulative effect upon adoption approach. The Company adopted the new standard effective January 1, 2018, using the modified retrospective approach. The only impact of the adoption of ASU 2014-09 was to reclassify the Company's grant income as revenue.

Recent Accounting Standards Not Yet Adopted

Improvements to Non-Employee Share-Based Payment Accounting

In June 2018, the FASB issued ASU 2018-07 “Improvements to Non-employee Share-Based Payment Accounting”, which simplifies the accounting for share-based payments granted to non-employees for goods and services. Under the ASU, most of the guidance on such payments to non-employees would be aligned with the requirements for share-based payments granted to employees. The amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity’s adoption date of Topic 606. The Company is currently evaluating the impact of the new standard on its consolidated financial statements.

Leases

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) in order to increase transparency and comparability among organizations by, among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. For public companies, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach and early adoption is permitted. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous U.S. GAAP. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. The Company adopted Topic 842 on January 1, 2019, using the optional transition method to apply the new guidance as of January 1, 2019, rather than as of the earliest period presented, and elected the package of practical expedients described above. Based on the analysis, the Company expects to recognize additional operating liabilities of approximately $670,000, with corresponding ROU assets of approximately the same amount as of January 1, 2019 based on the present value of the remaining lease payments.

SEC Disclosure Update and Simplification

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule was effective on November 5, 2018. The Company is evaluating the impact of this guidance on its consolidated financial statements. The Company anticipates its first presentation of changes in shareholders’ equity in accordance with the new guidance, will be included in its Form 10-Q for the quarter ended March 31, 2019.

NOTE 4: ASSET ACQUISITIONS

The Asset Acquisition

On October 17, 2018, the Company completed its acquisition with Marker Cell Therapy, Inc., formerly known as Marker Therapeutics, Inc., a privately-held Delaware corporation (“Marker Cell”), in accordance with the terms of an Agreement and Plan of Merger and Reorganization dated as of May 15, 2018 (the “Merger Agreement”) by and among the Company, Timberwolf Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of the Company (“Merger Sub”), and Marker. On October 17, 2018, pursuant to the Merger Agreement, Merger Sub was merged with and into Marker Cell (the “Merger”), with Marker Cell being the surviving corporation and becoming a wholly-owned subsidiary of the Company. In connection with the Merger, the Company changed its name to Marker Therapeutics, Inc. and Marker Cell changed its name to Marker Cell Therapy, Inc. At the effective time of the Merger, the former Marker Cell stockholders received (i) an aggregate of 13,914,255 shares of the Company’s common stock which equaled the number of shares of the Company’s common stock issued and outstanding immediately prior to the effective time of the Merger, and (ii) an aggregate of 5,046,003 warrants which equaled the number of the Company’s warrants and stock options issued and outstanding immediately prior to the effective time of the Merger.

Securities Purchase Agreements

On October 17, 2018, concurrent with the completion of the Merger, the Company issued to certain accredited investors in a private placement transaction (the "Financing"), an aggregate of 17,500,000 shares of its common stock, and warrants to purchase 13,437,500 shares of common stock at an exercise price of $5.00 per share with a five-year term, for gross proceeds of $70 million pursuant to the terms of the Securities Purchase Agreements, dated June 8, 2018, by and among the Company and certain accredited investors (the "Securities Purchase Agreements").

Accounting Treatment

The Company concluded that the merger should be accounted for as an asset acquisition by the Company rather than as a business combination under Accounting Standards Codification (ASC) 805, Business Combinations. The merger was accounted for as an asset acquisition because substantially all the fair value of the assets being acquired are concentrated in a group of similar assets. Furthermore, the acquired assets did not have outputs or employees. The assets acquired by the Company under the merger include a license, other associated intellectual property, documentation and records, and related materials. Because Marker's intellectual property had not yet received regulatory approval, the $116.0 million purchase price paid for these assets was expensed in the Company's statement of operations for the fiscal year ended December 31, 2018. The Common Stock issued for the asset acquisition was valued at $116.0 million which is equal to the 13,914,255 common shares issued to Marker multiplied by $8.34, the closing price of the Company's Common Stock as of October 17, 2018.

The Company also considered whether the merger should be accounted for as a reverse acquisition by Marker. The purpose of the merger is for the Company to acquire the assets of Marker so that the Company can expand its product and service offerings. While the former TapImmune and Marker stockholders hold an equal number of Board seats in the combined entity, the Company concluded that Marker would not be deemed the accounting acquirer under ASC 805, and therefore the merger is not a reverse acquisition.

NOTE 5: 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, 2018 and 2017, respectively:

	For the Years Ended December 31,	
	2018	2017
Numerator:		
Net loss	$ (147,957,910)	$ (10,982,177)
Denominator:		
Weighted average common shares outstanding	19,091,926	9,453,483
Net loss per share data:		
Basic and Diluted	$ (7.75)	$ (1.16)

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,	
	2018	2017
Common stock options	4,120,000	489,000
Common stock purchase warrants	22,989,000	6,517,500
Common stock warrants - liability treatment	27,000	3,500
Potentially dilutive securities	27,136,000	7,010,000

NOTE 6: PROPERTY AND EQUIPMENT

Property and equipment consist of the following as of December 31, 2018 and 2017, respectively:

		For the years ended December 31,	
	Estimated Useful Lives	2018	2017
Computers and equipment	3-5 Years	$ 66,000	$ -
Office furniture	5 Years	82,000	-
Total		$ 148,000	$ -
Less: accumulated depreciation		-	-
Property and equipment, net		$ 148,000	$ -

Furniture and computer equipment were placed in use on January 1, 2019, therefore no depreciation expense was recorded during the year ended December 31, 2018.

NOTE 7: ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities consist of the following as of December 31, 2018 and 2017, respectively:

	December 31, 2018	December 31, 2017
Accounts payable	$ 1,619,000	$ 1,015,000
Compensation and benefits	416,000	162,000
Professional fees	236,000	32,000
Technology license fees	80,000	105,000
Investor relations fees	297,000	110,000
Other	106,000	89,000
Total accounts payable and accrued liabilities	$ 2,754,000	$ 1,513,000

NOTE 8: 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 December 31, 2018 and 2017, respectively:

	Weighted Average Inputs For the Years Ended December 31,	
	2018	2017
Stock price	$ 5.55	$ 3.92
Exercise price	$ 9.72	$ 1.20
Contractual term (years)	1.08	0.78
Volatility (annual)	99%	63%
Risk-free rate	2%	1%
Dividend yield (per share)	0%	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, 2018 and 2017, respectively:

	Warrant Liability
Balance - January 1, 2017	$ 14,500
Change in fair value of warrant liability	(5,500)
Balance – December 31, 2017	9,000
Change in fair value of warrant liability	40,000
Balance – December 31, 2018	$ 49,000

NOTE 9: 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 Derivative liability – warrants:

	Fair value measured at December 31, 2018			
	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Fair value at December 31, 2018
Warrant liability	$ -	$ -	$ 49,000	$ 49,000

	Fair value measured at December 31, 2017			
	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Fair value at December 31, 2017
Warrant liability	$ -	$ -	$ 9,000	$ 9,000

There were no transfers between Level 1, 2 or 3 during the years ended December 31, 2018 and 2017, 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 10: STOCKHOLDERS' EQUITY

Preferred Stock

The Company has authorized up to 5,000,000 shares of preferred stock, $0.0001 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.

Series A Preferred Stock - The Company has designated up to 1,250,000 shares of Series A Preferred Stock, $0.0001 par value per share, for issuance. To date, the Company has not issued any Series A preferred shares.

Series B Preferred Stock - The Company has designated up to 1,500,000 shares of Series B Preferred Stock, $0.0001 par value per share, for issuance. To date, the Company has not issued any Series B preferred shares.

Common Stock

The Company has authorized up to 150,000,000 shares of common stock, $0.0001 par value per share, for issuance. Significant 2018 and 2017 common stock transactions were as follows:

2018 Common Stock Transactions

The Merger

Pursuant to the Merger discussed in Note 4 above, the Company issued 13,914,255 shares of common stock to shareholders of Marker Cell Therapy, Inc. The fair market value of the shares issued pursuant to the asset acquisition was $116.0 million.

Securities Purchase Agreements

Pursuant to the financing discussed in Note 4 above, the Company issued 17,500,000 shares of its common stock to the participating accredited investors. Net proceeds, after transaction offering costs of $6.2 million, were $63.8 million.

Common Stock Purchase Agreement

On May 14, 2018, the Company's largest stockholder Eastern Capital Limited entered into a Common Stock Purchase Agreement with the Company pursuant to which it purchased 1,300,000 shares of common stock at a price per share of $2.40 providing gross proceeds to the Company of $3.12 million.

Exercise and Repricing of Warrants Held by Existing Institutional Investors

On May 14, 2018, certain institutional holders of outstanding warrants entered into Warrant Exercise Agreements with the Company that provide for an amendment to the exercise price of the warrants being exercised at $2.50 per share. Upon closing of the Warrant Exercise Agreements, such institutional holders immediately exercised warrants for 782,505 shares of common stock providing aggregate proceeds to the Company of approximately $2.0 million.

The fair value relating to the modification of exercise prices on the repriced and exercised warrants was treated as deemed dividend on the statement of stockholders' equity of $728,000.

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 included in the modification is as follows:

	Weighted Average Inputs	
	Before Modification	**After Modification**
Exercise price	$ 9.93	$ 2.50
Contractual term (years)	2.37	2.37
Volatility (annual)	79%	79%
Risk-free rate	1.5%	1.5%
Dividend yield (per share)	0%	0%

Exercise of Stock Warrants

In addition to the exercise and repricing of warrants discussed above, during the twelve months ended December 31, 2018, certain outstanding warrants were exercised by warrant holders providing aggregate proceeds to the Company of approximately $2.4 million and resulted in the issuance of 716,819 shares of common stock.

Additionally, 280,760 of the stock warrants exercised were exercised on a cashless basis, which resulted in approximately 204,000 of warrant shares being cancelled due to use of cashless exercise provisions.

Exercise of Stock Options

In January 2018, 10,416 shares of common stock were issued pursuant to stock option exercises at an exercise price equal to $1.74 per share.

Consulting Arrangements

During the twelve months ended December 31, 2018, the Company issued 274,012 shares of common stock in connection with consulting agreements. The fair value of the common stock of approximately $1.8 million was recognized as stock-based compensation expense, $1.7 million in general and administrative expenses and $0.1 million in research and development expenses.

2018 Management and Board Compensation

During the twelve months ended December 31, 2018, the Company issued 53,774 shares of common stock in connection with board of director and management agreements. The fair value of the common stock of approximately $0.5 million was recognized as stock-based compensation expense in general and administrative expenses. 7,561 shares of common stock, with a fair value of $0.1 million, were withheld to satisfy certain payroll liabilities, as applicable to an award to a former director.

2017 Common Stock Transactions

June 2017 Private Placement Transaction

On June 26, 2017, the Company completed private placement of units with certain accredited investors. In the private placement transaction, the Company sold 1,503,567 shares of common stock for $3.97 per share and five-year warrants to purchase an equal number of shares of common stock, at an exercise price of $3.97 per share, for $0.125 per warrant, with one common share and one warrant being sold together as a unit for a total of $4.095 per unit. The Company issued and sold an aggregate of 1,503,567 million units for aggregate gross proceeds of $6.2 million. The Company incurred $0.8 million in agency fees and legal costs. In connection with the offering, the Company reduced the exercise price for the warrants to purchase an aggregate of 653,187 shares of common stock issued to investors in the private placement that closed in August 2016 from $6.00 per share to $3.97 per share.

In addition, the Company issued five-year warrants to the placement agent in the offering providing for the purchase of up to 150,357 shares of Company common stock for $3.97 per share.

June 2017 Exercise and Repricing of Warrants Held by Existing Institutional Investors

On June 23, 2017, certain existing institutional shareholders of the Company who hold various outstanding warrants (i.e. C, D, E and F) to purchase Company common stock, entered into warrant repricing and exercise agreements.

Series E repriced and exercised warrants

Approximately 168,000 of Series E warrants were repriced from $15.00 per share to $3.97 per share and exercised immediately for gross proceeds of approximately $0.7 million. Series E warrants to purchase approximately 187,000 shares of Company common stock being reduced from $15.00 per share to $4.50 per share.

Series C, D & F repriced warrants

Additionally, the exercise prices for certain investors of Series C, Series D and Series F warrants were reduced as follows:

Series	Number of Warrant Shares Repriced	Pre-reduced Price	Post-reduced Price
Series C	313,750	$ 6.00	$ 4.00
Series D	312,500	$ 9.00	$ 4.00
Series F	292,500	$ 7.20	$ 4.00

The fair value relating to the modification of exercise prices on the repriced warrants was treated as deemed dividend on the statement of stockholders' equity of $0.6 million.

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 included in the modification is as follows:

	Before Modification	After Modification
Exercise price	$ 8.32	$ 4.04
Contractual term (years)	3.34	3.34
Volatility (annual)	200%	200%
Risk-free rate	2%	2%
Dividend yield (per share)	0%	0%

2017 Management Compensation

On March 9, 2017, the Company issued 12,761 shares of stock to Dr. Glynn Wilson. The fair value of the common stock of $55,000 was recognized as stock-based compensation in general and administrative expenses. The issuance was based on the closing price or our common stock of $4.31 per share.

On March 9, 2017, the Company issued 5,220 shares of stock to our former Chief Operating Officer. The fair value of the common stock of $22,500 was recognized as stock-based compensation in general and administrative expenses. The issuance was based on the closing price or our common stock of $4.31 per share.

On September 22, 2017, the Company granted Mr. Hoang 250,000 shares of unregistered, fully vested restricted common stock. The Company recorded $0.8 million of stock-based compensation based on the fair value of the common stock at September 22, 2017. 70,289 shares of common stock, with a fair value of $0.2 million, were withheld (at the closing price of the Company's common stock on the NASDAQ Capital Market on September 22, 2017) to satisfy certain payroll liabilities, as applicable to the award.

On September 22, 2017, the Company granted Dr. Wilson 100,000 shares of unregistered, fully vested restricted common stock. The Company recorded $0.3 million of stock-based compensation based on the fair value of the common stock at September 22, 2017. 27,350 shares of common stock, with a fair value of $0.1 million, were withheld (at the closing price of the Company's common stock on the NASDAQ Capital Market on September 22, 2017) to satisfy certain payroll liabilities, as applicable to the award.

Consulting Arrangements

During fiscal 2017, the Company issued 0.2 million shares of common stock as part of consulting agreements. The fair value of the common stock of $0.6 million was recognized as stock-based compensation in general and administrative expenses.

NOTE 11: WARRANTS

Share Purchase Warrants

A summary of the Company's share purchase warrants as of December 31, 2018 and 2017, 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, 2017	**5,059,000**	**$ 8.49**	**3.68**	**$ 1,713,000**
Issued	1,654,000	3.97	-	-
Exercised for cash	(168,000)	15.00	-	-
Expired or cancelled	(25,000)	30.50	-	-
Balance - December 31, 2017	**6,520,000**	**6.11**	**3.16**	**1,739,000**
Issued	18,484,000	4.45	-	-
Cashless exercised	(281,000)	4.03	-	-
Exercised for cash	(1,499,000)	6.78	-	-
Expired or cancelled	(208,000)	4.00	-	-
Balance -December 31, 2018	**23,016,000**	**$ 4.78**	**4.29**	**$ 26,066,000**

2018 Warrant Transactions

The Merger

Pursuant to the Merger discussed in Note 4 above, the Company issued 5,046,003 stock warrants to shareholders of Marker Cell Therapy, Inc. at an exercise price of $2.99 per share with a five-year term.

Securities Purchase Agreements

Pursuant to the financing discussed in Note 4 above, the Company issued 13,437,500 stock warrants to certain accredited investors at an exercise price of $5.00 per share with a five-year term.

Exercise and Repricing of Warrants Held by Existing Institutional Investors

On May 14, 2018, certain institutional holders of outstanding warrants entered into Warrant Exercise Agreements with the Company that provide for an amendment to the exercise price of the warrants being exercised at $2.50 per share. Upon closing of the Warrant Exercise Agreements, such institutional holders immediately exercised warrants for 782,505 shares of common stock providing aggregate proceeds to the Company of approximately $2.0 million.

The fair value relating to the modification of exercise prices on the repriced and exercised warrants was treated as deemed dividend on the statement of stockholders' equity of $728,000.

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 included in the modification is as follows:

	Weighted Average Inputs	
	Before Modification	After Modification
Exercise price	$ 9.93	$ 2.50
Contractual term (years)	2.37	2.37
Volatility (annual)	79%	79%
Risk-free rate	1.5%	1.5%
Dividend yield (per share)	0%	0%

Exercise of Stock Warrants

In addition to the exercise and repricing of warrants discussed above, during the twelve months ended December 31, 2018, certain outstanding warrants were exercised by warrant holders providing aggregate proceeds to the Company of approximately $2.4 million and resulted in the issuance of 716,819 shares of common stock.

Additionally, 280,760 of the stock warrants exercised were exercised on a cashless basis, which resulted in approximately 204,000 of warrant shares being cancelled due to use of cashless exercise provisions.

2017 Warrant Transactions

June 2017 Private Placement Transaction

On June 26, 2017, the Company completed private placement of units with certain accredited investors. In the private placement transaction, the Company sold 1,503,567 shares of common stock for $3.97 per share and five-year warrants to purchase an equal number of shares of common stock, at an exercise price of $3.97 per share, for $0.125 per warrant, with one common share and one warrant being sold together as a unit for a total of $4.095 per unit. The Company issued and sold an aggregate of 1,503,567 million units for aggregate gross proceeds of $6.2 million. The Company incurred $0.8 million in agency fees and legal costs. In connection with the offering, the Company reduced the exercise price for the warrants to purchase an aggregate of 653,187 shares of common stock issued to investors in the private placement that closed in August 2016 from $6.00 per share to $3.97 per share.

June 2017 Exercise and Repricing of Warrants Held by Existing Institutional Investors

On June 23, 2017, certain existing institutional shareholders of the Company who hold various outstanding warrants (i.e. C, D, E and F) to purchase Company common stock, entered into warrant repricing and exercise agreements.

Series E repriced and exercised warrants

Approximately 168,000 of Series E warrants were repriced from $15.00 per share to $3.97 per share and exercised immediately for gross proceeds of approximately $0.7 million. Series E warrants to purchase approximately 187,000 shares of Company common stock being reduced from $15.00 per share to $4.50 per share.

Series C, D & F repriced warrants

Additionally, the exercise prices for certain investors of Series C, Series D and Series F warrants were reduced as follows:

Series	Number of Warrant Shares Repriced	Pre-reduced Price	Post-reduced Price
Series C	313,750	$ 6.00	$ 4.00
Series D	312,500	$ 9.00	$ 4.00
Series F	292,500	$ 7.20	$ 4.00

The fair value relating to the modification of exercise prices on the repriced warrants was treated as deemed dividend on the statement of stockholders' equity of $0.6 million.

June 2017 Agent Warrants

Pursuant to an agency agreement, dated May 12, 2017, by and between Katalyst Securities LLC and us, Katalyst agreed to act as our placement agent in connection with the June 26, 2017 private placement offering.

Pursuant to the agreement, we agreed to pay to Katalyst: (i) an aggregate cash fee for placement agent and financial advisory services equal to 10% of the gross proceeds of the Offering; (ii) a non-accountable expense allowance in the amount of Seventy Thousand Dollars ($70,000); and (iii) five-year warrants to purchase a number of shares of our common stock equal to 10% of the number of shares sold in the offering. The Katalyst Warrants have the same terms as the private placement warrants issued in the offering. Based on the 1,503,567 shares of common stock sold in the private placement, we issued five-year warrants to Katalyst providing for the purchase of up to 150,357 shares of Company common stock for $3.97 per share.

NOTE 12: STOCK OPTION PLANS

Options to Purchase Shares of Common Stock

2014 Stock Omnibus Plan

On March 19, 2014, the Board adopted the 2014 Omnibus Stock Option Plan ("2014 Plan"), which replaced the 2009 Stock Incentive Plan. The 2014 Plan allowed 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 2014 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 2014 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.

The 2014 Plan was amended in February 2015 to provide for grants to consultants, and again in November 2015 to (i) increase the number of shares reserved for issuance under the Plan to 0.6 million shares; (ii) provide the Board and Committee administering the Plan with full discretion on the vesting period for Service-Vesting Awards under the Plan, including the grant of Awards with less than the Minimum Vesting Requirement (as such terms are defined in the Plan), and (iii) provide the Board and Committee administering the Plan with the ability to grant stock bonuses to executive officers.

On August 29, 2017, the 2014 Plan was amended to increase the shares reserved under the Plan to 1.4 million shares, and on October 16, 2018 the 2014 Plan was amended to increase the shares reserved under the Plan to 8.0 million shares. As of December 31, 2018, approximately 3.4 million options are available to be issued from the 2014 Plan.

Stock Options

A summary of the Company's employee 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, 2017	430,624	$ 7.41	$ 39,000	8.9
Granted	40,000	3.88	-	9.4
Exercised	-	-	-	-
Forfeited/expired	(34,827)	6.71	-	-
Outstanding as of December 31, 2017	435,797	-	42,000	8.1
Granted	2,464,855	8.79	-	9.8
Exercised	(10,416)	1.74	-	-
Forfeited/expired	(63,226)	6.00	-	-
Outstanding as of December 31, 2018	2,827,010	$ 8.61	$ 113,000	9.5
Options vested and exercisable	1,761,567	$ 8.75	$ 193,000	9.2

A summary of the Company's non-employee 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, 2017	3,471	$ 14.77	$ -	8.7
Granted	50,000	2.62	-	9.9
Exercised	-	-	-	-
Forfeited/expired	(13)	120.00	-	-
Outstanding as of December 31, 2017	53,458	$ 3.38	$ 65,000	9.7
Granted	1,240,000	-	-	9.8
Exercised	-	-	-	-
Forfeited/expired	-	-	-	-
Outstanding as of December 31, 2018	1,293,458	$ 8.86	$ 179,000	9.7
Options vested and exercisable	53,458	$ 3.38	$ 147,000	9.7

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, 2018, 2017, respectively, were as follows:

	For the Years Ended December 31,	
	2018	2017
Exercise price	$ 8.89	$ 3.25
Expected term (years)	10.0	10.0
Expected stock price volatility	200%	217%
Risk-free rate of interest	3%	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,	
	2018	2017
Stock Compensation expenses:		
Research and development	$ 1,265,000	$ 98,000
General and administrative	15,086,000	2,640,000
Total stock compensation expenses	$ 16,351,000	$ 2,738,000

At December 31, 2018, the total stock-based compensation cost related to unvested awards not yet recognized was $14.7 million. The expected weighted average period compensation costs to be recognized was 2.0 years. Future option grants will impact the compensation expense recognized.

NOTE 13: GRANT INCOME

During the years ended December 31, 2018 and 2017, the Company received $0.2 million 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 $0.2 million of grant income as revenue.

NOTE 14: COMMITMENTS AND CONTINGENCIES

Operating Lease Obligations

The Company was a party to several operating leases as of December 31, 2018, primarily for office space at certain locations.

Aggregate future minimum annual payments under operating leases at December 31, 2018, are as follows:

Year	Operating Leases
2019	$ 294,000
2020	234,000
2021	229,000
2022	71,000
2023	3,000
Thereafter	1,000
Total minimum rentals	$ 832,000

Total rental expense under the Company's operating leases was $175,600 and $121,200 for the years ended December 31, 2018 and 2017, respectively.

NOTE 15: 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 16: RELATED PARTY TRANSACTIONS

Payment made to Mr. John Wilson. In connection with the Merger discussed in Note 4, Mr. John Wilson, the former CEO of Marker Cell, was to be reimbursed for certain funds he advanced to Marker Cell prior to the closing of the Merger. Following the consummation of the Merger, in connection with the obligation to reimburse Mr. Wilson for such expenses, the Company paid Mr. Wilson $100,000 as part of the transaction expenses the Company incurred. At the effective time of the Merger, and as part of the terms thereof, Mr. Wilson became a director of the Company.

The Baylor College of Medicine ("BCM") Sponsored Research Agreement. On November 16, 2018, in furtherance of the BCM License Agreement and as contemplated by the terms thereof, the Company entered in a Sponsored Research Agreement ("SRA") with BCM, which provided for the conduct of research for the Company by credentialed personnel at Baylor's Center for Cell and Gene Therapy. The research is to be supervised by the BCM's Co-Investigators Dr. Vera and Dr. Leen as set forth and named in the SRA. The SRA has a four-year term. Pursuant to the SRA, the Company has agreed to pay BCM up to $256,272 for years one and two under the SRA with $76,882 paid up front and $153,764 paid in equal monthly installments over two years and a final payment of $25,626 after receipt of the final written report. Payments for years three and four are to be covered by an amendment. During the year ended December 31, 2018, the Company paid BCM $0 under the SRA as the upfront payment was made in January 2019. Neither Dr. Vera nor Dr. Leen received any of these payments or are entitled to receive any portion of these payments. Dr. Vera and Dr. Leen do however indirectly benefit from such payments in connection with their status as BCM employees.

The Consulting Agreement-Dr. Vera. On October 19, 2018, after the closing of the 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. The consulting agreement provided for the payment of an annual base consulting fee of $350,000 for services to the Company, discretionary cash payment by the Company up to a maximum of 35% of the base consulting fee, and an award of 500,000 stock options. The consulting agreement is terminable by either party upon 30 days prior written notice. One quarter of the stock options awarded vest on the first anniversary of the award and the remainder vest evenly in equal monthly installments over a three-year period upon the continued performance of consulting services by Dr. Vera over such period. Dr. Vera, an accomplished individual in his field, has another consulting arrangement with parties unrelated to the Company, that have licensed intellectual property from BCM that resulted from his research and development efforts. He may pursue similar arrangements in the future. During the year ended December 31, 2018, Dr. Vera was paid $60,577 by the Company under his consulting agreement.

NOTE 17: INCOME TAXES

The Company has no income tax expense due to operating losses incurred for the years ended December 31, 2018 and 2017.

The effects of temporary differences that give rise to significant portions of the deferred tax assets as of December 31, 2018 and 2017 are as follows:

	For the years ended December 31,	
	2018	**2017**
Deferred tax assets:		
Net operating loss carryforward	$ 13,596,000	$ 9,690,000
Stock-based compensation	5,741,000	1,556,000
License agreements	206,000	223,000
Research and development	406,000	406,000
Charitable contributions	3,000	3,000
	19,952,000	11,878,000
Less: Valuation allowance	(19,952,000)	(11,878,000)
Deferred tax assets, net of valuation allowance	$ -	$ -

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"), which makes broad and complex changes to the U.S. tax code. Certain of these changes may be applicable to the Company, including but not limited to, reducing the U.S. federal corporate tax rate from 34 percent to 21 percent, creating a new limitation on deductible interest expense, eliminating the corporate alternative minimum tax ("AMT"), modifying the rules related to uses and limitations of net operating loss carryforwards generated in tax years ending after December 31, 2017, and changing the rules pertaining to the taxation of profits earned abroad. Changes in tax rates and tax laws are accounted for in the period of enactment. The Tax Act reduces the corporate tax rate to 21 percent, effective January 1, 2018.

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, 2018 and 2017. The Company decreased the prior period deferred tax asset by $4.8 million with a corresponding increase in its valuation allowance. This immaterial adjustment related to the reduction in the federal tax rates from 34% to 21% and had no impact on the prior period financial statements. Consequently, the valuation allowance increased by $8.1 million as of December 31, 2018. The Company has research and development tax credit carryforwards of $406,000 to offset future federal income taxes. The research and development tax credit carryforwards begin to expire in 2030.

The Company has approximately $57.0 million of federal and $37.3 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 $15.4 million generated in 2018 are subject to an 80% limitation on taxable income, do not expire and will carry forward indefinitely. The state net operating loss carryforwards of $21.8 million, if not utilized, will begin to expire in 2035. The state net operating loss carryforwards of $15.4 million generated in 2018 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.

For the years ended December 31, 2018 and 2017, 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, 2018		For the years ended December 31, 2017	
U.S. federal statutory rate	$ (31,071,000)	21.00%	$ (3,734,000)	34.00%
State taxes, net of federal benefit	(1,383,000)	0.93%	(416,000)	3.79%
Federal tax rate change	-	0.00%	6,275,000	-57.14%
Permanent Differences				
- Non-deductible write-off of acquired R&D expenses	24,369,000	-16.47%	-	0.00%
- Change in fair value of derivative liabilities	8,000	-0.01%	(2,000)	0.02%
- Other permanent differences	4,000	0.00%	(161,000)	1.47%
Change in valuation allowance	8,073,000	-5.46%	(1,914,000)	17.43%
Other	-	0.00%	(48,000)	0.44%
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, 2018, and 2017, 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, 2018 and 2017. 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.

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 C-1	8-K	000-27239	4.8	3/10/15	
4.8	Form of Placement Agent Warrant Common Stock Purchase Warrants-Series D-1	8-K	000-27239	4.9	3/10/15	
4.9	Form of Placement Agent Warrant Common Stock Purchase Warrants-Series E-1	8-K	000-27239	4.10	3/10/15	
4.10	Form of Amended Series A Warrant	8-K	000-27239	4.2	8/11/16	
4.11	Form of Amended Series C Warrant	8-K	000-27239	4.3	8/11/16	
4.12	Form of Amended Series D Warrant	8-K	000-27239	4.4	8/11/16	
4.13	Form of Amended Series E Warrant	8-K	000-27239	4.5	8/11/16	
4.14	Form of Amended Series A-1 Warrant	8-K	000-27239	4.6	8/11/16	
4.15	Form of Amended Series D-1 Warrant	8-K	000-27239	4.7	8/11/16	
4.16	Form of Amended Series E-1 Warrant	8-K	000-27239	4.8	8/11/16	
4.17	Form of Series F Warrant	8-K	000-27239	4.9	8/11/16	

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
4.18	Form of Series F-1 Warrant	8-K	000-27239	4.10	8/11/16	
4.19	Form of August 2016 Private Placement Warrant	8-K	000-27239	4.1	8/11/16	
4.20	Form of 2016 Private Placement Agent Warrant	8-K	000-27239	4.11	8/11/16	
4.21	Form of June 2017 Private Placement Warrant	8-K	001-37939	4.1	6/22/17	
4.22	Form of 2017 Private Placement Agent Warrant	8-K	001-37939	4.2	6/22/17	
4.23	Form of Registration Rights Agreement August 2016 Private Placement	8-K	000-27239	10.2	8/11/16	
4.24	Form of Registration Rights Agreement June 2017 Private Placement	8-K	001-37939	10.2	6/22/17	
10.1	Form of Securities Purchase Agreement, dated as of January 12, 2015, by and among the Company and the Purchasers	8-K	000-27239	10.1	1/12/15	
10.2	Securities Purchase Agreement, dated as of March 9, 2015, by and among the Company and Eastern Capital Limited	8-K	000-27239	10.1	3/9/15	
10.3	Form of Restructuring Agreement dated May 28, 2015	8-K	000-27239	10.1	6/3/15	
10.4	Amended and Restated Restructuring Agreement, dated as of June 2, 2015	8-K	000-27239	10.1	6/5/15	
10.5	Form of Subscription Agreement August 2016 Private Placement	8-K	000-27239	10.1	8/11/16	
10.6	Form of Registration Rights Agreement August 2016 Private Placement	8-K	000-27239	10.2	8/11/16	
10.7	Form of Warrant Amendment Agreement August 2016 Private Placement	8-K	000-27239	10.3	8/11/16	
10.8	Agency Agreement August 2016 Private Placement	8-K	000-27239	10.4	8/11/16	
10.9	Form of Subscription Agreement June 2017 Private Placement	8-K	001-37939	10.1	6/22/17	
10.10	Form of Registration Rights Agreement June 2017 Private Placement	8-K	001-37939	10.2	6/22/17	
10.11	Form of Warrant Exercise Agreement	8-K	001-37939	10.3	6/22/17	
10.12	Agency Agreement June 2017 Private Placement	8-K	001-37939	10.4	6/22/17	
10.13	First Amendment to Agency Agreement June 2017 Private Placement	8-K	001-37939	10.1	6/26/17	
10.14	Form of Securities Purchase Agreement (including registration rights)	8-K	001-37939	10.1	6/8/18	
10.15	Form of Private Placement Warrant	8-K	001-37939	4.1	6/8/18	
10.16	Form of Private Placement Warrant	8-K	001-37393	4.2	6/8/18	
10.17	Form of Marker Warrant	8-K	001-37939	2.1	5/15/18	

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
10.18	Registration Rights Agreement	8-K	001-37939	2.1	5/15/18	
10.19	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	
10.20	License and Assignment Agreement with Mayo Foundation for Medical Education and Research dated May 19, 2016**	10-Q	000-27239	10.7	8/15/16	
10.21	Exclusive License Agreement between Baylor College of Medicine and Marker Therapeutics, Inc. dated March 16, 2018***					X
10.22	Sponsored Research Contract between Baylor College of Medicine and Marker Therapeutics, Inc. dated November 16, 2018***					X
10.23	2009 Stock Incentive Plan*	DEF14-C	000-27239	B	1/29/10	
10.24	2014 Omnibus Stock Ownership Plan, as amended through August 29, 2017*	8-K	001-37939	10.1	9/5/17	
10.25	Amendment to 2014 Omnibus Stock Ownership Plan, as amended *	8-K	001-37939	4.4	10/17/18	
10.26	Form of Stock Option Award Agreement –Employee*	8-K	001-37939	10.3	10/23/18	
10.27	Form of Stock Option Award Agreement – Non-Employee Director*	S-8	333-228056	10.1	10/30/18	
10.28	Form of Stock Option Award Agreement – Consultant*	8-K	001-37939	10.2	10/23/18	
10.29	Form of Restricted Stock Award Agreement – Consultant*	10-Q	000-27239	10.7	11/16/15	
10.30	Employment Agreement between TapImmune, Inc. and Dr. Glynn Wilson, dated November 12, 2015*	10-Q	000-27239	10.8	11/16/15	
10.31	Amendment to Employment Agreement between TapImmune Inc. and Glynn Wilson, dated as of July 18, 2016*	8-K	000-27239	10.1	7/19/16	
10.32	Amendment to Employment Agreement between TapImmune Inc. and Glynn Wilson, dated as of September 22, 2017*	8-K	001-37939	10.2	9/25/17	
10.33	Employment Agreement between TapImmune Inc. and Peter Hoang dated as of September 22, 2017*	8-K	001-37939	10.1	9/25/17	
10.34	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	
10.35	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	
10.36	Employment Agreement between Marker Therapeutics, Inc. and Anthony Kim dated as of November 27, 2018*	8-K	001-37939	10.3	12/3/18	
10.37	Consulting Agreement between Dr. Juan Vera and Marker Therapeutics, Inc. dated October 19, 2018*	8-K	001-37939	10.1	10/23/18	

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
10.38	Consulting Agreement between Dr. Ann Leen and Marker Therapeutics, Inc. dated October 19, 2018*					X
10.39	Form of Director and Officer Indemnification Agreement*					X
10.40	Amendment to Employment Agreement between Marker Therapeutics, Inc. and Peter Hoang, dated March 14, 2019*					X
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.

Exhibit 10.21

CONFIDENTIAL TREATMENT REQUESTED BY MARKER THERAPEUTICS, INC.

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

EXCLUSIVE LICENSE AGREEMENT

Re: BLG 10-001, entitled "Generation of CTL Lines with Specificity Against Multiple Tumor Antigens or Multiple Viruses;"
BLG 10-048, entitled "Pepmixes to Generate Multiviral CTLs with Broad Specificity;" and
BLG 16-019 and BLG 16-100, entitled "Immunogenic Antigen Identification from a Pathogen and Correlation to Clinical Efficacy"

This Exclusive License Agreement (hereinafter called this "**Agreement**"), to be effective as of the 16th day of March, 2018 (hereinafter called the "**Agreement Date**"), is by and between Baylor College of Medicine (hereinafter called "**BCM**"), a Texas nonprofit corporation having its principal place of business at One Baylor Plaza, Houston, Texas 77030, and Marker Therapeutics, Inc., a corporation organized under the laws of Delaware and having a principal place of business at 33 5th Avenue N.W., New Brighton, Minnesota (hereinafter, referred to as "**LICENSEE**").

WITNESSETH:

WHEREAS, BCM's mission is to advance human health through the integration of education, research, patient care and community service; and

WHEREAS, BCM is the owner of the Subject Technology and Patent Rights as defined below; and

WHEREAS, BCM is willing to grant a royalty bearing, worldwide, exclusive license to BCM's rights in the Subject Technology and Patent Rights to LICENSEE on the terms set forth herein; and

WHEREAS, LICENSEE desires to obtain said exclusive license under BCM's rights in the Subject Technology and Patent Rights.

NOW, THEREFORE, for and in consideration of the promises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto expressly agree as follows:

1. DEFINITIONS AS USED HEREIN

1.1 The term "Affiliates" shall mean any Person, directly or indirectly, controlling, controlled by or under common control with such Person, for so long as such control exists. For purposes of this definition, "control" means: (a) direct or indirect ownership of at least fifty percent (50%) of the entity's common stock or other ownership interest having the right to vote for the election of directors of such corporate entity or (b) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such entity, whether through the ownership of voting securities, by contract or otherwise.

1.2 The term "Agreement" shall have the meaning given such term in the first paragraph of this Agreement.

1.3 The term "Agreement Date" shall have the meaning given such term in the first paragraph of this Agreement.

1.4 The term "Annual Progress Report" shall have the meaning given such term in Section 5.1.

1.5 The term "Applicable Law" shall mean any United States federal, state, local or foreign law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation, or any governmental order, or any license, franchise, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.

1.6 The term "BCM" shall have the meaning given such term in the first paragraph of this Agreement.

1.7 The term "BCM Claims" shall have the meaning given such term in Section 16.1(i).

1.8 The term "BCM Developers" shall mean the following:

(i) BLG 10-001, entitled "Generation of CTL Lines with Specificity Against Multiple Tumor Antigens or Multiple Viruses," Ann Leen, Cliona M. Rooney, Ulrike Gerdemann, Juan F. Vera Valdes;

(ii) BLG 10-048, entitled "Pepmixes to Generate Multiviral CTLs with Broad Specificity," Ann Leen, Juan F. Vera Valdes, Cliona Rooney, Ulrike Gerdemann;

(iii) BLG 16-019, entitled "Immunogenic Antigen Identification from a Pathogen and Correlation to Clinical Efficacy," Ann Marie Leen, Pailbel Aguayo-Hiraldo, Ifigeneia Tzannou, Juan F. Vera Valdes; and

(iv) BLG 16-100, entitled "Immunogenic Antigen Identification from a Pathogen and Correlation to Clinical Efficacy," Ann Marie Leen, Sarah Kogan Nicholas, and Ifigeneia Tzannou.

1.9 The term "Commercially Reasonable Efforts" means with respect to the performing Party, its Affiliates and its Sublicenses, a level of efforts and resources, not less than reasonable efforts and resources, that is consistent with the efforts and resources utilized by Persons of similar size, type and stage of development to develop and commercialize products similar to the Licensed Products, as applicable, and would typically devote to a product or compound owned by it or to which is has the rights of the type it has hereunder, taking into account scientific and commercial factors, including the competitiveness of alternative third party products in the marketplace, the patent or other proprietary position of the Licensed Product(s), the regulatory requirements involved and the potential profitability of the Licensed Product(s) marketed or to be marketed.

1.10 The term "Confidential Information" shall mean any proprietary and secret ideas, proprietary technical information, know-how and proprietary commercial information or other similar confidential, non-public or proprietary information that are owned by the disclosing Party. The term "Confidential Information" is further defined in Section 17.

1.11 The term "Disclosing Party" shall mean the Party disclosing Confidential Information to the other Party.

1.12 The term "Distinct Product" is a Licensed Product for which a separate and distinct Investigational New Drug (IND) application or Biologics License Application (BLA), or their non-US equivalents, is required by a regulatory authority to be filed with respect thereto to clinically develop in humans and obtain approval to market such product. For the avoidance of doubt, any combination product comprising a Licensed Product on the one hand, and another active agent (whether or not another Licensed Product), on the other hand, shall be deemed to be a Distinct Product separate from any such Licensed Product, if the combination product is subject to a separate and distinct IND or BLA, or their non-US equivalents. For further avoidance of doubt, a Licensed Product which is administered as a concurrent therapy (and not a combination product) along with another product which contains a different active agent, wherein each product is subject to a separate IND or BLA (or their non-US equivalents), shall not be considered a different Distinct Product from the Licensed Product when administered alone.

1.13 The term "Field" shall mean all diagnostic and therapeutic applications or uses in oncology, including, but not limited to, prophylaxis, adjuvant and treatment.

1.14 The term "GAAP" shall mean generally accepted accounting principles in the United States as in effect from time to time.

1.1 The term "Indemnified Parties" shall have the meaning given such term in Section 16.1(i).

1.15 The term "Infringement Claim" shall have the meaning given such term in Section 9.9.

1.16 The term "Instituting Party" shall have the meaning given such term in Section 9.7(ii).

1.17 The term "Legal Costs" shall mean all reasonable legal fees and expenses, filing or maintenance fees, assessments and all other costs and expenses related to prosecuting, obtaining and maintaining patent protection on the Patent Rights in the United States and foreign countries.

1.18 The term "Licensed Product(s)" shall mean any product, process or service that incorporates, utilizes or is made with the use of the Subject Technology and/or Patent Rights.

1.19 The term "LICENSEE" shall have the meaning given such term in the first paragraph of this Agreement.

1.20 The term "Liquidity Event" means the first time one of the following occurs: (i) the closing of any sale, consolidation, merger or other transaction, directly or indirectly, in one or a series of related transactions, in which a "person" or "group" (as such terms are used in Section 13(d) of the Securities Exchange Act of 1934, as amended) acquires securities of LICENSEE constituting more than fifty percent (50%) of the total voting power of all of the then issued and outstanding securities of LICENSEE, or (ii) the sale of all or substantially all of the business or assets of LICENSEE; provided, however, that Liquidity Event shall not include the TapImmune Transaction; and provided, further, that if the TapImmune Transaction occurs, the term LICENSEE, as used in this definition, shall mean TapImmune Inc. (or any successor thereto).

1.21 The term "Liquidity Event Proceeds" means the total amount of consideration (including cash, securities or other property) paid or received, or to be paid or received, by LICENSEE or the equity holders of LICENSEE (including holders of options, warrants and convertible securities) from or in connection with a Liquidity Event; provided, however, that any contingent payments will be paid when and if paid to the LICENSEE or the equity holders of LICENSEE. For the purpose of calculating the value of consideration from or received or receivable in connection with or in anticipation of a Liquidity Event, any securities (other than a promissory note) will be valued at the time of the closing of the Liquidity Event on the same basis as such fair market value shall be determined in connection with any fee payable to any investment bank engaged by LICENSEE in connection with such Liquidity Event; provided, however, that if LICENSEE has not engaged any investment bank in connection with such Liquidity Event, then any securities will be valued on the following basis: (i) if such securities are traded on a stock exchange, the securities will be valued at the average last sale or closing price for the ten (10) trading days immediately prior to the closing of the Liquidity Event; and (ii) if such securities are traded primarily in over-the-counter transactions, the securities will be valued at the mean of the closing bid and asked quotations similarly averaged over a ten (10) trading day period immediately prior to the closing of the Liquidity Event. If the TapImmune Transaction occurs, then the term LICENSEE, as used in this definition, shall mean TapImmune Inc. (or any successor thereto).

1.22 The term "Major Markets" would be any of US, Germany, Italy, France, Spain, The United Kingdom, or Japan.

1.23 The term "Marketing Authorization(s)" shall mean all approvals necessary from the relevant Regulatory Authority to permit a Party or its sublicense(s) to market and sell a Licensed Product in a particular country, including without limitation a New Drug Application and Biologics License Application.

1.24 The term "Net Sales" shall mean on a country-by-country and License Product-by-Licensed Product basis, with respect to any period for each country, the gross amounts invoiced by LICENSEE or its Affiliates or Sublicensees, (each, a "Selling Party") to unrelated third parties for sales of a Licensed Product in the Field in such country, less the following deductions to the extent included in the gross invoiced sales price for such Licensed Product or otherwise directed paid, incurred, allowed, accrued or specifically allocated, and documented by the Selling Parties with respect to the sale of such Licensed Product in such country:

(i) discounts, including customary trade, quantity or cash discounts, credits adjustments or allowances, including those granted on account of price adjustments, billing errors, rejected or recalled goods, or damaged goods;

(ii) rebates and chargebacks allowed, given or accrued (including cash, governmental and managed care rebates, hospital or other buying group chargebacks, cash and non-cash coupons, retroactive price reductions, and governmental taxes in the nature of a rebated based on usage levels or sales of such Licensed Product);

(iii) taxes, including but not limited to sales, excise, turnover, inventory, value-added, import, export, excise (including annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Action of 2010 (Pub. L. No. 111-48) and other comparable laws) and other taxes,levied on, absorbed, determined or imposed with respect to the sale, production, transportation, import, export, delivery or use of such Licensed Product (excluding income or net profit taxes or franchise taxes of any kind);

(iv) reasonable charges for delivery or transportation of Licensed Products to customers through the use of third party delivery or transportation services, if separately stated.

Net Sales will be determined in accordance with GAAP. Without limiting the generality of the foregoing, transfers of dispositions of a Licensed Product for charitable, promotional (including samples), pre-clinical, clinical, or regulatory purposes will be excluded from Net Sales, as will sales or transfers of a Licensed Product among the Selling Parties.

Subject to the above deductions, Net Sales shall be deemed to occur on, and only on, the first sale by a Selling Party to a non-sublicensee third party. If non-monetary consideration is received by a Selling Party for the Licensed Product in the relevant country, Net Sales will be calculated based on the average price charged for such Product, as applicable, during the preceding period, or in the absence of such sales, the fair market value of the Licensed Product, as applicable, as determined by the Parties in good faith.

1.25 The term “Non-Instituting Party” shall have the meaning given such term in Section 9.7(ii).

1.26 The term “Orphan Drug Status” shall mean the period of exclusivity accompanying an orphan drug/medicines designation granted by a governmental drug regulatory body, such as FDA or EMA.

1.27 The term “Party” shall mean either LICENSEE or BCM, and “Parties” shall mean LICENSEE and BCM.

1.28 The term “Patent Rights” shall mean only BCM’s ownership rights in the patent applications and patents listed in Appendix A and any and all divisions, reissues, re-examinations, renewals, continuations, continuations-in-part (to the extent the claims in the continuations-in-part are directed to the subject matter described in the patent applications and patents listed in Appendix A), substitutions, and all patents granted thereon and extensions thereof, and all other counterpart, pending or issued patents in all other countries. For the avoidance of doubt, Patent Rights shall also include an exclusive sublicense in the Field to the exclusive license that BCM received from Wilson Wolf Manufacturing under the Reciprocal Exclusive License Agreement, attached as Appendix E.

1.29 The term “Person” shall mean any individual or corporation, association, partnership, limited liability company, joint venture, joint stock or other company, business trust, trust, organization, university, college, governmental authority or other entity of any kind.

1.30 The term “Receiving Party” shall mean the Party receiving Confidential Information from the other Party.

1.31 The term “Research Collaboration Agreement” shall mean that certain Research Collaboration Agreement to be negotiated in good faith and signed, within one hundred eighty (180) days from the Agreement Date, between BCM and LICENSEE, encompassing research related to the Patent Rights or Subject Technology created by BCM during the term of the Research Collaboration Agreement.

1.32 The term “Royalties” shall have the meaning given such term in Section 4.3.

1.33 The term “Sale” shall mean the act of selling, leasing, or otherwise transferring, providing, or furnishing for use for any consideration. Correspondingly, “Sell” shall mean to make or cause to be made a Sale, and "Sold" shall mean to have made or caused to be made a Sale.

1.34 The term “Subject Technology” shall mean BCM’s rights in the technical, scientific information, methods, processes, techniques, data and results, in all cases, whether or not confidential or proprietary, in written, electronic or other forms, directly related to the Patent Rights, and all BCM Confidential Information developed as of the Agreement Date, by the Developers related to the Patent Rights, owned and controlled by BCM and supplied by BCM as of the Agreement Date (identified in Appendix B), or created by BCM during the term of and funded under the Research Collaboration Agreement pertaining to the Field as directed under the LICENSEE’s sponsored research project to develop the deliverables, together with any progeny, mutants or derivatives thereof supplied by BCM or created by LICENSEE.

1.35 The term “Sublicensee” shall mean any third party to which LICENSEE or its Affiliates grants any or all of the rights licensed by BCM to LICENSEE under Section 2.1.

1.36 The term “Sublicensing Revenue” shall mean all (i) cash, (ii) sublicensing fees and (iii) all other payments and the cash equivalent thereof, which are paid to LICENSEE by the Sublicensees of its rights hereunder, but excluding the following payments:

(i) payments made in consideration for the issuance of equity or debt securities of LICENSEE to the extent not exceeding the fair market value thereof;

(ii) that portion of payments for direct or fully burdened expenses (collectively not to exceed one hundred fifty percent (150%) of direct expenses) associated with research or development as calculated in accordance with GAAP, to the extent that such expenses are incurred after the date of and in connection with such sublicense;

(iii) royalties on sales of Licensed Products by the Sublicensee (payment for which has been otherwise provided in Paragraph 4.3);

(iv) milestone payments for Distinct Products by the Sublicensee (payment for which has been otherwise provided in Paragraph 4.4);

(v) payments for supply of Licensed Products for use in clinical trials by or on behalf of, or for resale by, the Sublicensee;

(vi) withholding taxes or other amounts actually withheld from the amounts paid to LICENSEE; and

(vii) amounts received in connection with a merger, consolidation or sale of substantially all of the business or assets of LICENSEE, subject to the one-time liquidity incentive as stipulated in Section 4.6.

1.37 The term "TapImmune Transaction" shall mean the contemplated merger of LICENSEE with and into a wholly-owned subsidiary of TapImmune Inc., pursuant to which, among other things, the shareholders of LICENSEE will receive common stock and warrants of TapImmune Inc. constituting approximately 50% of the issued and outstanding securities of TapImmune Inc. (and, for the avoidance of doubt, any shares of LICENSEE held by BCM shall be treated the same as other outstanding shares of the same class in such transaction). If the TapImmune Transaction occurs, then the term LICENSEE, as used in this definition, shall mean TapImmune Inc. (or any successor thereto).

1.38 The term "Term" shall have the meaning given such term in Section 10.

1.39 The term "Third Party Activities" shall have the meaning given such term in Section 9.7.

1.40 The term "Valid Claim" shall mean, with respect to a particular country, (a) a claim of a pending patent application within the Patent Rights that has been pending for no more than seven (7) years following the earliest national stage filing date for such patent or patent application, that is being prosecuted in good faith, and that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling or (b) a claim of an issued and unexpired patent included within the Patent Rights, which has not been revoked, or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which decision is unappealed or unappealable within the time allowed for appeal and which has not been cancelled, withdrawn, abandoned, disclaimed, denied, or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise. For clarity, a claim of a patent application that ceased to be a Valid Claim under clause (a) before it issued because it had been pending too long, but subsequently issued and is otherwise described by this clause (b) shall again be considered to be a Valid Claim once it issues; provided that with respect to the payment of any royalties if said claim with said pendency period subsequently issues said pending claim, shall be considered a Valid Claim, during the entire pendency period in the Patent Rights. A Licensed Product is covered by a Valid Claim if its manufacture, use, sale, offer of sale, marketing, commercialization, distribution, importation or exportation by LICENSEE in a given country would, but for the rights granted by BCM to LICENSEE under this Agreement, infringe such Valid Claim.

2. License Grant. Subject to the reservations of rights set forth in Paragraph 2.2, BCM hereby grants to LICENSEE and,GRANT OF LICENSE

2.1 License Grant. Subject to the reservations of rights set forth in Paragraph 2.2, BCM hereby grants to LICENSEE and, at LICENSEE's option, to its Affiliates, an exclusive, worldwide, sublicensable license under BCM's rights in the Patent Rights and Subject Technology, to make, have made, use, market, sell, offer to sell, lease, import, or export Licensed Products in the Field.

2.2 Restrictions on License. The grant in Section 2.1 shall be further subject to, restricted by and be non-exclusive with respect to:

(i) the making or use of the Subject Technology and Patent Rights by BCM for its non-commercial research, patient care, teaching and other educationally related purposes;

(ii) the making or use of the Subject Technology and Patent Rights by the Developers for non-commercial research purposes at academic or research institutions;

(iii) any non-exclusive license of the Subject Technology and/or Patent Rights that BCM grants to other academic or research institutions for non-commercial research purposes;

(iv) the making or use of the Subject Technology and Patent Rights by academic and research institutions for internal, non-commercial research purposes pursuant to any license granted in accordance with clause (iii) above; and

(v) any nonexclusive license of the Subject Technology and/or Patent Rights that BCM is required by law or regulation to grant to the United States of America or to a foreign state pursuant to an existing or future treaty with the United States of America.

2.3 Government Reservation. Rights under this Agreement are subject to rights required to be granted to the Government of the United States of America pursuant to 35 USC Sections 200-212, including a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject inventions throughout the world.

2.4 No Implied Licenses. Except as otherwise specifically set forth herein, only the licenses granted pursuant to the express terms of this Agreement shall be of any legal force and effect. No license or other intellectual property rights shall be created by implication in any patents, technology and/or Confidential Information owned by BCM or controlled by BCM with the right to license, even if such patents, technology, or Confidential Information is necessary to exploit the Subject Technology and/or Patent Rights.

3. License Grant. Subject to the reservations of rights set forth in Paragraph 2.2, BCM hereby grants to LICENSEE and,DILIGENCE

3.1 LICENSEE will, and will cause its Affiliates and each of its Sublicensees, to use Commercially Reasonable Efforts to develop and commercialize Licensed Product(s) in at least one of the Major Markets as soon as practicable.

3.2 With respect to development toward a Licensed Product, LICENSEE will accomplish each of the following diligence milestones by the dates set forth herein.

(i) Dosing of first patient in a phase II clinical trial (or foreign equivalent) of a Licensed Product for the first clinical indication on or before the second anniversary of the Agreement Date;

(ii) Dosing of first patient in a phase II clinical trial (or foreign equivalent) of a Licensed Product for a second clinical indication on or before the date that is 180 days following the second anniversary of the Agreement Date; and

(iii) Dosing of first patient in a phase II clinical trial (or foreign equivalent) of a Licensed Product for a third clinical indication on or before the third anniversary of the Agreement Date.

3.3 Beginning on the first anniversary of the Agreement Date and continuing annually until the first commercial Sale of the first Licensed Product, LICENSEE will, and will cause its Affiliates and each of its Sublicensees to provide annual summary updates to BCM summarizing the activities undertaken by LICENSEE, its Affiliates and each of its Sublicensees to continue the development and commercialization of the Licensed Products. In the event that BCM determines that LICENSEE or its Affiliates and its Sublicensees have not used Commercially Reasonable Efforts to continue the development and commercialization of Licensed Products or has failed to achieve a Diligence Milestone, BCM will have the right to provide a written request to LICENSEE to provide further written evidence that LICENSEE, its Affiliates and each of its Sublicensees has undertaken continual and regular activities to continue the Licensed Products development and commercialization. In the event that LICENSEE is unable to show that it, its Affiliates and/or each of its Sublicensees have undertaken such continual regular activities to develop and commercialize the Licensed Products, then LICENSEE (on behalf of it and its Affiliates and each of its Sublicensees) will have an obligation to provide a detailed development plan to BCM for the continued development and commercialization of the Licensed Products, and would thereafter provide summary updates of activities every six (6) months. If such activities thereafter continued to show a lack of Commercially Reasonable Efforts for the development and commercialization of the Licensed Products, then BCM would have the right to terminate the license. The Parties agree that if they are unable to agree as to whether the evidence provided by LICENSEE (on behalf of it and its Affiliates and each of its Sublicensees) shows continual and regular activities to continue the Licensed Product development and commercialization, a third-party arbitrator would be jointly retained to review the evidence and make an independent determination and such determination will be final. LICENSEE's obligation to provide summary updates will stop upon the first commercial Sale of a Licensed Product in a Major Market.

3.4 Notwithstanding the foregoing, the Parties acknowledge that it might be commercially reasonable, under certain circumstances, for LICENSEE to determine not to launch a Licensed Product in a specific country, and failure under such circumstances to launch such Licensed Product shall not be a breach of this Agreement.

4. License Grant. Subject to the reservations of rights set forth in Paragraph 2.2, BCM hereby grants to LICENSEE and, PAYMENTS

4.1 Equity Award. As partial consideration for the rights conveyed by BCM under this Agreement, LICENSEE shall issue shares of common stock, par value $0.0001 per share, in LICENSEE to BCM in an amount equal to twelve percent (12%) of the total outstanding shares of common stock of LICENSEE on a fully-diluted basis as of the Agreement Date. LICENSEE represents and warrants that such securities shall be (i) duly authorized, validly issued, fully paid and nonassessable and (ii) free and clear of all liens (other than any restrictions under applicable securities laws). LICENSEE shall issue one or more certificates evidencing such common stock to BCM within 15 business days of the execution of this Agreement.

4.2 Responsibility for Legal Costs. In addition to the foregoing license execution fee, LICENSEE shall reimburse BCM for all Legal Costs incurred prior to execution of this Agreement. Such payment shall be due within thirty (30) days of receipt of invoice from BCM. As provided for in Paragraph 9.1 herein, LICENSEE will be responsible for all Legal Costs incurred after the Agreement Date. LICENSEE's share of Legal Costs shall be reduced on a pro-rata basis should BCM license additional fields of use to a third party(ies). BCM agrees to provide LICENSEE with thirty (30) days' written notice should BCM license additional fields of use to other third parties. With respect to any disputed payment, such dispute shall be resolved via the Dispute Resolution process set forth in Section 14.

4.3 Royalty on Net Sales. In addition to the foregoing, subject to the terms and conditions of this Agreement, LICENSEE shall pay BCM a royalty on Net Sales on a country-by-country basis as set forth below. Collectively the royalty payments that are the subject of this Paragraph 4.3 are termed "**Royalties**" for purposes of this Agreement and shall be due and payable as provided in Section 5 and delivered to BCM in accordance with the invoice instructions provided below.

Condition	Royalty on Net Sales	Orphan Drug Status?	Valid Claim?	Duration	Aggregate Net Sales per Calendar Year
1	0.65%	No	No	10 years post first commercial Sale	Less than $500M
2	[***REDACTED***]%	Yes	No	Until Orphan Drug Status expires, then reverts to condition 1	Less than $500M
3	[***REDACTED***]%	No	Yes	Life of patent having a Valid Claim covering such Licensed Product(s)	Less than $500M
4	[***REDACTED***]%	Yes	Yes	Until Orphan Drug Status expires, then reverts to condition 3	Less than $500M
5	[***REDACTED***]%	No	No	10 years post first commercial Sale	$500M to $1.0B
6	[***REDACTED***]%	Yes	No	Until Orphan Drug Status expires, then reverts to condition 5	$500M to $1.0B
7	[***REDACTED***]%	No	Yes	Life of patent having a Valid Claim covering such Licensed Product(s)	$500M to $1.0B
8	[***REDACTED***]%	Yes	Yes	Until Orphan Drug Status expires, then reverts to condition 7	$500M to $1.0B
9	[***REDACTED***]%	No	No	10 years post first commercial Sale	$1.0B and over
10	[***REDACTED***]%	Yes	No	Until Orphan Drug Status expires, then reverts to condition 9	$1.0B and over
11	[***REDACTED***]%	No	Yes	Life of patent having a Valid Claim covering such Licensed Product(s)	$1.0B and over
12	[***REDACTED***]%	Yes	Yes	Until Orphan Drug Status expires, then reverts to condition 11	$1.0B and over
13	5.00%	Yes	Yes	Blockbuster Product; reverts to 4.25% upon expiration of Orphan Drug Status, or in the event Orphan Drug Status was not granted	$2.0B and over

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

(i) Third-Party Royalty Reduction. If LICENSEE, its Affiliate or a Sublicensee becomes obligated to pay additional royalties to a third party(ies) with respect to third party-owned patent rights or technology necessary for the use, manufacture or sale of a Licensed Product, LICENSEE may deduct [***REDACTED***] percent ([***REDACTED***]%) of the amount owing to such third party(ies) from the amounts owing to BCM with respect to such Licensed Product; provided that (i) LICENSSE shall provide BCM with documentation supporting such obligations and the amount thereof to the reasonable satisfaction of BCM and (ii) under no circumstance shall the royalties due to BCM be less than [***REDACTED***] percent ([***REDACTED***]%) of the amount that would otherwise have been payable under Paragraph 4.3 as a result of such deduction.

(ii) Combination Product. In the event that a Licensed Product is sold in combination with another product, component or service for which no royalty would be due hereunder if sold separately, Net Sales from such combination sales for purposes of calculating the amounts due under this Paragraph 4.3 shall be calculated by multiplying the Net Sales of the combination product by the fraction A/(A + B), where A is the average gross selling price during the previous calendar quarter of the Licensed Product sold separately and B is the gross selling price during the previous calendar quarter of the combined product(s), component(s) and/or service(s). In the event that a substantial number of such separate sales were not made during the previous calendar quarter then the Net Sales shall be as reasonably allocated by LICENSEE between such Licensed Product and such other product(s), component(s) or service(s) based upon their relative importance and proprietary protection.

(iii) Single Royalty. Only one royalty under Paragraph 4.3 shall be paid with respect to each unit of Licensed Product sold, without regard to whether more than one Valid Claim within the Patent Rights is applicable to such unit. It is understood that no royalty shall be due with respect to use or transfers of Licensed Products for use in research or development activities prior to regulatory approval of said Licensed Product(s) and the first commercial Sale.

4.4 Milestone Payments. LICENSEE shall also pay BCM the following one-time milestone payments set forth below following the first achievement of such milestone by LICENSEE, its Affiliate or Sublicensee:

(i) Upon the first dosing of the first patient in the first phase III clinical trial (or foreign equivalent) for the first (1^{st}) Distinct Product, LICENSEE shall make a [***REDACTED***] dollar($[***REDACTED***]) payment to BCM;

(ii) Upon the first dosing of the first patient in the first phase III clinical trial (or foreign equivalent) for the second (2^{nd}) Distinct Product, LICENSEE shall make a [***REDACTED***] dollar ($[***REDACTED***]) payment to BCM;

(iii) Upon receipt of final FDA approval of the first Marketing Authorization for the first (1st) Distinct Product, LICENSEE shall make a [***REDACTED***] dollar($[***REDACTED***]) payment to BCM;

(iv) Upon receipt of final FDA approval of the first Marketing Authorization for the second (2nd) Distinct Product, LICENSEE shall make a [***REDACTED***] dollar ($[***REDACTED***]) payment to BCM; and

(v) Upon first attainment of annual Net Sales of greater than five hundred million ($500,000,000) for the first (1st) Distinct Product, LICENSEE will make a [***REDACTED***] dollar ($[***REDACTED***]) payment to BCM;

(vi) Upon first attainment of annual Net Sales of greater than five hundred million ($500,000,000) for the second (2nd) Distinct Product, LICENSEE will make a [***REDACTED***] dollar ($[***REDACTED***]) payment to BCM;

(vii) Upon first attainment of annual Net Sales of greater than one billion ($1,000,000,000) for the first (1st) Distinct Product, LICENSEE will make a [***REDACTED***] dollar ($[***REDACTED***]) payment to BCM;

(viii) Upon first attainment of annual Net Sales of greater than one billion ($1,000,000,000) for the second (2nd) Distinct Product, LICENSEE will make a [***REDACTED***] dollar ($[***REDACTED***]) payment to BCM;

(ix) Upon first attainment of annual Net Sales of greater than two billion ($2,000,000,000) for any of the Distinct Products, LICENSEE will make a [***REDACTED***] dollar ($[***REDACTED***]) payment to BCM. For the avoidance of doubt, this payment is a one-time payment that will be paid for the first Licensed Product that attains annual Net Sales of greater than $2,000,000,000; and

(x) LICENSEE shall notify BCM in writing within thirty (30) days following the achievement of each milestone. The annual Net Sales for Distinct Products subject to the Net Sales level-dependent milestone payments shall be calculated on a calendar year basis, beginning January 1st and ending December 31st. BCM will then invoice LICENSEE for payment of such milestone and LICENSEE shall pay the invoice within fifteen (15) days upon receipt of the invoice. Milestones are to be paid regardless of whether LICENSEE, its Affiliate or LICENSEE's Sublicensee attains such milestone.

4.5 Sublicense Revenue Payments. In the event LICENSEE sublicenses the Subject Technology and Patent Rights under this Agreement, LICENSEE agrees to pay to BCM all Sublicensing Revenue received by LICENSEE under the applicable sublicense agreement according to the following schedule:

(i) [***REDACTED***] percent ([***REDACTED***]%) of Sublicensing Revenue shall be payable to BCM if the sublicense agreement is executed before the first dosing of the first patient in the first phase II clinical trial for the first (1st) Licensed Product;

(ii) [***REDACTED***] percent ([***REDACTED***]%) of Sublicensing Revenue shall be payable to BCM if the sublicense agreement is executed on or after the first dosing of the first patient in the first phase II clinical trial for the first (1st) Licensed Product, but before the first dosing of the first patient in the first pivotal/phase III clinical trial for the first (1st) Licensed Product;

(iii) [***REDACTED***] percent ([***REDACTED***]%) of Sublicensing Revenue shall be payable to BCM if the sublicense agreement is executed on or after the first dosing of the first patient in the first pivotal/phase III clinical trial for the first (1st) Licensed Product; and

(iv) [***REDACTED***] percent ([***REDACTED***]%) of Sublicensing Revenue shall be payable to BCM if the sublicense agreement is executed on or after receipt of the final FDA approval (or its equivalent in other jurisdictions) of the first Marketing Authorization for the first (1st) Licensed Product.

(v) To the extent that Sublicense Revenue represents an unallocated combined payment for both a sublicense of the Patent Rights and Subject Technology as well as other third party-owned intellectual property, undertakings or subject matter, such Sublicense Revenue from such sublicensing arrangement for purposes of calculating payments due to BCM shall be reasonably allocated by LICENSEE between such Patent Rights and Subject Technology and such other intellectual property, undertakings or subject matter, based on their relative value consistent with comparable industry standard arms' length transactions, provided that (i) LICENSEE shall provide BCM with documentation supporting such allocation to the reasonable satisfaction of BCM and (ii) under no circumstance shall the percentage of sublicense revenue due BCM be less than [***REDACTED***] percent ([***REDACTED***]%) of the amounts stipulated in Section 4.5(i) through (iv). If BCM reasonably disputes LICENSEE's allocation of Sublicense Revenue with respect to a particular sublicense, then, upon written notice by either Party to the other, such dispute may be submitted for resolution pursuant to Section 14. Neither Party shall be deemed in breach of this Agreement by reason of a failure to agree on such amount (or with respect to LICENSEE, to pay the disputed amount); provided in the case of LICENSEE, that it has paid the undisputed portion of such Sublicense Revenue and, following resolution pursuant to Section 14 promptly pays any amount determined to be due thereunder.

4.6 One-Time Liquidity Incentive. Within sixty (60) days upon the first occurrence of a Liquidity Event, LICENSEE will make or cause to be made a one-time cash milestone payment to BCM equal to [***REDACTED***] percent ([***REDACTED***]%) of the Liquidity Event Proceeds, provided, that if any portion of the Liquidity Event Proceeds is a contingent payment, any such contingent amounts shall be paid when and if such amounts are paid to LICENSEE or its equity holders. This payment obligation will terminate if LICENSEE terminates this Agreement within two (2) years of the Agreement Date and no Liquidity Event has occurred prior to such termination, but will otherwise remain applicable and shall survive termination or expiration of this Agreement. Upon the payment of the Liquidity Event Proceeds to BCM upon consummation of a Liquidity Event, all rights of BCM under this Section 4.6 shall thereafter terminate.

4.7 Payment Addresses. Payments sent by check are to be made payable to "Baylor College of Medicine" and shall be sent to the address below. If payments are sent by wire transfer, they shall be sent using wiring instructions provided in Appendix D. All payments shall reference BLG number(s) listed on the front page of the Agreement.

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

BCM Tax ID #: 74-1613878
Baylor College of Medicine
Licensing Group
P.O. Box 301503
Dallas, Texas 75303-1503
Telephone No. 713-798-6821
Facsimile No. 713-798-1252
E-Mail: blg@bcm.tmc.edu

4.8 Payments shall be deemed received only upon confirmation that all funds have been received by the **LICENSING GROUP** as referenced above. LICENSEE hereby accepts responsibility for ensuring that payment is addressed correctly.

4.9 LICENSEE Payment Contact. For questions about payments, BCM can contact LICENSEE at the address below:

Marker Therapeutics, Inc.
ATTN: President and CEO
33 5th Avenue N.W.
New Brighton, Minnesota
Telephone No. 651-628-9259
Facsimile No. 651-628-9507
E-Mail: john.wilson@wilsonwolf.com

4.10 Payment Conditions. All payments due hereunder are payable in United States dollars. No transfer, exchange, collection or other charges, including any wire transfer fees, shall be deducted from such payments. For sales of Licensed Products in currencies other than the United States, LICENSEE shall use exchange rates published in The Wall Street Journal on the last business day of the six (6) month period that such payment is due.

4.11 Late Payments. Late payments shall be subject to a charge of [***REDACTED***] percent ([***REDACTED***]%) per month**,** the interest being compounded annually, or [***REDACTED***] dollars ($[***REDACTED***]), whichever is greater. LICENSEE shall calculate the correct late payment charge, and shall add it to each such late payment. Said late payment charge and the payment and acceptance thereof shall not negate or waive the right of BCM to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment. LICENSEE shall indemnify BCM for all attorneys' fees and costs BCM incurs in obtaining a full payment of that which is owed to BCM.

4.12 Taxes. LICENSEE may withhold from payment made to BCM under this Agreement any tax required to be withheld by LICENSEE under the laws of the country or jurisdiction where LICENSEE has commercially sold Licensed Product(s) or any other Applicable Law. If any tax is withheld by LICENSEE, LICENSEE shall provide BCM receipts or other evidence of such withholding and payment to the appropriate tax authorities on a timely basis following that tax payment.

5. REPORTING

5.1 Annual Progress Report. No later than sixty (60) days after December 31 of each calendar year, LICENSEE shall provide to BCM a written annual progress report describing LICENSEE's progress on all research and development and commercial activities, during the most recent twelve (12) month period ending December 31 and plans for the forthcoming year ("**Annual Progress Report**"). If multiple technologies are covered by the license granted hereunder, the progress report shall provide the information set forth above for each technology. At BCM's request, LICENSEE shall also provide any reasonable additional data BCM requires to evaluate LICENSEE's performance of its obligations hereunder. For the avoidance of doubt, any such report and data shall be the Confidential Information of LICENSEE.

5.2 Notification of First Sale. LICENSEE shall notify BCM the date on which LICENSEE (including any Affiliate) and/or the Sublicensees make a first commercial Sale of a Licensed Products in each country in which it occurs within thirty (30) days of occurrence.

5.3 Royalty Reports. LICENSEE shall submit to BCM within forty-five (45) days after March 31, June 30, September 30 and December 31, a written report on a form provided by BCM (a current version of which is attached as Appendix C) setting forth for such calendar quarter at least the following information:

(i) the number of Licensed Products sold by LICENSEE and Sublicensees in each country;

(ii) total billings for such Licensed Products;

(iii) the gross amount of monies or cash equivalent or other consideration which is received for sales, leases, licenses or other modes of transfer of Licensed Products by LICENSEE;

(iv) the identity of that consideration which is received instead of money for sales, leases, licenses or other modes of transfer of Licensed Products by LICENSEE;

(v) aggregate deductions from the gross amount as expressly permitted herein to determine the Net Sales thereof, for the avoidance of doubt, LICENSEE will not provide itemized deductions from gross sales to Net Sales;

(vi) the amount of Royalties due thereon, or, if no Royalties are due to BCM for any reporting period, the statement that no Royalties are due;

(vii) the amount of Sublicensing Revenue received by LICENSEE; and

(viii) the amount of other payments due BCM, including but not limited to, milestone payments, minimum royalty payments and maintenance fee payments.

The royalty report shall be certified as correct by an officer of LICENSEE. After termination, but not expiration, of this Agreement, LICENSEE will continue to submit royalty reports and payments to BCM as per LICENSEE's obligations under this Agreement until all Licensed Products made, used, marketed, leased or imported under this Agreement have been sold, destroyed or expired.

5.4 Payment to Accompany Royalty Reports. LICENSEE shall pay to BCM with each such Royalty report the amount of Royalties and other payments due with respect to such calendar quarter.

5.5 Notification of Merger or Acquisition. In the event of acquisition, merger, change of corporate name, or change of make-up, organization, or identity, LICENSEE shall notify BCM in writing within thirty (30) days after the closing date of such event.

5.6 Entity Status. If LICENSEE or Sublicensee does not qualify as a "small entity" as provided by the United States Patent and Trademark Office, LICENSEE must notify BCM immediately.

6. TRANSFER OF SUBJECT TECHNOLOGY

6.1 Transfer Schedule. Upon receipt of the equity award described in Paragraph 4.1, BCM shall, within thirty (30) days thereof, provide LICENSEE with reasonable quantities of the Subject Technology. The Parties understand and agree that BCM will use reasonable efforts to provide the Subject Technology within thirty (30) days of receipt of the license fee, however the Parties acknowledge that unforeseen circumstances might delay delivery and such failure to provide the Subject Technology based on such unforeseen circumstances shall not be considered a breach of this Agreement by BCM.

6.2 Transfer Address and Payment. Such Subject Technology shall be sent to the address below, via UPS overnight courier using LICENSEE's courier account number [***REDACTED***].

Marker Therapeutics, Inc.
ATTN: President and CEO
33 5th Avenue N.W.
New Brighton, Minnesota
Telephone No. 651-628-9259
Facsimile No. 651-628-9507
E-Mail: john.wilson@wilsonwolf.com

7. RECORDS AND INSPECTION

7.1 Accounting Records. LICENSEE shall maintain, and shall cause its Sublicensees to maintain, complete and accurate records relating to the rights and obligations under this Agreement and any amounts payable to BCM in relation to this Agreement, which records shall contain sufficient information to permit BCM to confirm the accuracy of any reports delivered to BCM and compliance in other respects with this Agreement. The relevant party shall retain such records for at least five (5) years following the end of the calendar year to which they pertain.

7.2 Audit by BCM. During the Term of this Agreement as defined below and for a period of two (2) years thereafter, BCM or its representatives shall have the right to inspect the books and records of LICENSEE in conjunction with the performance of LICENSEE's obligations under the terms and conditions of this Agreement. The scope of such audit and inspection activities may include the review of records supporting activities performed by LICENSEE in conjunction with its obligations under this Agreement, as well as processes and related process internal controls and support systems, the quality and accuracy of which are directly related to the performance of LICENSEE's obligations under the terms and conditions of this Agreement. LICENSEE agrees to provide representatives of BCM reasonable access to books, records, systems and processes, and shall cooperate fully with BCM's representatives in support of their inspection and audit activities during LICENSEE's normal business hours. Prior to commencing an audit, BCM shall require the representatives performing the audit enter into an appropriate confidentiality agreement, obligating the representatives to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are not less restrictive than the obligations set forth in Section 17.

In respect for each audit of LICENSEE's books and records: (i) the LICENSEE may be audited only once per year, (ii) no records for any given year for LICENSEE may be audited more than once; provided that the LICENSEE's records shall still be made available if such records impact another financial year which is being audited, and (iii) BCM shall only be entitled to audit books and records of LICENSEE from the five (5) calendar years prior to the calendar year in which the audit request is made.

In order to initiate an audit for a particular calendar year, BCM must provide LICENSEE with written notice of one or more proposed dates of the audit not less than thirty (30) days prior to the first proposed date. LICENSEE will reasonably accommodate the scheduling of such audit and the Parties shall mutually agree on the audit date. LICENSEE shall provide BCM with full and complete access to the applicable books and records and otherwise reasonably cooperate with such audit.

7.3 Payment Deficiency. If a payment deficiency is determined, LICENSEE and it Sublicensee(s), as applicable, shall pay the outstanding amounts within thirty (30) days of receiving written notice thereof, plus interest on such outstanding amounts as described in Section 5.

7.4 Responsibility for Audit Costs. BCM will pay for any audit done under Paragraph 7.2. However, in the event that the audit reveals an underpayment of Royalties or fees by more than five percent (5%) for the period being audited, the cost of the audit shall be paid by LICENSEE. If the underpayment is less than five percent (5%) but more than two percent (2%) for the period being audited, LICENSEE and BCM shall each pay fifty percent (50%) of the cost of the audit.

7.5 Use of Audit Information. Any information received by BCM pursuant to this Section 7 shall be deemed to be Confidential Information for the purposes of Section 17. Such information shall be used solely for the purpose for which the audit was conducted.

8. SUBLICENSES

All sublicenses granted by LICENSEE of its rights hereunder shall be consistent with and subject to the terms and conditions of this Agreement and LICENSEE shall remain fully responsible to BCM for the performance of its Sublicensees with respect to LICENSEE's obligations under the terms of this Agreement. Any act or omission of a Sublicensee which would be a material breach of this Agreement if performed by LICENSEE shall be deemed to be a breach by LICENSEE of this Agreement susceptible to cure within the cure period specified in Section 11.1. Each sublicense agreement granted by LICENSEE shall include an audit right of the same scope as provided in Section 7 hereof with respect to LICENSEE. LICENSEE shall give BCM prompt notification of the identity and address of each Sublicensee with whom it concludes a sublicense agreement and shall supply BCM with a copy of each such sublicense agreement.

9. PATENTS AND INFRINGEMENT

9.1 Patent Prosecution Responsibility. For the Term of this Agreement as defined below, BCM shall be responsible for filing, prosecuting and maintaining all patent applications and patents included in the Patent Rights, and LICENSEE agrees to pay all previously unreimbursed Legal Costs, which 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. BCM shall select all outside counsel for prosecution of the Patent Rights and such counsel shall represent BCM in such prosecution. For so long as LICENSEE is the sole LICENSEE of the Patent Rights, BCM shall instruct its patent counsel to invoice LICENSEE directly for all such Legal Costs. LICENSEE agrees to pay all such invoices within thirty (30) days of receipt.

9.2 Notification of Intent Not to Pursue. In the event that LICENSEE decides not to pay for the costs associated with either: (i) the prosecution of certain patent applications within the Patent Rights to issuance or (ii) maintenance of any United States or foreign issued patent on the Patent Rights, LICENSEE shall timely notify BCM in writing thereof. LICENSEE's right under this Agreement to practice the invention under the patent not being pursued shall immediately terminate upon the giving of such notice. If LICENSEE fails to notify BCM at least thirty (30) calendar days prior to the deadline for taking any action for such patent or patent application, as the case may be, for BCM to assume said costs prior to the abandonment or expiration of any Patent Rights, LICENSEE shall be considered in default of this Agreement as per that Patent Right.. LICENSEE’s right under this Agreement to practice the invention under the patent or patent application for which LICENSEE does not pay for its share (as set forth in Section 9.1) shall immediately terminate with respect to such jurisdiction upon the giving of such notice.

9.3 Notification of Patent Prosecution Action. BCM agrees to keep LICENSEE fully informed, at LICENSEE's expense, of all prosecutions and other actions pursuant to this Section 9, including submitting to LICENSEE all serial numbers and filing dates, and copies of all substantive documentation submitted to, or received from, the patent offices in connection therewith. With respect to any substantive submissions that BCM is requires to or otherwise intends to submit to a patent office with respect to a Patent Right, BCM shall act in good faith and provide a draft of such submission to LICENSEE for its review and comment as soon as reasonably practical prior to the deadline for, or the intended filing date of, such submission. LICENSEE shall have the right to review and comment upon any such submission by BCM to a patent office, and will provide such comments within thirty (30) days after receiving such submission (provided, that if no comments are received prior to the deadline for such submission, then BCM may proceed with such submission. BCM shall consider in good faith any suggestions or recommendations of LICENSEE concerning the preparation, filing, prosecution and maintenance thereof as may be applicable to the Field.

9.4 Extension of Patent Term for Licensed Products. LICENSEE shall have the first right, but not the obligation, to seek patent term extension, including supplemental protection certificates and the like available under Applicable Law, under the Patent Rights, for Licensed Product(s). BCM shall cooperate with LICENSEE in seeking patent term extensions for Licensed Product(s) under the Patent Rights pertaining solely in the Field; provided, however, that if patent term extension is to be pursued by a third party before LICENSEE for a patent licensed to the third party in any separate field of use and contains Valid Claims both within and outside and/or overlapping the Field, then BCM shall notify LICENSEE so that all the Parties can work in good faith to determine which Party is to pursue the patent term extension. All such actions shall be at LICENSEE’s expense.

9.5 Patent Procedures for Biosimilars. The Parties shall cooperate, at LICENSEE's expense, with respect to the content and submission of any patent listings in connection with patent linkage systems and/or a generic/biosimilar application filing, in each case in the Field, including providing the third party generic/biosimilar application with a list of patents that could reasonably be asserted; and a designation of patents available for license.

9.6 Cooperation. BCM agrees to reasonably cooperate with LICENSEE, at LICENSEE's expense, to whatever extent is reasonably necessary to provide LICENSEE the full benefit of the license granted herein.

9.7 Infringement Procedures. During the Term of this Agreement as defined below, each Party shall promptly inform the other of any suspected infringement of any claims in the Patent Rights or the misuse, misappropriation, theft or breach of confidence or other proprietary rights in or to the Subject Technology and/or Patent Rights by a third party (collectively "**Third Party Activities**"), and with respect to such activities as are suspected. Any action or proceeding against such Third Party Activities shall be instituted as following:

(i) BCM shall have the first right, but not the obligation, to institute an action or proceeding against Third Party Activities. If BCM fails to bring such an action or proceeding within a period of three (3) months after receiving notice or otherwise having knowledge of such Third Party Activities, then LICENSEE shall have the right, but not the obligation, to prosecute the same solely with respect to the activities in the Field at its own expense, using legal counsel of its choice acceptable to BCM, whose acceptance shall not be unreasonably withheld, conditioned, or delayed.

(ii) The Party not instituting the action or the proceeding (the "**Non-Instituting Party**") will reasonably cooperate with the Party instituting the action or the proceeding (the "**Instituting Party**") in such action. In addition, if the Non-Instituting Party cooperates in such action, such cooperation shall be at the Instituting Party's sole expense. Should either BCM or LICENSEE commence action under the provisions of this Paragraph 9.7 and thereafter elect to abandon the same, it shall give timely notice to the other Party who may, if it so desires, continue prosecution of such action or proceeding. All recoveries, whether by judgment, award, decree or settlement, from infringement of any claims in the Patent Rights or the misuse, misappropriation, theft or breach of confidence or other proprietary rights in or to the Subject Technology and/or Patent Rights by a third party shall be apportioned as follows: (a) the Party bringing the action or proceeding shall first recover an amount equal the costs and expenses incurred by such Party directly related to the prosecution of such action or proceeding, (b) the Party cooperating in such action or proceeding shall then recover costs and expenses incurred by such Party, if any, directly related to its cooperation in the prosecution of such action or proceeding and (c) the remainder shall be shared by the parties, with the Party bringing the action allocated eighty percent (80%) and the Party cooperating in such action allocated twenty percent (20%) of such amounts.

(iii) In the case of an action pursuant to Paragraph 9.7(i) or (ii), BCM and LICENSEE may decide to jointly prosecute an action or proceeding after it has been instituted by one Party. The action shall then be continued in the name or names they both agree is expedient for efficient prosecution of such action. Alternatively, BCM and LICENSEE may agree to jointly institute an action against Third Party Activities in which case each of the Parties shall cooperate with the other Party as required of a Non-Instituting Party pursuant to Paragraph 9.7(iv). LICENSEE and BCM shall agree to the manner in which they shall exercise control over any joint action or proceeding, providing however that if they cannot agree, BCM shall have the right to unilaterally decide on control. In such joint action or proceeding, the out-of-pocket costs shall be borne equally, and any recovery or settlement shall be shared equally.

9.8 Consent to Settle. Neither BCM nor LICENSEE shall settle any action covered by Paragraph 9.7 without first obtaining the consent of the other Party, which consent will not be unreasonably withheld.

9.9 Defense of Infringement Claims. If any third party asserts a claim, demand, action, suit or proceeding against LICENSEE (or any of its Affiliates or Sublicensees), alleging that any Licensed Product, the use or practice of the Subject Technology or Patent Rights, infringes, misappropriates, misuses or violates, or breaches any confidence or other proprietary rights in, the intellectual property rights of any Person (any such claim, demand, action, suit or proceeding being referred to as and "**Infringement Claim**"), LICENSEE shall promptly notify BCM in writing specifying the facts, to the extent known, in reasonable detail. In the case of any such Infringement Claim, LICENSEE shall assume control of the defense and shall have the exclusive right to settle any Infringement Claim against LICENSEE without the consent of BCM; provided, however, if such settlement requires any payment from BCM or decrease in BCM's rights under this Agreement, LICENSEE shall be required to obtain BCM's consent, which consent will not be unreasonably withheld.

9.10 Liability for Losses. Subject to Paragraph 16.1, BCM shall not be liable for any losses incurred as the result of an action for infringement brought against LICENSEE as the result of LICENSEE's exercise of any right granted under this Agreement. The decision to defend or not defend shall be in LICENSEE's sole discretion.

10. TERM

Unless sooner terminated as otherwise provided in Section 11, the license to employ Patent Rights and Subject Technology granted herein as part of Section 2 shall expire on a Licensed Product-by-Licensed Product and country-by-country basis, on the later of (i) the date of expiration of the last Valid Claim of the Patent Rights to expire that covers the sale of such Licensed Product in such country or (ii) the first date following the tenth (10^{th}) anniversary of the first commercial Sale of the first Licensed Product by LICENSEE in such country ("**Term**"). After such expiration, but not termination, the licenses granted to LICENSEE pursuant to Section 2 shall survive and become perpetual, paid-in-full (*i.e.*, royalty-free) license in such country and with respect to such Licensed Product.

11. TERMINATION

11.1 Termination for Default. In the event of material default or failure by LICENSEE of its overall obligations under this Agreement to perform any of the terms, covenants or provisions of this Agreement, including failure to make timely payment, taken as a whole, LICENSEE shall have thirty (30) days after BCM has provided written notice of such material default or failure to correct such default or failure. BCM shall not have the right to cancel and terminate this Agreement if LICENSEE has cured or corrected the default or failure before the end of such thirty (30) calendar day notice period and so notifies BCM, stating the manner of the cure as set forth in Section 11.1(i). If such material default or failure is not cured or corrected within such thirty (30) day period, BCM shall have the right, at its option, to cancel and terminate this Agreement. The failure of BCM to exercise such right of termination, for non-payment of Royalties/fees or otherwise, shall not be deemed to be a waiver of any right BCM might have, nor shall such failure preclude BCM from exercising or enforcing said right upon any subsequent failure by LICENSEE.

(i) Notwithstanding the foregoing, if a material default or failure is not susceptible to cure within the cure period specified in this Section 11.1, BCM's right of termination shall be suspended only if, and for so long as, (i) LICENSEE has provided BCM with a written plan that is reasonably calculated to effect a cure, (ii) such plan is reasonably acceptable to BCM, provided acceptance of such a plan is at BCM's sole but reasonable discretion; and (iii) LICENSEE commits to and does carry out such plan; provided, however, that, unless mutually agreed by the Parties in such plan, in no event shall such suspension of the BCM's right to terminated extend beyond sixty (60) days after the original cure period.

(ii) Notwithstanding the foregoing, if either Party is alleged to be in material breach and disputes such termination through the dispute resolution procedures set forth in this Agreement, then the other Party's right to terminate this Agreement shall be tolled for so long as such 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 such material breach after such determination within the cure period provided in this Section 11.1.

11.2 Termination for Insolvency. BCM shall have the right, at its option, to cancel and terminate this Agreement in the event that LICENSEE shall (i) become involved in insolvency, dissolution, bankruptcy or receivership proceedings affecting the operation of its business or (ii) make an assignment of all or substantially all of its assets for the benefit of creditors, or in the event that (iii) a receiver or trustee is appointed for LICENSEE and LICENSEE shall, after the expiration of thirty (30) days following any of the events enumerated above, have been unable to secure a dismissal, stay or other suspension of such proceedings.

11.3 Termination by Licensee. LICENSEE shall have the right in its sole discretion to terminate this Agreement upon sixty 60) days written notice to BCM.

11.4 Effect of Termination. Subject to Section 10, in the event of termination of this Agreement, but not expiration, all rights to the Subject Technology and Patent Rights shall revert to BCM, except to the extent necessary to exercise any surviving right or license hereunder. Except as expressly set forth herein, at the date of any early termination of this Agreement, LICENSEE and any Sublicensee shall immediately cease using any of the Subject Technology and Patent Rights and LICENSEE and any Sublicensee in possession of any Subject Technology shall immediately destroy any Subject Technology in its possession and send to BCM a written affirmation of such destruction signed by an officer of LICENSEE and each such Sublicensee; provided, however, that LICENSEE, its Affiliates and Sublicensees may sell any Licensed Products actually in the possession of LICENSEE, such Affiliates or Sublicensees on the effective date of termination, provided that LICENSEE continues to submit royalty reports to BCM and pays to BCM the Royalties on all such sales in accordance with Paragraph 5.3 with respect thereto and otherwise complying with the terms of this Agreement and sell all Licensed Products within six (6) months after the effective date of termination.

11.5 Effect of Termination on Sublicensees. LICENSEE shall provide, in all sublicenses granted by it under this Agreement, that LICENSEE's interest in such sublicenses shall, at BCM's option, terminate or be assigned to BCM upon termination of this Agreement, provided, however, that any validly issued sublicense in good standing on the date of termination shall survive any termination or expiration of this Agreement provided that the Sublicensee agrees to be bound by the applicable terms of this Agreement with respect to activities of the Sublicensee under such sublicense.

11.6 No Refund. In the event this Agreement is terminated pursuant to this Section 11, or expires as provided for in Section 10, BCM is under no obligation to refund any payments made by LICENSEE to BCM prior to the effective date of such termination or expiration.

11.7 Survival of Termination. No termination of this Agreement shall constitute a termination or a waiver of any rights of either Party against the other Party accruing at or prior to the time of such termination. The obligations of Sections 4, 5, 7, 11, 13, 14, 15, 16, 17 and 18 shall survive termination of this Agreement.

12. ASSIGNABILITY

Without the prior written approval of BCM, which will not be unreasonably withheld, neither this Agreement nor the rights granted hereunder shall be transferred or assigned in whole or in part by LICENSEE to any person or entity whether voluntarily or involuntarily, by operation of law or otherwise. Notwithstanding the foregoing, LICENSEE may assign this Agreement and its rights and obligations hereunder without BCM's consent, (i) in connection with the transfer or sale of all or substantially all of its assets or the business of LICENSEE to which this Agreement relates, (ii) in connection with the closing of the TapImmune Transaction or any other merger, reorganization or similar transaction effected within nine (9) months of the Agreement Date, or (iii) to any Affiliate; so long as, in each case, LICENSEE gives BCM prompt notice of such action and the successor entity or Affiliate, as the case may be, acknowledges its consent and agreement to the terms of this Agreement in writing before or contemporaneously with such assignment; and so long as such action is not entered into solely to satisfy creditors of LICENSEE. This Agreement shall be binding upon and shall inure to the benefit of the respective successors, legal representatives and assignees of each of the Parties.

13. GOVERNMENTAL COMPLIANCE

13.1 Compliance with Applicable Laws. LICENSEE shall at all times during the Term of this Agreement and for so long as it shall use the Subject Technology and/or Patent Rights, or sell Licensed Products, conduct its activities under this Agreement, and require its Sublicensees to conduct their activities under this Agreement, in compliance in all material respects with all laws that may control the import, export, manufacture, use, sale, marketing, distribution and other commercial exploitation of the Subject Technology, Patent Rights, Licensed Products or any other activity undertaken pursuant to this Agreement.

13.2 Requirement for U.S. Manufacture. If required by U.S. law, LICENSEE agrees that Licensed Products leased or sold in the United States shall be manufactured substantially in the United States. BCM shall reasonably cooperate with and assist LICENSEE, at LICENSEE's request and expense, to obtain waivers to such requirement.

13.3 Export Control Regulations. The Subject Technology is subject to, and LICENSEE agrees to comply in all respects with, U.S. law including but not limited to U.S. export controls under the Export Administration Regulations (15 C.F.R. Part 734 et seq.) and U.S. economic sanctions and embargoes codified in 31 C.F.R. Chapter V. LICENSEE agrees that LICENSEE bears sole responsibility for understanding and complying with current U.S. trade controls laws and regulations as applicable to its activities subject to this Agreement. Without limitation on the general agreement to comply set forth in the first sentence of this Section 13.3, LICENSEE agrees not to sell any goods, services, or technologies subject to this Agreement, or to release or disclose or re-export the same: (i) to any destination prohibited by U.S. law, including any destination subject to U.S. economic embargo; (ii) to any end-user prohibited by U.S. law, including any person or entity listed on the U.S. government's Specially Designated Nationals list, Denied Persons List, Debarred Parties List, Unverified List, or Entities List; (iii) to any foreign national in the U.S. or abroad without prior license if required; or (iv) to any user, for any use, or to any destination without prior license if required.

14. DISPUTE RESOLUTION

14.1 Amicable Resolution. The Parties shall attempt to settle any controversy between them amicably. To this end, a senior executive from each Party shall consult and negotiate to reach a solution. The Parties agree that the period of amicable resolution shall toll any otherwise applicable statute of limitations.

14.2 Failure to Amicably Resolve. If the senior executives from each Party fail to meet or if the matter remains unresolved for a period of sixty (60) days, then either Party may initiate proceedings to resolve such dispute in accordance with this Section 14.2. The parties hereby irrevocably submit to the jurisdiction of a state or federal court of competent jurisdiction in Harris County, Texas, agree that any litigated dispute will be conducted solely in such courts and, by execution and delivery of this Agreement, each (a) accepts, generally and unconditionally, the jurisdiction of such court and any related appellate court and (b) irrevocably waives any objection it may now or hereafter have as to the venue of any such suit, action or proceeding brought in such court or that such court is an inconvenient forum.

14.3 Construction and Jurisdiction. This Agreement shall be deemed to be subject to, and have been made under, and shall be construed and interpreted in accordance with the laws of the State of Texas. No conflict-of-laws rule or law that might refer such construction and interpretation to the laws of another state, republic, or country shall be considered. This Agreement is performable in part in Harris County, Texas, and the Parties mutually agree that personal jurisdiction and venue shall be proper in the state and federal courts situated in Harris County, Texas, and agree that any litigated dispute will be conducted solely in such courts.

15. NOTICES

15.1 Addresses for Notices. All notices, reports or other communication pursuant to this Agreement shall be sent to such Party via (i) United States Postal Service postage prepaid, (ii) overnight courier, or (iii) facsimile transmission, addressed to it at its address set forth below or as it shall designate by written notice given to the other Party. Notice shall be sufficiently made, or given and received (a) on the date of mailing or (b) when a facsimile printer (or similar facsimile transmission technology) reflects transmission.

In the case of BCM:

Patrick Turley
Associate General Counsel
Baylor College of Medicine
One Baylor Plaza, BCM210-600D
Houston, TX 77030
Telephone No. 713-798-6821
Facsimile No. 713-798-1252
E-Mail: blg@bcm.tmc.edu

In the case of LICENSEE:

Marker Therapeutics, Inc.
ATTN: President & CEO
33 5th Avenue N.W.
New Brighton, Minnesota
Telephone No. 651-628-9259
Facsimile No. 651-628-9507
E-Mail: john.wilson@wilsonwolf.com

15.2 Use of Reference Number. Each such report, notice or other communication shall include **BLG number(s)** listed on the front page of this Agreement.

16. INDEMNITY, INSURANCE & WARRANTIES

16.1 INDEMNITY.

(i) EACH PARTY SHALL NOTIFY THE OTHER OF ANY CLAIM, LAWSUIT OR OTHER PROCEEDING RELATED TO THE SUBJECT TECHNOLOGY AND PATENT RIGHTS. LICENSEE AGREES THAT IT WILL DEFEND, INDEMNIFY AND HOLD HARMLESS BCM, ITS FACULTY MEMBERS, SCIENTISTS, RESEARCHERS, EMPLOYEES, STUDENTS, OFFICERS, TRUSTEES AND AGENTS AND EACH OF THEM (THE "**INDEMNIFIED PARTIES**") FROM AND AGAINST ANY AND ALL CLAIMS, CAUSES OF ACTION, LAWSUITS OR OTHER PROCEEDINGS (THE "**BCM CLAIMS**") FILED OR OTHERWISE INSTITUTED AGAINST ANY OF THE INDEMNIFIED PARTIES RELATED DIRECTLY OR INDIRECTLY TO OR ARISING OUT OF THE DESIGN, PROCESS, MANUFACTURE OR USE BY THIRD PARTY OF THE LICENSED PRODUCTS EVEN THOUGH SUCH BCM CLAIMS AND THE LIABILITIES, COSTS (INCLUDING, BUT NOT LIMITED TO, THE PAYMENT OF ALL REASONABLE ATTORNEYS' FEES AND COSTS OF LITIGATION OR OTHER DEFENSE) RELATED THERETO RESULT IN WHOLE OR IN PART FROM THE NEGLIGENCE OF ANY OF THE INDEMNIFIED PARTIES OR ARE BASED UPON DOCTRINES OF STRICT LIABILITY OR PRODUCT LIABILITY; PROVIDED, HOWEVER, THAT SUCH INDEMNITY SHALL NOT APPLY TO ANY BCM CLAIMS ARISING FROM THE GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT OF ANY INDEMNIFIED PARTY. LICENSEE WILL ALSO ASSUME RESPONSIBILITY FOR ALL REASONABLE COSTS AND EXPENSES RELATED TO SUCH BCM CLAIMS FOR WHICH IT IS OBLIGATED TO INDEMNIFY THE INDEMNIFIED PARTIES PURSUANT TO THIS PARAGRAPH 16.1, INCLUDING, BUT NOT LIMITED TO, THE PAYMENT OF ALL REASONABLE ATTORNEYS' FEES AND COSTS OF LITIGATION OR OTHER DEFENSE.

(ii) LICENSEE FURTHER AGREES NOT TO SETTLE ANY CLAIM AGAINST AN INDEMNIFIED PARTY WITHOUT THE INDEMNIFIED PARTY'S WRITTEN CONSENT WHICH CONSENT SHALL NOT BE UNREASONABLY WITHHELD. LICENSEE FURTHER AGREES TO KEEP THE INDEMNIFIED PARTIES FULLY APPRISED OF THE BCM CLAIMS.

(iii) IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY CONSEQUENTIAL, INDIRECT, SPECIAL, INCIDENTAL, OR PUNITIVE DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, INCLUDING BUT NOT LIMITED TO LOSS OF ANTICIPATED PROFIT, FROM ITS PERFORMANCE OR NONPERFORMANCE OF ITS OBLIGATIONS UNDER THIS AGREEMENT, EXCEPT TO THE EXTENT ANY OF THE FOREGOING DAMAGES OR LOSSES (A) ARE SUBJECT TO ANY THIRD PARTY CLAIMS, OR (B) ARE DETERMINED BY A COURT OF COMPETENT JURISDICTION TO BE THE APPROPRIATE MEASURE OF DIRECT DAMAGES WITH RESPECT TO THE MATTERS GIVING RISE TO THE CLAIM.

16.2 Insurance.

(i) LICENSEE shall maintain insurance with creditworthy insurance in accordance with Applicable Laws against such risks and consistent with prevailing business practices utilized by Person's of similar size, type and stage of development to develop products similar to the Licensed Products and reasonable in light of LICENSEE'S level of resources, business operations and availability of coverage, which coverage shall not be less than: (a) worker's compensation insurance within statutory limits, (b) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than one million dollars ($1,000,000) per occurrence with an annual aggregate of two million dollars ($2,000,000) and (c) upon initiation of any human clinical study, products liability insurance, with limits of not less than three million dollars ($3,000,000) per occurrence with an annual aggregate of five million dollars ($5,000,000).

(ii) At such time that LICENSEE receives commercialization approval from a national regulatory body for any Licensed Product(s), LICENSEE shall for so long as LICENSEE manufactures, uses or sells any Licensed Product(s), maintain in full force and effect policies of (a) worker's compensation insurance within statutory limits, (b) employers' liability insurance with limits of not less than one million dollars ($1,000,000) per occurrence, (c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than twenty million dollars ($20,000,000) per occurrence with an annual aggregate of forty million dollars ($40,000,000) and (d) products liability insurance, with limits of not less than ten million dollars ($10,000,000) per occurrence with an annual aggregate of twenty five million dollars ($25,000,000).

(iii) Such coverage(s) shall be purchased from a carrier or carriers having an A. M. Best rating of at least A- (A minus) and shall name BCM as an additional insured. LICENSEE shall provide to BCM copies of certificates of insurance within thirty (30) days after execution of this Agreement. Upon request by BCM, LICENSEE shall provide to BCM copies of said policies of insurance. It is the intention of the Parties hereto that LICENSEE shall, throughout the Term of this Agreement and for any period in which the statute of limitations has not expired, continuously and without interruption, maintain in force the required insurance coverages set forth in this Paragraph 16.2. Failure of LICENSEE to comply with this requirement shall constitute a default of LICENSEE allowing BCM, at its option, to immediately terminate this Agreement.

(iv) BCM reserves the right to request additional policies of insurance where appropriate and commercially reasonable in light of LICENSEE's business operations and availability of coverage, in which case the Parties will negotiate in good faith a mutually agreed amendment to this Section 16.2.

16.3 NO WARRANTY. LICENSEE ACKNOWLEDGES THAT BCM DOES NOT PROVIDE ANY WARRANTIES AND THAT LICENSEE TAKES THE PATENT RIGHTS AND SUBJECT TECHNOLOGY ON AN "AS IS" BASIS.

16.4 Disclaimer of Warranty. BCM MAKES NO WARRANTIES OR REPRESENTATIONS, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF FITNESS OR MERCHANTABILITY, REGARDING OR WITH RESPECT TO THE SUBJECT TECHNOLOGY, PATENT RIGHTS OR LICENSED PRODUCTS AND BCM MAKES NO WARRANTIES OR REPRESENTATIONS, EXPRESS OR IMPLIED, OF THE PATENTABILITY OF THE SUBJECT TECHNOLOGY, PATENT RIGHTS OR LICENSED PRODUCTS OR OF THE ENFORCEABILITY OF ANY PATENTS ISSUING THEREUPON, IF ANY, OR THAT THE SUBJECT TECHNOLOGY, PATENT RIGHTS OR LICENSED PRODUCTS ARE OR SHALL BE FREE FROM INFRINGEMENT OF ANY PATENT OR OTHER RIGHTS OF THIRD PARTIES. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS CONFERRING BY IMPLICATION, ESTOPPEL OR OTHERWISE ANY LICENSE OR RIGHTS UNDER ANY PATENTS OF BCM OTHER THAN THE PATENT RIGHTS, REGARDLESS OF WHETHER SUCH PATENTS ARE DOMINANT OR SUBORDINATE TO THE PATENT RIGHTS.

17. CONFIDENTIALITY

17.1 Scope. The Receiving Party shall not, directly or indirectly, disclose, divulge or reveal to any Third Party the Disclosing Party's Confidential Information without the Disclosing Party's prior written consent except as set forth herein. Receiving Party shall maintain the Disclosing Party's Confidential Information in confidence and use the same only in accordance with this Agreement. Employees, agents or subcontractors of Receiving Party shall be given access to the Disclosing Party's Confidential Information only on a legitimate "need to know" basis and after agreeing to be bound in writing to not divulge or reveal the Disclosing Party's Confidential Information. The public disclosure by a Receiving Party with the permission of the Disclosing Party of any one component of that which was identified as or constituted the Confidential Information of the Disclosing Party shall not prevent the other components from retaining their status as Confidential Information and the property of the Disclosing Party.

17.2 Exclusion. Such obligation of confidentiality shall not apply to information which the Receiving Party can demonstrate that (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no fault of the Receiving Party; (iii) was known to the Receiving Party prior to disclosure thereof by the Disclosing Party; (iv) was lawfully disclosed to the Receiving Party by a third party which was not under an obligation of confidence to the Disclosing Party with respect thereto; (v) was approved for public release by prior written permission of the Disclosing Party; (vi) is required to be submitted to a governmental agency for the purpose of obtaining product approval, provided that the recipient will make a good faith attempt to obtain confidential treatment of the information by such agency; or (v) was independently developed by the Receiving Party without the use of or reference to Confidential Information provided by the Disclosing Party.

17.3 Compliance with Applicable Law. If the recipient of Confidential Information becomes legally compelled to disclose any Confidential Information in order to comply with Applicable Laws or with an order issued by a court or regulatory body with competent jurisdiction, the recipient shall (x) provide prompt written notice to the disclosing Party so that the disclosing Party may seek a protective order or other appropriate remedy or waive its rights under this Section 17; and (y) disclose only the portion of Confidential Information that it is legally required to furnish; provide that, in connection with such disclosure, the Receiving Party shall use commercially reasonable efforts to obtain assurance that confidential treatment will be given with respect to such Confidential Information. If any Party is required to file this Agreement with any Governmental Authority, such Party shall redact the terms of this Agreement to the extent possible in order to keep particularly sensitive provisions confidential.

17.4 Confidentiality of Agreement. Unless otherwise provided for in this Agreement, the Parties agree that this Agreement and its terms are to be considered Confidential Information of both Parties. Notwithstanding the foregoing, LICENSEE may disclose the terms of this Agreement to the extent required by securities or other applicable laws, or rules of any recognized stock exchange, to existing or prospective investors, acquirers, partners, collaborators, licensees, contractors, and to LICENSEE's accountants, attorneys and other professional advisors, in each case on a need-to-know basis and subject to customary confidentiality restrictions.

17.5 Return and Destruction. Upon the termination or expiration of this Agreement, upon the request of the Disclosing Party, the Receiving Party shall promptly redeliver to the Disclosing Party all Confidential Information provided to the Receiving Party in tangible form or destroy the same and certify in writing that such destruction occurred; provided, however, that nothing in this Agreement shall require the alteration, modification, deletion or destruction of computer backup tapes made in the ordinary course of business. All notes or other work product prepared by the Receiving Party based upon or incorporating Confidential Information of the Disclosing Party shall be destroyed, and such destruction shall be certified in writing to the Disclosing Party. Notwithstanding the foregoing, legal counsel to the Receiving Party shall be permitted to retain in its files one copy of all Confidential Information to evidence the scope of and to enforce the Party's obligation of confidentiality under this Section 17.

17.6 Prior Agreements. The provisions of this Section 17 shall supersede and replace any prior agreements among BCM and LICENSEE and all Confidential Information previously disclosed by the parties shall be deemed to have been disclosed hereunder.

18. ADDITIONAL PROVISIONS

18.1 Use of BCM Name. LICENSEE agrees that it shall not use in any way the name of "Baylor," "Baylor College of Medicine" or any logotypes or symbols associated with BCM or the names of any of the scientists or other researchers at BCM without the prior written consent of BCM.

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

18.2 Marking of Licensed Products. To the extent required by Applicable Law, commercially feasible and consistent with prevailing business practices, LICENSEE shall mark, and shall require its Sublicensees to mark, all Licensed Products that are manufactured or sold under this Agreement with the number of each issued patent under the Patent Rights that applies to such Licensed Product.

18.3 BCM's Disclaimers. Neither BCM, nor any of its faculty members, scientists, researchers, employees, students, officers, trustees or agents assume any responsibility for the manufacture, product specifications, sale or use of the Subject Technology, Patent Rights or Licensed Products which are manufactured by or sold by LICENSEE unless subject to other agreements between BCM and LICENSEE.

18.4 Independent Contractors. The Parties hereby acknowledge and agree that each is an independent contractor and that neither Party shall be considered to be the agent, representative, master or servant of the other Party for any purpose whatsoever, and that neither Party has any authority to enter into a contract, to assume any obligation or to give warranties or representations on behalf of the other Party. Nothing in this relationship shall be construed to create a relationship of joint venture, partnership, fiduciary or other similar relationship between the Parties.

18.5 Non-Waiver. The Parties covenant and agree that if a Party fails or neglects for any reason to take advantage of any of the terms provided for the termination of this Agreement or if a Party, having the right to declare this Agreement terminated, shall fail to do so, any such failure or neglect by such Party shall not be a waiver or be deemed or be construed to be a waiver of any cause for the termination of this Agreement subsequently arising, or as a waiver of any of the terms, covenants or conditions of this Agreement or of the performance thereof. None of the terms, covenants and conditions of this Agreement may be waived by a Party except by its written consent.

18.6 Reformation. The Parties hereby agree that neither Party intends to violate any public policy, statutory or common law, rule, regulation, treaty or decision of any government agency or executive body thereof of any country or community or association of countries, and that if any word, sentence, paragraph or clause or combination thereof of this Agreement is found, by a court or executive body with judicial powers having jurisdiction over this Agreement or any of the Parties hereto, in a final, unappealable order to be in violation of any such provision in any country or community or association of countries, such words, sentences, paragraphs or clauses or combination shall be inoperative in such country or community or association of countries, and the remainder of this Agreement shall remain binding upon the Parties hereto. In lieu of such inoperative words, sentences, paragraphs or clauses, or combination of clauses, there will be added automatically as part of this Agreement, a valid, enforceable and operative provision as close to the original language as may be possible which preserves the economic benefits to the Parties.

18.7 Force Majeure. No liability hereunder shall result to a Party by reason of delay in performance caused by force majeure that is circumstances beyond the reasonable control of the Party, including, without limitation, acts of God, fire, flood, war, terrorism, civil unrest, labor unrest, or shortage of or inability to obtain material or equipment.

18.8 Section and Paragraph Headings. The section and paragraph headings used in this Agreement are intended for purposes of reference and convenience only, and shall not factor into any interpretation of the Agreement.

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

18.9 Entire Agreement. The terms and conditions herein constitute the entire agreement between the Parties with respect to the subject matter hereof and shall supersede all previous agreements, whether electronic, oral or written, between the Parties hereto with respect to the subject matter hereof, except for the Research Collaboration Agreement which, once executed, shall not be amended, modified or superseded in any respect by the terms of this Agreement. No agreement of understanding bearing on this Agreement shall be binding upon either Party hereto unless it shall be in writing and signed by the duly authorized officer or representative of each of the Parties and shall expressly refer to this Agreement. Except as set forth in Section 18.10, electronic communication between the Parties shall not constitute an agreement of understanding, unless it is subsequently reduced to writing and signed by the duly authorized officer or representative of each of the Parties and shall expressly refer to this Agreement.

18.10 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument. Counterpart signature pages delivered by facsimile or similar electronic transmission (including via e-mail in PDF format) shall be deemed binding as originals.

[Signatures follow on next page.]

CONFIDENTIAL TREATMENT REQUESTED BY MARKER THERAPEUTICS, INC.

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

IN WITNESS WHEREOF, the Parties hereto have executed and delivered this Agreement in multiple originals by their duly authorized officers and representatives on the respective dates shown below, but effective as of the Agreement Date.

MARKER THERAPEUTICS, INC.

Name: /s/ John Wilson
John Wilson

Title: Chief Executive Officer

Date: 3/14/2018

BAYLOR COLLEGE OF MEDICINE

Name: /s/ Adam Kuspa, Ph.D.
Adam Kuspa, Ph.D.

Title: Senior Vice President and Dean of Research

Date: 3/23/18

CONFIDENTIAL TREATMENT REQUESTED BY MARKER THERAPEUTICS, INC.

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

Appendix A
BCM's Patent Applications and Patents

Law Firm Ref. No. BCM Ref. No.	Title and Patent Number (if issued)	Country	Developer(s)	Appln. No.	Filing Date and Issue Date	Assignment	Priority Information
HO-P03681US0 BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS	US	Ann Marie Leen, Cliona Rooney; Ulrike Gerdemann; Juan Vera	61/236,261 Expired	24-Aug-2009	BCM	n/a
BAYM.P0016US BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS OR MULTIPLE VIRUSES	US	Leen, Ann M.; Gerdemann, Ulrike; Rooney, Cliona; Vera Valdes Juan F.; Wilson, John R.	12/862,409	24-Aug-2010	BCM; Wilson Wolf	USAN 61/236,261 Filing Date: 24-Aug-2009
BAYM.P0016US.C1 BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS OR MULTIPLE VIRUSES	US	Leen, Ann M.; Gerdemann, Ulrike; Rooney, Cliona; Vera Valdes Juan F.; Wilson, John R.	15/246,241	24-Aug-2016	BCM; Wilson Wolf	USAN 12/862,409 and USAN 61/236,261 Filing Date: 24-Aug-2009
BAYM.P0016WO BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS OR MULTIPLE VIRUSES	PCT	Leen, Ann M.; Gerdemann, Ulrike; Rooney, Cliona; Vera Valdes Juan F.; Wilson, John R.	PCT/US2010/046505	24-Aug-2010	BCM; Wilson Wolf	USAN 61/236,261 Filing Date: 24-Aug-2009
BAYM.P0016EP BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS OR MULTIPLE VIRUSES EP Patent No. 2470644	EP	Leen, Ann M.; Gerdemann, Ulrike; Rooney, Cliona; Vera Valdes Juan F.; Wilson, John R.	EP 10814245.6	24-Aug-2010 Issue Date: 21-Sep-2016	BCM; Wilson Wolf	USAN 61/236,261 Filing Date: 24-Aug-2009

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

Law Firm Ref. No. BCM Ref. No.	Title and Patent Number (if issued)	Country	Developer(s)	Appln. No.	Filing Date and Issue Date	Assignment	Priority Information
BAYM.P0016ECH BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS OR MULTIPLE VIRUSES	CH	Leen, Ann M.; Gerdemann, Ulrike; Rooney, Cliona; Vera Valdes Juan F.; Wilson, John R.	10814245.6	24-Aug-2010	BCM; Wilson Wolf	
BAYM.P0016EDE BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS OR MULTIPLE VIRUSES	DE	Leen, Ann M.; Gerdemann, Ulrike; Rooney, Cliona; Vera Valdes Juan F.; Wilson, John R.	10814245.6	24-Aug-2010	BCM; Wilson Wolf	
BAYM.P0016EDK BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS OR MULTIPLE VIRUSES	DK	Leen, Ann M.; Gerdemann, Ulrike; Rooney, Cliona; Vera Valdes Juan F.; Wilson, John R.	10814245.6	24-Aug-2010	BCM; Wilson Wolf	
BAYM.P0016EFR BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS OR MULTIPLE VIRUSES	FR	Leen, Ann M.; Gerdemann, Ulrike; Rooney, Cliona; Vera Valdes Juan F.; Wilson, John R.	10814245.6	24-Aug-2010	BCM; Wilson Wolf	

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

Law Firm Ref. No. BCM Ref. No.	Title and Patent Number (if issued)	Country	Developer(s)	Appln. No.	Filing Date and Issue Date	Assignment	Priority Information
BAYM.P0016EGB BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS OR MULTIPLE VIRUSES	GB	Leen, Ann M.; Gerdemann, Ulrike; Rooney, Cliona; Vera Valdes Juan F.; Wilson, John R.	10814245.6	24-Aug-2010	BCM; Wilson Wolf	
BAYM.P0016EIE BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS OR MULTIPLE VIRUSES	IE	Leen, Ann M.; Gerdemann, Ulrike; Rooney, Cliona; Vera Valdes Juan F.; Wilson, John R.	10814245.6	24-Aug-2010	BCM; Wilson Wolf	
BAYM.P0016ENL BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS OR MULTIPLE VIRUSES	NL	Leen, Ann M.; Gerdemann, Ulrike; Rooney, Cliona; Vera Valdes Juan F.; Wilson, John R.	10814245.6	24-Aug-2010	BCM; Wilson Wolf	
BAYM.P0016ENO BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS OR MULTIPLE VIRUSES	NO	Leen, Ann M.; Gerdemann, Ulrike; Rooney, Cliona; Vera Valdes Juan F.; Wilson, John R.	10814245.6	24-Aug-2010	BCM; Wilson Wolf	
BAYM.P0016ESE BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS OR MULTIPLE VIRUSES	SE	Leen, Ann M.; Gerdemann, Ulrike; Rooney, Cliona; Vera Valdes Juan F.; Wilson, John R.	10814245.6	24-Aug-2010	BCM; Wilson Wolf	

Law Firm Ref. No. BCM Ref. No.	Title and Patent Number (if issued)	Country	Developer(s)	Appln. No.	Filing Date and Issue Date	Assignment	Priority Information
BAYM.P0016EP.D1 BLG 10-001 BLG 10-048	GENERATION OF CTL LINES WITH SPECIFICITY AGAINST MULTIPLE TUMOR ANTIGENS OR MULTIPLE VIRUSES	EP	Leen, Ann M.; Gerdemann, Ulrike; Rooney, Cliona; Vera Valdes Juan F.; Wilson, John R.	EP 16180607.0	24-Aug-2010	BCM; Wilson Wolf	USAN 61/236,261 Filing Date: 24-Aug-2009
BAYM.P0059US.P1 BLG 10-048	PEPMIXES TO GENERATE MULTIVIRAL CTLS WITH BROAD SPECIFICITY	US	Ann Marie Leen, Cliona Rooney, Ulrike Gerdemann, Juan F. Vera Valdes	61/596,875 Expired	09-Feb-2012	BCM	n/a
BAYM.P0059WO BLG 10-048	PEPMIXES TO GENERATE MULTIVIRAL CTLS WITH BROAD SPECIFICITY	PCT	Ann Marie Leen, Cliona Rooney, Ulrike Gerdemann, Juan F. Vera Valdes	PCT/US2013/025342	08-Feb-2013	BCM	USAN 61/596,875 Filing Date: 09-Feb-2012
BAYM.P0059US BLG 10-048	PEPMIXES TO GENERATE MULTIVIRAL CTLS WITH BROAD SPECIFICITY	US	Ann Marie Leen, Cliona Rooney, Ulrike Gerdemann, Juan F. Vera Valdes	14/377,825	08-Aug-2014	BCM	USAN 61/596,875 Filing Date: 09-Feb-2012
BAYM.P0059US.C1 BLG 10-048	PEPMIXES TO GENERATE MULTIVIRAL CTLS WITH BROAD SPECIFICITY	US	Ann Marie Leen, Cliona Rooney, Ulrike Gerdemann, Juan Vera	15/905,176	26-Feb-2018	BCM	USAN 61/596,875 Filing Date: 09-Feb-2012

Law Firm Ref. No. BCM Ref. No.	Title and Patent Number (if issued)	Country	Developer(s)	Appln. No.	Filing Date and Issue Date	Assignment	Priority Information
BAYM.P0059EP BLG 10-048	PEPMIXES TO GENERATE MULTIVIRAL CTLS WITH BROAD SPECIFICITY	EP	Ann Marie Leen, Cliona Rooney, Ulrike Gerdemann, Juan F. Vera Valdes	EP 13746524.1	08-Feb-2013	BCM	USAN 61/596,875 Filing Date: 09-Feb-2012
BAYM.P0168US.P1 BLG 16-019 BLG 16-100	IMMUNOGENIC ANTIGEN IDENTIFICATION FROM A PATHOGEN AND CORRELATION TO CLINICAL EFFICACY	US	Ann Marie Leen, Paibel Aguayo-Hiraldo, Ifigeneia Tzannou	62/220,884 Expired	18-Sep-2015	BCM	n/a
BAYM.P0168WO BLG 16-019 BLG 16-100	IMMUNOGENIC ANTIGEN IDENTIFICATION FROM A PATHOGEN AND CORRELATION TO CLINICAL EFFICACY	PCT	Ann Marie Leen, Paibel Aguayo-Hiraldo, Ifigeneia Tzannou, Juan F. Vera Valdes	PCT/US2016/052487	19-Sep-2016	BCM	USAN 62/220,884 Filing Date: 18-Sep-2015

Appendix B
Subject Technology

List of Subject Technology to be sent by BCM to LICENSEE.

1. BLG 10-001, entitled “Generation of CTL Lines with Specificity Against Multiple Tumor Antigens or Multiple Viruses”

2. BLG 10-048, entitled “ Pepmixes to Generate Multiviral CTLs with Broad Specificity”

3. BLG 16-019, entitled “Immunogenic Antigen Identification from a Pathogen and Correlation to Clinical Efficacy”

4. BLG 16-100, entitled “Immunogenic Antigen Identification from a Pathogen and Correlation to Clinical Efficacy”

CONFIDENTIAL TREATMENT REQUESTED BY MARKER THERAPEUTICS, INC.

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

Appendix C
Royalty Report

BLG #: _____
Licensee: _____
Reporting Period: _____
Prepared By _____ **Date:** _____
Approved By _____ **Date:** _____

Please prepare a separate report for each product line. Then combine all product lines into a summary report.

Product Line Code (SKU): _____

Country	Units Sold	Exchange Rate	Total Billings (USD)	Gross Sales (USD)	Less Deductions* (USD)	Net Sales (USD)	Royalty Rate	Royalty Amount
USA								
Canada								
Europe								
Japan								
Other								
Total								**$**
Net Royalty Payable (USD)								**$**
Sublicensing Revenue (USD)								**$**
Other Payments- Milestones, Minimum Royalties, Maintenance Fees (USD)								**$**
Total Payment Due (USD)								**$**

*Deduction Description:

CONFIDENTIAL TREATMENT REQUESTED BY MARKER THERAPEUTICS, INC.

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

APPENDIX D
FORM OF INVOICE

Baylor Licensing Group
One Baylor Plaza
BCM210-600D
Houston, TX 77030
Phone: 713-798-6821
Fax: 713-798-1252

INVOICE

DATE

RE: XXXXXXXXXXXXX Fee
BLG #

Dear:

Please let this letter serve as an INVOICE for the XXXXXXXXXX fee of $XXXX for the above-referenced technology, as stated in the License Agreement, between LICENSEE and Baylor College of Medicine. **Please include interest per paragraph 3.5 of the license agreement.**

Please make the check payable to Baylor College of Medicine Please address payment to the address listed below and include BLG ref XX-XXX on all payments.

Should you choose to send payment via wire; I have attached a copy of our wire transfer instructions for your convenience.

Baylor College of Medicine
Licensing Group
P.O. Box 301207
Dallas, TX 15303-1207

I appreciate your attention to this matter.

Best regards,

Nellie Villarreal
Administrative Coordinator
/nv

CONFIDENTIAL TREATMENT REQUESTED BY MARKER THERAPEUTICS, INC.

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

ALL WIRE TRANSFER FEES ARE TO BE PAID BY THE SENDER (NOT BAYLOR COLLEGE OF MEDICINE).

Wire Instructions (Incoming)

[***REDACTED***]

Exhibit 10.22

SPONSORED RESEARCH CONTRACT

THIS CONTRACT, effective the 16th day of November, 2018 (hereinafter the "Effective Date"), is entered into by and between Baylor College of Medicine (hereinafter "Baylor") and Marker Therapeutics, Inc., a Delaware corporation, with principal offices located at 3200 Southwest Freeway Suite 2240, Houston, TX 77027 (hereinafter "Sponsor"), governing research to be conducted at Baylor in the laboratory of Dr. Juan Vera (hereinafter "Principal Investigator").

The parties agree as follows:

WHEREAS the Sponsor is interested in scientific research related to the manufacturing of T-cells; and

WHEREAS Baylor has on its staff certain scientists and technicians who possess unique knowledge and experience in substantive fields relating to such research; and

WHEREAS Baylor and Marker Therapeutics, Inc., entered into a license agreement dated March 16, 2018 ("License"); and

WHEREAS the proposed research is intended, to advance the development of the technology licensed by way of the License; and

WHEREAS Marker Therapeutics, Inc., changed its name to Marker Cell Therapy, Inc., merged into Taplmmune, Inc., a Nevada corporation and Taplmmune, Inc. changed its name to Marker Therapeutics, Inc. and reincorporated in Delaware; and

WHEREAS the Sponsor is willing to fund such research by Baylor.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and conditions hereinafter recited, the parties do hereby agree as follows:

1. Definitions

For purposes of this Contract, the following definitions apply:

1.1 "Affiliate(s)" shall mean any corporation or business entity which is controlled by, controls, or is under common control of the Sponsor at the time of execution of this Contract. For this purpose, the meaning of the word "control" shall include, without limitation, direct or indirect ownership of more than fitly percent (50%) of the voting shares of such corporation, or fifty percent (50%) of the ownership interests in such other business entity.

1.2 "Contract Period" shall mean the period commencing on the Effective Date of this Contract and terminating on the fourth anniversary of the Effective Date. This Contract may be extended for an additional term by the mutual written consent of the duly authorized representatives of Baylor and the Sponsor.

1.3 "FDA" shall mean the United States Food and Drug Administration.

1.4 "Project Research" shall mean research pertaining to T-cell manufacturing as described more fully in Exhibit A (which is incorporated herein by reference and made part of this Contract) or such modifications of Exhibit A as may be mutually agreed upon in writing by duly authorized representatives of Baylor and the Sponsor.

1.5 "Project Funds" shall mean those funds paid by the Sponsor to Baylor for the Project Research in accordance with this Contract. Project Funds are detailed in Exhibit A "Budget". Baylor and Sponsor have negotiated the budgets for years I and 2 of this Agreement. The budgets for years 3 and 4 will be negotiated by Baylor and Sponsor during the final six months of year 2. The Budget is inclusive of all indirect and overhead costs.

1.6 "Project Team" shall mean the Principal Investigator and the research technicians under the Principal Investigator's direction and control who are supported in whole or in part by the Project Funds.

2. Research

2.1 **Conduct of Project Research.** During the Contract Period, the Project Team shall conduct Project Research on behalf of the Sponsor.

2.2 **Meetings.** During the Contract Period, the Principal Investigator and representatives of the Sponsor shall meet from time to time to discuss the planning and progress of the Project Research.

2.3 **Reporting Obligations.** Baylor shall advise the Sponsor of the results of the Project Research and, at least once every six (6) months during the Contract Period, provide the Sponsor with written progress reports concerning the Project Research. A final written report setting forth the results achieved under and pursuant to the Project Research shall be submitted by Baylor to the Sponsor within ninety (90) days of termination of the research which is the subject of this Contract. Such final report shall include: a complete summary of the research carried out and detailed experimental protocols of the research performed in the course of the Project Research.

2.4 **Obligation to Provide Data.** Baylor shall, throughout the term of this Contract, provide to the Sponsor copies of all data and other information generated by or on behalf of the Project Team pursuant to this Contract including, without limitation, all raw data obtained as a result of studies conducted in the course of Project Research and all experimental procedures developed under the Project Research in sufficient written detail to permit the Sponsor's personnel to employ such procedures in their own research.

2.5 **Compliance with Applicable Laws.** All studies done in connection with the Project Research shall be carried out in strict compliance with any applicable federal, state, or local laws, regulations, or guidelines governing the conduct of such research.

2.6 **Project Team Personnel Changes.** Baylor shall promptly advise the Sponsor in respect to any changes in the personnel comprising the Project Team. If, for any reason, the Principal Investigator ceases to be associated with Baylor, or otherwise becomes unavailable to work on the Project Research, a qualified replacement scientist at Baylor shall be mutually appointed by Baylor and the Sponsor to be the Principal Investigator, or, at the Sponsor's sole option, this Contract shall be terminated on thirty (30) days written notice.

3. Payments

3.1 **Payment Terms.** With respect to the years 1 and 2 budgets, the Sponsor shall pay Baylor the Project Funds amount of two hundred fifty six thousand two hundred seventy two Dollars ($256,272.00) in the following manner:

(a) on or before the Effective Date, the Sponsor shall pay Baylor the sum or ($76,882.00) Dollars:

(b) One hundred fifty three thousand seven hundred sixty four dollars ($153,764.00) shall be paid in equal monthly installments on or before the first day of each month for the duration of the Contract Period.

(c) A final payment that includes all outstanding payments due will be sent by the Sponsor to Baylor within thirty (30) days of receipt by the Sponsor of the final written report, as set forth in Section 2.3.

(d) With respect to the years 3 and 4 budgets, Sponsor shall pay the Project Funds for those years on a similar schedule as that for the payments set forth above for years 1 and 2.

3.2 **Late Payments.** In the event that any payment due hereunder is not made when due, the payment shall accrue interest beginning on the first day of the month following the date when such payment is due, calculated at the annual rate of the sum of (a) [***REDACTED***] percent ([***REDACTED***]%) plus (b) the prime interest rate quoted by Citibank. N.A., New York, New York, on the date such payment is due, or on the date payment is made, whichever is higher, the interest being compounded on the last day of each calendar month, provided that in no event shall said annual rate exceed the maximum legal interest rate for corporations. Such payment when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate or waive the right of Baylor to any other remedy, legal or equitable, to which Baylor may be entitled because of the delinquency of the payment.

3.3 **Direction of Payments**

Payments under the terms of this Contract shall be made by check payable to:

Name on check: Baylor College of Medicine
Tax ID #: [***REDACTED***]
Grants and Contracts Dept.
P.O. Box 301207
Dallas, Texas 75303-1207

4. Non-Disclosure Agreement and Publications

4.1 **Scope of Confidentiality.** Nothing in this Contract shall be construed to limit the freedom of the Principal Investigator, physicians, research scientists, or other individuals conducting the Project Research, whether paid under this Contract or otherwise, to engage in similar research performed independently under other grants, contracts, or agreements with parties other than the Sponsor. Baylor, the Principal Investigator, and the Sponsor agree to use reasonable efforts to prevent disclosure of information under and pursuant to this Contract which is designated in writing as being “CONFIDENTIAL”.

4.2 **Confidentiality Obligations.** Baylor and the Sponsor further agree that, except as provided in Section 4.3, 4.4 and 5.1 below, they will not use, except in furtherance of this Contract, and not disclose orally, by written publication, or otherwise, any Project Research results except that such information may be disclosed insofar as such disclosure is necessary to allow either Baylor or the Sponsor, as the case may be, (i) to defend itself against litigation, (ii) to file and prosecute patent applications on any invention conceived or reduced to practice under the Project Research, or (iii) to comply with judicial decree or government action. Notwithstanding the above, such obligation of confidentiality shall not apply to information that at the time of disclosure:

(a) is in the public domain;

(c) has come into the public domain through no fault of Baylor; was known to the receiving party prior to its disclosure by the disclosing party;

(d) is disclosed by a third party not under an obligation of non-disclosure;

(e) is required by law or legal process to be disclosed; or

(f) written permission for disclosure has been granted to the disclosing party by Baylor or the Sponsor, as the case may be.

Additionally, Baylor may use Project Research results in non-commercial research, so long as such non-commercial research is not made available to a commercial third party.

4.3 **Publication Procedures.** In the exercise of the rights of academic freedom of an educational institution and its faculty, Baylor, the Principal Investigator, and the Project Team shall have the right to publish in scientific or other journals, or to present at professional conferences or other meetings, the results of the Project Research conducted under this Contract. In order to permit the Sponsor the opportunity to request protection of patent and proprietary rights relating to the Project Research, a copy of each proposed publication shall be provided to the Sponsor thirty (30) days in advance of submission for publication to permit the Sponsor time to review the subject matter of such publication. Requests for protection of patent and proprietary rights shall be made to Baylor in writing within thirty (30) days of receipt of the proposed publication. Upon such request, Baylor shall make reasonable efforts to secure patent protection as per Section 5.3. Any final proposed publication provided to the Sponsor shall be considered as acceptable for submission for publication unless the Sponsor notifies Baylor and the Principal Investigator within thirty (30) days of receipt of the proposed publication. The Sponsor shall also receive final drafts of any proposed publication and the Sponsor shall be named in the publication as the sponsor of the Project Research or, as the case may be, the licensee of such technology. The right to review publications as set forth herein shall extend only to the work product of the Principal Investigator and the Project Team pursuant to the Project Research and not to the work product of other research conducted in the laboratories of the Principal Investigator, or member of the Project Team, or in the laboratories of other researchers at Baylor.

4.4 **Sponsor Sharing of Confidential Information.** Sponsor may share Project Research results with potential collaborators, and/or investors as needed, provided potential collaborators, and/or investors are under obligations of confidentiality similar to those hereunder. Upon the earliest of (a) publication by Baylor per term 4.3 above, or (b) 18 months have passed from completion of the Project Research hereunder, Sponsor may share the Project Research results for any purpose.

5. Ownership and Patents

5.1 **Ownership.** Baylor shall have sole and exclusive ownership rights to any invention of a product, device, process, or method, whether patentable or unpatentable (an "Invention") arising out of the Project Research subject to the right of the Sponsor to take an exclusive, or non-exclusive, fee-bearing, royalty-bearing license to the Invention, as set forth in Section 5.2 below. Notwithstanding the foregoing, Inventions arising out of the Project Research hereunder, which directly relate to the technology licensed to Sponsor under the License, and which were funded by the Sponsor, shall be incorporated by amendment into the License.

5.2 **Right of First Review.** Baylor grants to the Sponsor the right of first review with respect to any Invention, discovered from the performance of the Project Research, under the following the terms:

(a) The Sponsor shall comply with the terms of non-disclosure, as set forth in Section 4 of this Contract.

(b) Baylor shall notify the Sponsor, in writing, of the Invention and provide the Sponsor with sufficient detail to evaluate the Invention.

(c) The Sponsor shall have forty-five (45) days after such notification to evaluate the Invention and notify Baylor, in writing, that the Sponsor desires to license the Invention.

(d) Upon notification by the Sponsor of its desire to acquire rights to the Invention, the Sponsor and Baylor shall negotiate, in good faith, for a period not to exceed sixty (60) days, unless extended by mutual written agreement of Baylor and the Sponsor, in an effort to arrive at terms and conditions satisfactory to Baylor and the Sponsor for the license by the Sponsor of the Invention.

(e) If Baylor and the Sponsor do not reach such agreement within said sixty-day (60-day) period, or if the Sponsor fails to notify Baylor within said forty-five-day (45-day) period, or if the Sponsor decides not to acquire the rights to the Invention, Baylor shall be free to deal with the Invention as Baylor in its discretion may decide, and Baylor shall have no further obligations to the Sponsor with respect to the Invention.

(f) The right of first review, as presented herein, shall terminate at the earlier of the (i) second anniversary of the Effective Date or (ii) the termination of this Contract, but only if Baylor has previously provided Company with written notification of all Inventions arising out of the Project Research. In the event Baylor has not provided such written notification as to an Invention, Baylor will provide Sponsor with written notification and the provisions of this section 5.2 will be carried out.

5.3 **Filing Obligations** With respect to inventions which the Sponsor has elected to take an exclusive, or non-exclusive, royalty-bearing license, as provided in Sections 5.1 and 5.2:

(a) Baylor shall be responsible for the preparation, filing, and prosecution of all patent applications covering any Invention arising out of the Project Research. The Sponsor shall be responsible for all costs and fees associated therewith from and after the Effective Date of such license and shall reimburse Baylor for such costs accrued prior to the Effective Date of such license. Baylor shall seek and consider the advice and counsel of the Sponsor in such filing / prosecution of patent applications. The Sponsor and its employees shall reasonably assist Baylor in the preparation, filing, and prosecution of such patent applications;

(b) the Sponsor shall also have the responsibility for filing all applications which may be required by health or regulatory authorities relating to the products arising from the Project Research including, without limitation, filing a New Drug Application with the FDA. All costs and expenses associated with such filings shall be borne by the Sponsor. The Sponsor shall own all right, title, and interest in any FDA or other regulatory approvals which are obtained by or on behalf of the Sponsor; and,

(c) Baylor and its employees shall reasonably assist the Sponsor with respect to any filings which may be required by appropriate health or regulatory authorities.

6. Termination

6.1 **Contract Period.** This Contract shall remain in effect for the Contract Period unless extended in accordance with the terms of this Contract, as outlined in Section 1.2.

6.2 **Termination for Default.** In the event that either party shall be in default of any of its obligations under this Contract and shall fail to remedy such default within sixty (60) days after receipt of written notice thereof, the party not in default shall have the option of canceling this Contract by giving thirty (30) days written notice of termination to the other party.

6.3 **Effects of Termination; Survival.** Termination of this Contract shall not affect the rights and obligations of the parties, which shall have accrued prior to termination, including, without limitation, the confidentiality obligations set forth in Section 4.1.

7. **Indemnification**

7.1 **Indemnity Obligation.** The Sponsor agrees to defend, indemnify and hold harmless Baylor, the Principal Investigator, Baylor's trustees, officers, agents, staff, employees, students, and faculty members, and its affiliated hospitals (all such parties are hereinafter referred to collectively as the "Indemnified Parties") from and against any and all third party liability, claims, lawsuits, losses, demands, damages, costs, and expenses (including reasonable attorney's fees and court costs), arising directly or indirectly out of the Project Research or the design, manufacture, sale or use of any embodiment or manifestation of the Project Research regardless of whether any and all such liability, claims, lawsuits, losses, demands, damages, costs, and expenses (including attorney's fees and court costs) arise in whole or in part from the negligence of any of the Indemnified Parties. Notwithstanding the foregoing, the Sponsor will not be responsible for any liability, claims, lawsuits, losses, demands, damages, costs, and expenses (including attorney's fees and court costs) which arise solely from:

(i) the gross negligence or intentional misconduct of Baylor or the Principal Investigator; and

(ii) actions by Baylor or the Principal Investigator in violation of applicable laws or regulations.

7.2 **Obligation to Defend.** The Sponsor agrees to provide a diligent defense against any and all liability, claims, lawsuits, losses, demands, damages, costs, and expenses (including attorney's fees and court costs), brought against the Indemnified Parties with respect to the subject of the indemnity contained in Section 7.1, whether such claims or actions are rightfully or wrongfully brought or filed.

7.3 **Indemnification Procedures.** Any Indemnified Party wishing to be indemnified as provided in Sections 7.1 and 7.2 shall:

(a) promptly after receipt of notice of any and all liability, claims, lawsuits losses, demands, damages, costs, and expenses, or after the commencement of any action, suit, or proceeding giving rise to the right of indemnification, notify the Sponsor, in writing, of said liability, claims, lawsuits, losses, demands, damages, costs, and expenses and send to the Sponsor a copy of all papers served on the Indemnified Party; the Indemnified Party's failure to notify the Sponsor will not relieve the Sponsor from any liability to the Indemnified Party;

(b) permit the Sponsor to retain counsel of its choosing to represent the Indemnified Party (but in the event that the Sponsor does not select counsel to represent the Indemnified Party within ten (10) days of notification of Sponsor per section 7.3(a), the Indemnified Party may select its own counsel, the fees and all costs of which counsel will be borne by the Sponsor); and

(c) allow the Sponsor to retain exclusive control of any such liability, claims, lawsuits, losses, demands, damages, costs, and expenses, including the right to make any settlement, except that the Sponsor will not have the right to make any settlement or take any other action which would be deemed to confess wrongdoing by any of the Indemnified Parties or could reasonably be expected to have a negative effect on the reputation of one of the Indemnified Parties, without the prior written consent of Baylor and the Indemnified Party involved.

8. Insurance

Insurance Coverage Limits. During the term of this Contract, the Sponsor shall maintain in full force and effect a policy or policies of:

(i) general liability insurance with limits of not less than $5,000,000 per occurrence and $5,000,000 annual aggregate; and

(ii) products liability insurance with limits of not less than $5,000,000 per occurrence and $5,000,000 annual aggregate.

Such policies shall name Baylor, the Principal Investigator, Baylor's trustees, officers, agents, staff, employees, students, and faculty members, and its affiliated hospitals as additional insureds. Such coverage(s) shall be purchased from a carrier or carriers deemed acceptable to Baylor and certificates of insurance evidencing the coverage(s) maintained will be provided.

10. Independent Contractors

The Sponsor and Baylor shall at all times act as independent parties and nothing contained in this Contract shall be construed or implied to create an agency or partnership. Neither party shall have the authority to contract or incur expenses on behalf of the other except as may be expressly authorized by collateral agreements. The Principal Investigator and members of the Project Team shall not be deemed to be employees of the Sponsor.

11. Use of Institution Name/Public Statements

11.1 The Sponsor agrees that it will not at any time during or following termination of this Contract use the name of Baylor or any other names, insignia, symbol(s), or logotypes associated with Baylor or any variant or variants thereof or the names of the Principal Investigator or any other Baylor faculty member or employee orally or in any literature, advertising, or other materials without the prior written consent of Baylor, which consent may be withheld at Baylor's sole discretion. Notwithstanding the foregoing, the Sponsor shall be permitted to state orally and in writing the fact that the Project Research is being conducted at Baylor under the direction of the Principal Investigator.

11.2 Baylor agrees to make no public presentations about the Project Research outside of appropriate scientific meetings, to issue no news releases about the Project Research, and neither party shall make use of the other's name in any form of public information without the written permission of the other party.

12. Choice of Law

Any disputes or claims arising under this Contract shall be governed by the laws of the State of Texas, Harris County, City of Houston as the site for the performance of the Project Research.

13. Severability

If any one or more of the provisions of this Contract shall be held to be invalid, illegal or unenforceable, the validity, legality or enforceability of the remaining provisions of this Contract shall not in any way be affected or impaired thereby.

14. Waiver

The failure of any party hereto to insist upon strict performance of any provision of this Contract or to exercise any right hereunder will not constitute a waiver of that provision or right.

15. Notices

Any notice or communication required or permitted to be given or made under this Contract by one of the parties hereto to the other shall be in writing and shall be deemed to have been sufficiently given or made for all purposes if mailed by certified mail, postage prepaid, addressed to such other party at its respective address as follows:

If to the Sponsor:

Peter Hoang
President and CEO
Marker Therapeutics, Inc.
3200 Southwest Freeway, Suite 2240
Houston, TX 77027
917-916-6644

If to Baylor with respect to all non-technical matters:

Michael B. Dilling Ph.D., CLP
Director, Baylor Licensing Group
Baylor College of Medicine
Mail Stop BCM 210
One Baylor Plaza
Houston, Texas 77030-3411

If to Baylor with respect to technical questions:

(Investigator's name, address, and phone number)

Dr Juan F Vera
1 Baylor Plaza, MS: BCM505
jfvera@txch.org
832.824.4717

16. Assignment

This Contract may be assigned by the Sponsor to any parent, subsidiary, or affiliate of the Sponsor or to any successor in interest only by reason of any merger, acquisition, partnership, or license agreement only with Baylor's prior written approval which shall not be unreasonably withheld. Any assignment or attempt to assign, or any delegation or attempt to delegate, in the absence of such prior written consent, shall be void and without effect. This Contract may not be assigned by Baylor.

17. Entirety

With the exception of the License, this Contract represents the entire agreement of the parties and it expressly supersedes all previous written and oral communications between the parties with regard to the Project Research proposed hereunder. No amendment, alteration, or modification of this Contract or any exhibits attached hereto shall be valid unless executed in writing by authorized signatories of both parties.

18. Warranties

Baylor makes NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE RESULTS OF THE PROJECT RESEARCH OR OF THE MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF SUCH PROJECT RESEARCH OR RESULTS. Baylor shall not be liable for any direct, consequential, or other damages suffered by the Sponsor or any other party as a result of the conduct of the Project Research. All warranties made or to be made in connection with the Project Research shall be made by the Sponsor thereof and none of such warranties shall directly or indirectly by implication obligate in any way Baylor, the Principal Investigator, Baylor's trustees, officers, agents, staff, employees, students, and faculty members, and its affiliated hospitals.

CONFIDENTIAL TREATMENT REQUESTED BY MARKER THERAPEUTICS, INC.

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

IN WITNESS WHEREOF, the parties hereto have caused this Contract to be executed in duplicate counterpart original by their duly authorized representatives to be effective as of the Effective Date.

SPONSOR

By: /s/ Peter L. Hoang 11/16/18
Signature Date
Peter L. Hoang
President & CEO

BAYLOR COLLEGE OF MEDICINE

By: /s/ Michael B. Dilling Ph.D., CLP 11/26/2018
Signature Date
Michael B. Dilling Ph.D., CLP
Director, Baylor Licensing Group

I acknowledge that I have read this Contract in its entirety and that I shall use reasonable efforts to uphold my individual obligations and responsibilities set forth herein:

By: /s/ Juan F. Vera, M.D. 11/21/18
Signature Date
Principal Investigator

Juan F. Vera, M.D.
Typed Name

Principal Investigator
Title

By: /s/ Ann Leen, Ph.D. 11/21/18
Signature Date
Co-Investigator

Ann Leen, Ph.D.
Typed Name

Co-Investigator
Title

CONFIDENTIAL TREATMENT REQUESTED BY MARKER THERAPEUTICS, INC.

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

EXHIBIT A

WORKSCOPE

[***REDACTED***]

Deliverables:

[***REDACTED***]

Expected Deliverables:

[***REDACTED***]

CONFIDENTIAL TREATMENT REQUESTED BY MARKER THERAPEUTICS, INC.

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

BUDGET

Salaries and Wages

Name	% Effort	Year 1	Year 2
PI	1%	[***REDACTED***]	[***REDACTED***]
Co-Inv	2%	[***REDACTED***]	[***REDACTED***]
Postdoc	[***REDACTED***]%	[***REDACTED***]	[***REDACTED***]
Cell Proc Tech	[***REDACTED***]%	[***REDACTED***]	[***REDACTED***]
Rsch Tech	[***REDACTED***]%	[***REDACTED***]	[***REDACTED***]
Subtotal:	**[***REDACTED***]%**	**28,971**	**29,840**

Fringe Benefits

Name	% Effort	Year 1	Year 2
PI	1%	[***REDACTED***]	[***REDACTED***]
Co-Inv	2%	[***REDACTED***]	[***REDACTED***]
Postdoc	[***REDACTED***]%	[***REDACTED***]	[***REDACTED***]
Cell Proc Tech	[***REDACTED***]%	[***REDACTED***]	[***REDACTED***]
Rsch Tech	[***REDACTED***]%	[***REDACTED***]	[***REDACTED***]
Subtotal:	**[***REDACTED***]%**	**10,406**	**10,719**

Supplies (examples below)

	Year 1	Year 2
Tissue Culture	[***REDACTED***]	[***REDACTED***]
Monoclonal Antibodies	[***REDACTED***]	[***REDACTED***]
Immune Studies	[***REDACTED***]	[***REDACTED***]
Cytokines	[***REDACTED***]	[***REDACTED***]
Subtotal:	**39,625**	**40,814**

Total Direct Cost for All Year Modular Format	**[***REDACTED***]**	**[***REDACTED***]**
Indirect Cost for regular line items	**[***REDACTED***]**	**[***REDACTED***]**
Total Cost Direct and Indirect per year	**[***REDACTED***]**	**[***REDACTED***]**
Total Budget Requested All Year		**$256,272**

CONFIDENTIAL TREATMENT REQUESTED BY MARKER THERAPEUTICS, INC.

Portions herein identified by [***] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

Baylor College of Medicine — Baylor Licensing Group
Monetary Contract Routing Sheet

1. Contract Type: Sponsored Research Agreement BRAIN 54715-1
2. Contract Parties: Marker Therapeutics
3. Contract Principal Investigator: Juan Vera and Ann Leen
4. Effective Date: 11/16/2018
5. Contract Term: ending November 15, 2022
6. Termination without Cause: none
7. Payment Amount: up to $256,272 (years 1 and 2 only, years 3 and 4 will be covered in an amendment)
   (a) On or before Effective Date $76,882
   (b) Equal monthly installments of the remainder $153,764 for two years
8. %IDC: [***REDACTED***]

Principal Investigator Certification: I certify that I have read the contract and understand the business terms, that the contract is in Baylor's best interest, and that the activity is consistent with Baylor's mission.

Signature of Principal Investigator: /s/

Signature of Department Administrator: /s/

Signature of Department Chair: /s/

Exhibit 10.38

MARKER THERAPEUTICS, INC.

CONSULTING SERVICES AGREEMENT

This Consulting Services Agreement ("Agreement") is hereby made and entered into this 19th day of October, 2018 ("Effective Date") by and between Marker Therapeutics, Inc., a Delaware corporation, having an address at 3200 Southwest Freeway, Suite 2240, Houston, Texas 77027 and its subsidiaries ("Marker" or the "Company"), and Ann Leen, having an address at 2727 Drexel Drive, Houston, Texas 77027 ("Consultant"). Marker and Consultant are referred to herein collectively as the "Parties" and individually as a "Party."

WITNESSETH:

WHEREAS, Marker is in need of consulting assistance in the area of a Chief Scientific Officer;

WHEREAS, Consultant has represented that Consultant is qualified to perform and possesses the knowledge to perform those certain services set forth in this Agreement; and

WHEREAS, Marker desires to engage Consultant as an independent contractor to perform those services set forth herein, and Consultant desires to accept such engagement.

NOW, THEREFORE, in consideration of the above recitals, which are incorporated herein as covenants, the mutual promises herein made and exchanged and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Engagement. Marker hereby engages Consultant as an independent contractor to perform consulting services set forth in this Agreement and in **Schedule 1, Consulting Services**, which is attached hereto and incorporated herein by reference (collectively, the "Services" or "Consulting Services"). Consultant hereby accepts such engagement under the terms set forth herein.

2. Compensation. Marker shall pay Consultant pursuant to the terms of **Schedule 2, Compensation**, attached hereto. Consultant shall be entitled to reimbursement for reasonable expenses, including travel provided that Consultant submits itemized statements of such expenses in a form acceptable to the Company. All travel within the continental U.S. will be coach class unless otherwise authorized by an executive officer of the Company. Invoices are subject to review and approval by Marker and if approved, will be paid no later than 30 days after receipt.

3. Stock Option Award. Upon execution of the Agreement, Marker will grant Consultant pursuant to the Company's 2014 Omnibus Stock Ownership Plan, as amended options to acquire up to 500,000 shares of Marker's common stock (the "Options"), in accordance with the terms provided the Stock Option Award Agreement attached as Exhibit A. The Options shall become vested upon the Consultant's continued performance of Services under this Agreement for four years from the date of the grant of the Options with 125,000 shares of the Options vesting on the first anniversary of the date of grant and the remaining options vesting evenly over the following thirty six (36) months. The Options shall be exercisable at the closing price of Marker's common stock as of the date of the grant of such Options.

4. Term and Termination without Cause. The term of this Agreement shall be for twelve (12) months from the Effective Date and may be renewed by written agreement of the Parties (collectively the "Term"). Either Party may terminate this Agreement without cause by giving thirty (30) days notice providing written notice to the other Party, provided that this Agreement shall terminate automatically in the event of the death or disability of Consultant.

5. Breach, Right to Cure, and Termination for Cause. In the event either Party breaches any provision of this Agreement, the non-breaching Party may provide written notice of such breach to the breaching Party and the breaching Party shall have seven (7) days from the date of notice to cure such breach. If such breach is not cured within seven (7) days from the date of notice, the non-breaching Party may, in addition to any other remedies it may have, immediately terminate this Agreement by providing written notice to the breaching Party.

6. Consultant Status.

6.1 Independent Contractor. Consultant's relationship with Marker shall be that of an independent contractor, and Consultant acknowledges and agrees that in performing all Services, Consultant is acting solely as an independent contractor and not as an employee or agent of Marker and will not by reason of this Agreement or by reason of her Consulting Services to the Company be entitled to participate in or to receive any benefit or right under any of the Company's employee benefit or welfare plans. Consultant shall not hold herself out to be an employee or agent of Marker and may use Marker's name in her business only with prior written permission by Marker. Except as specifically authorized by the Company, Consultant shall not enter into any agreements or incur any obligations on behalf of the Company.

6.2 Taxes. Marker shall not be responsible to Consultant or to any governmental agency for the withholding of federal or state income, social security or other taxes which are customarily imposed upon the salaries of employees. Consultant acknowledges and agrees that as an independent contractor, Consultant is self-employed and that Consultant alone will be responsible for federal, state and local taxes, social security withholding, fees, assessments, self-employment taxes, and any other taxes on any compensation payable to Consultant by Marker under this Agreement (collectively the "Taxes").

6.3 Best Efforts. It is recognized that Consultant is not obligated to devote all of her time, energy and skill to the business interests of Marker but, at the same time, Consultant: (i) shall refrain from any other activity (for herself or any other company) that would compete with or conflict with the activities of Marker related to the generation and/or commercialization of T cells targeting non-viral tumor-associated antigens and/or cancer testis antigens; (ii) shall not engage in any other endeavor which would unreasonably interfere with Consultant's obligations under this Agreement; and (iii) shall devote such time as may be necessary for the performance of the Services. The Parties acknowledge that Consultant is employed by Baylor College of Medicine, a Texas non-profit corporation ("Baylor") and Marker has an exclusive license agreement with Baylor (the "License Agreement").

6.4 Non-Solicitation. During the Term of this Agreement and for a period of one (1) year subsequent to the termination or expiration of this Agreement, Consultant shall not, without the prior written consent of Marker, directly, indirectly, or through any other party solicit employees of Marker for employment by Consultant.

6.5 Non-Competition. During the Term of this Agreement and for a period of one (1) year subsequent to the termination or expiration of this Agreement, Consultant shall not, within the United States of America: (i) engage in any employment, business, or activity or provide services to any third party that is in any way competitive with the business or activities of Marker related to the generation and/or commercialization of T cells targeting non-viral tumor-associated antigens and/or cancer testis antigens, or (ii) assist any other person or organization in competing with Marker or engaging in competition with the business or activities of Marker related to the generation and/or commercialization of T cells targeting non-viral tumor-associated antigens and/or cancer testis antigens. For the avoidance of doubt business or activities related to the generation and/or commercialization of T cells targeting neo-epitopes are excluded from this agreement.

7. Release and Indemnification. Consultant shall be solely liable for any loss or damage to any person or property caused by the actions or omissions of Consultant. Consultant hereby waives, releases, discharges and indemnifies Marker and its employees, directors, officers and agents and holds the same harmless from and against, and Consultant assumes full responsibility for: (i) any and all liabilities, costs, actions, demands or damages whatsoever, including attorneys' costs and fees, with respect to or relating to any injury, sickness, harm or damage incurred by the Consultant that is related to this Agreement or the performance of the Services; (ii) injuries to persons, or damages to property, including theft, related to or resulting from Consultant's acts or omissions; (iii) the payment of any Taxes, including any fines, interest or penalties associated, imposed or required with respect to this Agreement; and (iv) any liabilities, claims, and liens of Consultant.

8. Confidential Information and Rights to Materials.

8.1 Definitions.

8.1.1 The term "Company Documentation" shall mean notes, memoranda, reports, lists, records, drawings, sketches, designs, specifications, software programs, books, files, forms, papers, accounts, data, documentation and other materials of any nature and in any form, whether written, printed or in digital format or otherwise, whether prepared or paid for by Consultant or anyone else relating to any matter related to the performance of the Services, the scope of the business of Marker, or Marker's dealings or affairs.

8.1.2 The term “Confidential Information” shall mean any information concerning the organization, business or finances of Marker or of any third party which Marker is under an obligation to keep confidential that is maintained by Marker as confidential. Such Confidential Information shall include, but is not limited to, trade secrets or confidential information respecting patient or research participant lists, patient records, procedures, business plans and strategies, projects, plans, proposals, research and development, inventions, products, designs, market research data or analyses, technical information, marketing activities and procedures, methods, know-how, techniques, systems, processes, credit, financial and other data concerning Marker. For purposes of this Agreement, Confidential Information shall not include any information: (i) that is publicly available at the time of disclosure; (ii) that is or becomes generally known to the public through no fault of the Consultant; (iii) that is obtained without restriction from an independent source having a bona fide right to use and disclose such information, without restriction as to further use or disclosure; (iv) that Marker approves in advance in writing for unrestricted release; or (v) that is required to be disclosed by law, provided that written notice of the intent to disclose based on such reason is provided to Marker by Consultant seven (7) days prior to the scheduled date of disclosure.

8.1.3 The term “Proprietary Rights and Inventions” shall mean any and all rights and materials, including, but not limited to, patentable or non-patentable inventions, discoveries, concepts, ideas, techniques, methods (excluding published or standard methods dedicated to the public), apparatus, formulas, trademark and service mark rights, patent rights, trade secret rights and all other proprietary rights, as well as improvements thereof, generated by, made or conceived by, or arising out of the efforts of Consultant, either solely or jointly with others, whether patentable or not and whether or not reduced to practice, while: (i) acting in furtherance of this Agreement, which includes performing the Services; or (ii) utilizing Marker’s facilities, personnel or materials. Proprietary Rights and Inventions shall be deemed Confidential Information. The Consultant has informed Marker, in writing, of any and all inventions which he claims as her own or otherwise intends to exclude from this Agreement because it was developed by her prior to the Effective Date. The Consultant acknowledges that after execution of this Agreement he shall have no right to exclude any Proprietary Rights and Inventions from this Agreement. Consultant shall make and maintain adequate and current written records of all Proprietary Rights and Inventions, and shall disclose all Proprietary Rights and Inventions promptly, fully and in writing to the Company immediately upon development of the same and at any time upon request.

8.2 Nondisclosure. Consultant acknowledges that Marker's Confidential Information is valuable, special and a unique asset of Marker, and that Consultant may, whether or not intentionally, gain access to and knowledge of the Confidential Information during Consultant's performance under this Agreement. In light of the highly competitive nature of the industry in which Marker's business is conducted, Consultant shall not reveal to any person or entity any Confidential Information, except as authorized by Marker in writing, and shall keep secret all matters entrusted to Consultant and shall not use or attempt to use any Confidential Information, except as may be required in the course of performing the Services under this Agreement, nor shall Consultant directly or indirectly use any Confidential Information in any manner that may injure or cause loss or may be calculated to injure or cause loss to Marker. The obligations of confidentiality and nonuse shall survive for ten (10) years from the expiration or termination of this Agreement, whichever occurs first. Furthermore, Consultant shall not make, use or permit to be used any Company Documentation otherwise than for the benefit of Marker, whether during the Term or after the termination or conclusion of this Agreement. All Company Documentation shall be and remain the sole and exclusive property of Marker. Immediately upon the termination or conclusion of this Agreement, Consultant shall immediately deliver all Company Documentation in her possession, and all copies thereof, to Marker.

8.3 Conveyance. Consultant hereby conveys, assigns, transfers and delivers to Marker, and agrees to convey, assign, transfer and deliver to Marker, all Proprietary Rights and Inventions, as well as Consultant's right, title and interest in and to any Proprietary Rights and Inventions, if any. Consultant shall not, at any time or in any manner, challenge Marker's ownership of such Proprietary Rights and Inventions. Consultant shall assist Marker or its representatives, at the expense of Marker, to obtain, maintain and enforce any United States and foreign letters patent for any Proprietary Rights and Inventions, that Marker may elect and shall execute, acknowledge and confirm in writing the complete ownership by Marker of the Proprietary Rights and Inventions, as requested by Marker from time to time. Consultant also agrees to execute an unconditional assignment to Marker of Consultant's right, title and interest in the Proprietary Rights and Inventions. In the event that the above provisions requiring Consultant's execution of an assignment to Marker is found invalid or void, Consultant agrees that Marker shall have a non-exclusive, royalty-free, perpetual license to make, use, sell or exploit such Proprietary Rights and Inventions. The Parties acknowledge the work Consultant performs for Baylor is subject to obligations Consultant has to Baylor, including as to work done at Baylor that would be part of the License Agreement.

8.4 Remedies. Consultant acknowledges and agrees that Marker's remedy at law for a breach or threatened breach of any of the provisions of Section 7 would be inadequate and the breach shall be per se deemed as causing irreparable harm to Marker. Therefore, in the event of a breach by Consultant of any of the provisions of Section 7, Consultant agrees that, in addition to any remedy at law available to Marker, including, but not limited to, monetary damages, Marker, without posting any bond, shall be entitled to obtain, and Consultant agrees not to oppose Marker's request for equitable relief in the form of specific performance, temporary restraining order, temporary or permanent injunction, or any other equitable remedy which may then be available to Marker. Nothing in this Agreement shall be construed as prohibiting Marker from pursuing any other remedies available to it for such breach or threatened breach.

8.5 Consultants' Third-Party Confidential Information. During the Term of this Agreement, Consultant will not improperly disclose to Marker or use in the conduct of the Services any proprietary or confidential information or trade secrets of any former employer or other third party to which Consultant owes a duty of confidentiality with respect to same, and that Consultant will not bring onto the premises of Marker any proprietary information belonging to a third party unless consented to in writing by such third party.

8.6 Return of property. The Consultant agrees that all originals and all copies of materials containing, representing, evidencing, recording, or constituting any Confidential Information, however and whenever produced (whether by the Consultant or others), shall be the sole property of the Company.

At any time upon request of the Company, the Consultant shall return promptly any and all Confidential Information, including customer or prospective customer lists, other customer or prospective customer information or related materials, computer programs, software, electronic data, specifications, drawings, blueprints, medical devices, samples, reproductions, sketches, notes, notebooks, memoranda, reports, records, proposals, business plans, or copies of them, other documents or materials, tools, equipment, or other property belonging to the Company or its customers which the Consultant may then possess or have under her control.

The Consultant further agrees that upon termination of her engagement she shall not take with her any documents or data in any form or of any description containing or pertaining to Confidential Information or any Inventions.

9. Binding. This Agreement shall be binding upon the Parties and their respective successors and permitted assigns.

10. Modification and Severability. This Agreement may not be modified orally. Modification to this Agreement may be made from time to time, provided that such modification is in writing, attached as an addendum to this Agreement and signed by both Parties. In the event any provision of this Agreement or any part thereof is held invalid or unenforceable, the validity and enforceability of the remaining portions of the Agreement shall not be affected.

11. Notice. Any notice, demand, payment, or communication required, permitted, or desired to be given in relation to this Agreement shall be deemed effectively given when personally delivered; when received by overnight courier; or five (5) days after being deposited in the United States mail, and sent first class with postage prepaid thereon, certified and return receipt requested, addressed as follows:

Consultant:	Ann Leen 2727 Drexel Drive Houston, Texas 77027
Marker:	Marker Therapeutics, Inc. Attention: Chief Executive Officer 3200 Southwest Freeway, Suite 2240 Houston, Texas 77027
With a copy to:	Shumaker, Loop & Kendrick, LLP Attention: Mark A. Catchur 101 E. Kennedy Boulevard Suite 2800 Tampa, Florida 33602

12. Survival. The provisions of Sections 6, 7, 8, and 14 shall survive termination or expiration of this Agreement.

13. Force Majeure. In the event Consultant shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials, failure of power or restrictive government or judicial orders or decrees, riots, insurrection, war, Acts of God, or any other reason or cause beyond Consultant's reasonable control, then performance of such act shall be excused for the reasonable period of such delay.

14. Governing Law. This Agreement has been entered into in the State of Texas and shall be governed by, construed and interpreted in accordance with the laws of the State of Texas without reference to conflict of laws principles or statutory rules of arbitration included therein. Any dispute and proceeding under this Agreement shall be subject to the exclusive jurisdiction and venue of the state and federal courts located in Harris County, Texas, and the Parties hereby consent to the exclusive personal jurisdiction and venue of these courts.

15. Non-Waiver. The failure of either Party to insist upon the strict performance of any term of this Agreement shall not constitute a waiver of such term or a waiver of the right to assert a breach thereof. No waiver of any breach shall alter or affect this Agreement, which shall continue in full force and effect until its expiration or termination.

16. Enforcement. The prevailing Party shall be entitled to collect from the other Party all reasonable fees, costs and expenses including attorneys' fees and costs incurred by the prevailing Party in connection with: (i) the enforcement of any available remedy for breach of this Agreement; or (ii) any dispute arising from or related to this Agreement or the relationship between the Parties.

17. Entire Agreement. This Agreement constitutes the entire understanding between the Parties and contains all the understandings between the Parties with respect to the subject matter hereof; this Agreement supersedes any and all other understandings, either oral or written, between the Parties with respect to the subject matter hereto.

18. Assignment. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns. This Agreement is not intended to confer upon any person other than the parties hereto any rights or remedies hereunder, except as otherwise expressly herein and shall not be assignable by operation of law or otherwise.

19. Protected Health Information. In the event that the Consultant requests or needs protected health information as defined under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") in order to perform the Services, then if permitted by law, Marker shall transfer the protected health information under a separate agreement (e.g. Business Associate Agreement).

20. Marker Premises. Consultant will abide by all laws, rules and regulations that apply to the performance of the Services and, when on Marker's premises, will comply with Marker's policies, procedures and standards with respect to conduct of visitors as made known to Consultant.

[Signature page to follow]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the Effective Date.

Marker Therapeutics, Inc.

By: /s/Peter Hoang
Peter Hoang
Chief Executive Officer

/s/Ann Leen
Ann Leen

SCHEDULE 1

CONSULTING SERVICES

(a) Scope. Company hereby retains Consultant, and Consultant hereby agrees to be retained by Company as its **Chief Scientific Officer**.

(b) Duties. During the term of this Agreement, Consultant shall be reasonably available to Marker via e-mail, telephone or in person to Marker for consulting services as its Chief Scientific Officer and perform the duties typically assigned to the chief scientific officer of a similarly situated company in the Company's industry. The Consultant shall also perform such other reasonable duties as may hereafter be requested of her by the Chief Executive Officer, consistent with the services and providing such further services to the Company as may reasonably be requested of her. Such consulting services as requested from time to time by Marker may include, but not be limited to, subject matter related to Marker's technologies under development, ongoing clinical studies, scientific research and other activities that are within the scope of duties of a Chief Scientific Officer. The Consultant will report to the Chief Executive Officer of the Company, and carry out the decisions and otherwise abide by and enforce the rules and policies of the Company.

(c) Performance and Time Commitment. The Consultant agrees to be available to render the Consulting Services as requested.

(d) Professional Standards. The Consultant agrees to devote her best efforts to performing the Consulting Services. The Consultant shall comply with all rules, procedures and standards promulgated from time to time by the Company with regard to the Consultant's access to and use of the Company's property, information, equipment and facilities.

SCHEDULE 2

COMPENSATION

The Compensation payable to Consultant shall consist of the following:

1. Annual Cash Consulting Fee. Marker will pay Consultant a base consulting fee of $350,000.00 in cash per year ("Base Consulting Fee"). The Consultant's base consulting fee shall be paid in approximately equal bi-weekly installments in accordance with the Company's customary payroll practices.

2. Discretionary Cash Payment. For each calendar year during the term of this Agreement, Consultant shall be eligible to receive a discretionary cash payment of a maximum of 35% of Consultant's Base Consulting Fee based on Consultant's services and commitment to Marker, prorated for partial years, to be paid within a reasonable time after the end of the applicable fiscal year of the Company, but in no event later than five days after the completion of the audit for the prior year it being understood that the Board of Directors of Marker may in its discretion pay such bonus earlier.

Exhibit 10.39

INDEMNIFICATION AGREEMENT

This Indemnification Agreement ("Agreement") is made and entered into as of October 17, 2018 by and between Marker Therapeutics, Inc., a Delaware corporation (the "Company") and [_____] ("Indemnitee").

RECITALS

WHEREAS, the Board of Directors of the Company (the "Board of Directors") believes that highly competent persons have become more reluctant to serve publicly-held corporations as directors or officers or in other capacities unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

WHEREAS, the Board of Directors has determined that, in order to attract and retain qualified individuals, the Company will attempt to maintain on an ongoing basis, at its sole expense, liability insurance to protect persons serving the Company and its subsidiaries from certain liabilities. Although the furnishing of such insurance has been a customary and widespread practice among United States-based corporations and other business enterprises, the Company believes that, given current market conditions and trends, such insurance may be available to it in the future only at higher premiums and with more exclusions. At the same time, directors, officers, and other persons in service to corporations or business enterprises are being increasingly subjected to expensive and time-consuming litigation relating to, among other things, matters that traditionally would have been brought only against the Company or business enterprise itself. The Bylaws of the Company (the "Bylaws") and the Certificate of Incorporation of the Company (the "Certificate of Incorporation") require indemnification of the officers and directors of the Company. Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware (the "DGCL"). The Bylaws, Certificate of Incorporation and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive, and thereby contemplate that contracts may be entered into between the Company and members of the board of directors, officers and other persons with respect to indemnification;

WHEREAS, the uncertainties relating to such insurance and to indemnification may increase the difficulty of attracting and retaining such persons;

WHEREAS, the Board of Directors has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests of the Company and its stockholders and that the Company should act to assure such persons that there will be increased certainty of such protection in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the Bylaws, Certificate of Incorporation and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder; and

WHEREAS, one of the conditions that Indemnitee requires in order to serve as a director and/or an officer of the Company is that Indemnitee be so indemnified.

NOW, THEREFORE, in consideration of the premises and the covenants contained herein, the Company and Indemnitee do hereby covenant and agree as follows:

Section 1. Services by Indemnitee. Indemnitee agrees to serve, as applicable, as a director, officer, employee or agent of the Company or, at the request of the Company, as a director, officer, employee, agent or fiduciary of another corporation, partnership, joint venture, trust or other enterprise. Indemnitee may at any time and for any reason resign from such position (subject to any other contractual obligation or any obligation imposed by operation of law), in which event the Company shall have no obligation under this Agreement to continue Indemnitee in such position. This Agreement shall not be deemed an employment contract between the Company (or any of its subsidiaries or any Marker Entity) and Indemnitee. Indemnitee specifically acknowledges that Indemnitee's employment with the Company (or any of its subsidiaries or any Marker Entity), if any, is at will, and the Indemnitee may be discharged at any time for any reason, with or without cause, except as may be otherwise provided in any written employment contract between Indemnitee and the Company (or any of its subsidiaries or any Marker Entity), other applicable formal severance policies duly adopted by the Board of Directors, or, with respect to service as a director or officer of the Company, by the Certificate of Incorporation, the Company's Bylaws, and the DGCL. The foregoing notwithstanding, this Agreement shall continue in force after Indemnitee has ceased to serve, as applicable, as an officer, director, agent or employee of the Company or, at the request of the Company, as a director, officer, employee, agent or fiduciary of another corporation, partnership, joint venture, trust or other enterprise, as provided in Section 13 hereof.

Section 2. Indemnity in Third-Party Proceedings. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 2 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of the Company to procure a judgment in its favor, by reason of Indemnitee's Corporate Status. Pursuant to this Section 2, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company and, in the case of a criminal Proceeding had no reasonable cause to believe that Indemnitee's conduct was unlawful. The parties hereto intend that this Agreement shall provide to the fullest extent permitted by law for indemnification in excess of that expressly permitted by statute, including, without limitation, any indemnification provided by the Certificate of Incorporation, the Bylaws, vote of its stockholders or disinterested directors or applicable law.

Section 3. Indemnity in Proceedings by or in the Right of the Company. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of the Company to procure a judgment in its favor, by reason of Indemnitee's Corporate Status. Pursuant to this Section 3, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company. No indemnification for Expenses shall be made under this Section 3 in respect of any claim, issue or matter as to which Indemnitee shall have been finally adjudged by a court to be liable to the Company, unless and only to the extent that the Delaware Court (as hereinafter defined) or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification.

Section 4. Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provision of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of Indemnitee's Corporate Status, a party to (or a participant in) and is successful, on the merits or otherwise, in defense of any Proceeding or any claim, issue or matter therein (including, without limitation, any Proceeding brought by or in the right of the Company), the Company shall indemnify Indemnitee with respect to, and hold Indemnitee harmless from and against, all Expenses actually and reasonably incurred by Indemnitee or on behalf of Indemnitee in connection therewith. If Indemnitee is not wholly successful in defense of such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall, to the fullest extent permitted by law, indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee or on behalf of Indemnitee in connection with or related to each successfully resolved claim, issue or matter. For purposes of this Section 4 and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, on substantive or procedural grounds, or settlement of any such claim prior to a final judgment by a court of competent jurisdiction with respect to such Proceeding, shall be deemed to be a successful result as to such claim, issue or matter; provided, however, that any settlement of any claim, issue or matter in such a Proceeding shall not be deemed to be a successful result as to such claim, issue or matter if such settlement is effected by Indemnitee without the Company' prior written consent, which consent shall not be unreasonably withheld, delayed or conditioned.

Section 5. Partial Indemnification. If Indemnitee is entitled under any provision of this Agreement or otherwise to indemnification by the Company for some or a portion of the Expenses incurred by Indemnitee or on behalf of Indemnitee in connection with a Proceeding or any claim, issue or matter therein, in whole or in part, the Company shall, to the fullest extent permitted by law, indemnify Indemnitee to the fullest extent to which Indemnitee is entitled to such indemnification.

Section 6. Indemnification For Additional Expenses to Secure Recovery or as a Witness.

(a) The Company shall, to the fullest extent permitted by law, indemnify Indemnitee with respect to, and hold Indemnitee harmless from and against, any and all Expenses and, if requested by Indemnitee, shall advance on an as-incurred basis (as provided in Section 8 of this Agreement) such Expenses to Indemnitee, which are incurred by Indemnitee in connection with any action or proceeding or part thereof brought by Indemnitee for (i) indemnification or advance payment of Expenses by the Company under this Agreement, any other agreement, the Certificate of Incorporation or Bylaws of the Company as now or hereafter in effect; or (ii) recovery under any director and officer liability insurance policies maintained by the Company.

(b) To the extent that Indemnitee is, by reason of Indemnitee's Corporate Status, a witness (or is forced or asked to respond to discovery requests) in any Proceeding to which Indemnitee is not a party, the Company shall, to the fullest extent permitted by law, indemnify Indemnitee with respect to, and hold Indemnitee harmless from and against, and the Company will advance on an as-incurred basis (as provided in Section 8 of this Agreement), all Expenses reasonably incurred by Indemnitee or on behalf of Indemnitee in connection therewith.

Section 7. Exclusions. Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnification payment in connection with any claim involving Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision; or

(b) for (i) expenses and the payment of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 16(b) of the Securities Exchange Act of 1934, as amended, or any similar successor statute, or (ii) the payment of amounts required to be reimbursed to the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002, as amended, or any similar statute; or

(c) except as provided in Section 11(d) of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnitees, unless (i) the Board of Directors authorized the Proceeding (or any part of any Proceeding) prior to its initiation or (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.

Section 8. Advances of Expenses. Notwithstanding any provision of this Agreement to the contrary (other than Section 11(d)), the Company shall advance, to the extent not prohibited by law, the Expenses incurred by Indemnitee in connection with any Proceeding (or any part of any Proceeding) not initiated by Indemnitee or any Proceeding initiated by Indemnitee with the prior approval of the Board of Directors as provided in Section 7(c), and such advancement shall be made within thirty (30) days after the receipt by the Company of a statement or statements requesting such advances from time to time, whether prior to or after final disposition of any Proceeding. Advances shall be unsecured and interest free. Advances shall be made without regard to Indemnitee's ability to repay the Expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. In accordance with Section 11(d), advances shall include any and all reasonable Expenses incurred pursuing an action to enforce this right of advancement, including Expenses incurred preparing and forwarding statements to the Company to support the advances claimed. The Indemnitee shall qualify for advances upon the execution and delivery to the Company of this Agreement, which shall constitute an undertaking providing that the Indemnitee undertakes to repay the amounts advanced (without interest) to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Company. No other form of undertaking shall be required other than the execution of this Agreement. This Section 8 shall not apply to any claim made by Indemnitee for which indemnity is excluded pursuant to Section 7.

Section 9. Indemnification Procedures.

(a) Notice of Proceeding. Indemnitee agrees to notify the Company promptly upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification or advancement of Expenses hereunder. Any failure by Indemnitee to notify the Company will not relieve the Company of its advancement or indemnification obligations under this Agreement unless, and only to the extent that, the Company can establish that such omission to notify resulted in actual and material prejudice to it which prejudice cannot be reversed or otherwise eliminated without any material negative effect on the Company, and the omission to notify the Company will, in any event, not relieve the Company from any liability which it may have to indemnify Indemnitee otherwise than under this Agreement. If, at the time of receipt of any such notice, the Company has director and officer liability insurance policies in effect, the Company will promptly notify the relevant insurers in accordance with the procedures and requirements of such policies.

(b) Defense; Settlement. Indemnitee shall have the sole right and obligation to control the defense or conduct of any claim or Proceeding with respect to Indemnitee. The Company shall not, without the prior written consent of Indemnitee, which may be provided or withheld in Indemnitee's sole discretion, effect any settlement of any Proceeding against Indemnitee or which could have been brought against Indemnitee or which potentially or actually imposes any cost, liability, exposure or burden on Indemnitee unless (i) such settlement solely involves the payment of money or performance of any obligation by persons other than Indemnitee and includes an unconditional, full release of Indemnitee by all relevant parties from all liability on any matters that are the subject of such Proceeding and an acknowledgment that Indemnitee denies all wrongdoing in connection with such matters and (ii) the Company has fully indemnified the Indemnitee with respect to, and held Indemnitee harmless from and against, all Expenses and other amounts incurred by Indemnitee or on behalf of Indemnitee in connection with such Proceeding. The Company shall not be obligated to indemnify Indemnitee against amounts paid in settlement of a Proceeding against Indemnitee if such settlement is effected by Indemnitee without the Company' prior written consent, which consent shall not be unreasonably withheld, delayed or conditioned, unless such settlement solely involves the payment of money or performance of any obligation by persons other than the Company and includes an unconditional release of the Company by any party to such Proceeding other than the Indemnitee from all liability on any matters that are the subject of such Proceeding and an acknowledgment that the Company denies all wrongdoing in connection with such matters.

(c) Request for Advancement; Request for Indemnification.

(i) To obtain advancement of Expenses under this Agreement, Indemnitee shall submit to the Company a written request therefor, together with such invoices or other supporting information as may be reasonably requested by the Company and reasonably available to Indemnitee, and, only to the extent required by applicable law which cannot be waived, an unsecured written undertaking to repay amounts advanced. The Company shall make advance payment of Expenses to Indemnitee no later than five (5) business days after receipt of the written request for advancement (and each subsequent request for advancement) by Indemnitee. If, at the time of receipt of any such written request for advancement of Expenses, the Company has director and officer insurance policies in effect, the Company will promptly notify the relevant insurers in accordance with the procedures and requirements of such policies. The Company shall thereafter keep such director and officer insurers informed of the status of the Proceeding or other claim and take such other actions, as appropriate to secure coverage of Indemnitee for such claim.

(ii) To obtain indemnification under this Agreement, at any time before or after submission of a request for advancement pursuant to Section 9(c)(i) of this Agreement, Indemnitee may submit a written request for indemnification hereunder. The time at which Indemnitee submits a written request for indemnification shall be determined by the Indemnitee in the Indemnitee's sole discretion. Once Indemnitee submits such a written request for indemnification (and only at such time that Indemnitee submits such a written request for indemnification), a Determination (as hereinafter defined) shall thereafter be made, as provided in and only to the extent required by Section 9(d) of this Agreement. In no event shall a Determination be made, or required to be made, as a condition to or otherwise in connection with any advancement of Expenses pursuant to Section 8 and Section 9(c)(i) of this Agreement. If, at the time of receipt of any such request for indemnification, the Company has director and officer insurance policies in effect, the Company will promptly notify the relevant insurers and take such other actions as necessary or appropriate to secure coverage of Indemnitee for such claim in accordance with the procedures and requirements of such policies.

(d) Determination. The Company agrees that Indemnitee shall be indemnified to the fullest extent permitted by law and that no Determination shall be required in connection with such indemnification unless specifically required by applicable law which cannot be waived. In no event shall a Determination be required in connection with indemnification for Expenses pursuant to Section 6 of this Agreement or incurred in connection with any Proceeding or portion thereof with respect to which Indemnitee has been successful on the merits or otherwise. Any decision that a Determination is required by law in connection with any other indemnification of Indemnitee, and any such Determination, shall be made within twenty (20) days after receipt of Indemnitee's written request for indemnification pursuant to Section 9(c)(ii) and such Determination shall be made either (i) by the Disinterested Directors (as hereinafter defined), even though less than a quorum, so long as Indemnitee does not request that such Determination be made by Independent Counsel (as hereinafter defined), or (ii) if so requested by Indemnitee, in Indemnitee's sole discretion, by Independent Counsel in a written opinion to the Company and Indemnitee. If a Determination is made that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within five (5) business days after such Determination. Indemnitee shall reasonably cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such Determination. Any Expenses incurred by Indemnitee in so cooperating with the Disinterested Directors or Independent Counsel, as the case may be, making such determination shall be advanced and borne by the Company (irrespective of the Determination as to Indemnitee's entitlement to indemnification) and the Company is liable to indemnify and hold Indemnitee harmless therefrom. If the person, persons or entity empowered or selected under this Section 9(d) to determine whether Indemnitee is entitled to indemnification shall not have made a determination within twenty (20) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall, to the fullest extent not prohibited by law, be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such twenty (20) day period may be extended for a reasonable time, not to exceed an additional twenty (20) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 9(d) shall not apply if the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 9(e).

(e) Independent Counsel. In the event Indemnitee requests that the Determination be made by Independent Counsel pursuant to Section 9(d) of this Agreement, the Independent Counsel shall be selected as provided in this Section 9(e). The Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Board of Directors, in which event the Board of Directors shall make such selection on behalf of the Company, subject to the remaining provisions of this Section 9(e)), and Indemnitee or the Company, as the case may be, shall give written notice to the other, advising the Company or Indemnitee of the identity of the Independent Counsel so selected. The Company or Indemnitee, as the case may be, may, within five (5) days after such written notice of selection shall have been received, deliver to Indemnitee or the Company, as the case may be, a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 15 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If a written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or a court of competent jurisdiction has determined that such objection is without merit. If, within ten (10) days after submission by Indemnitee of a written request for indemnification pursuant to Section 9(c)(ii) of this Agreement and after a request for the appointment of Independent Counsel has been made, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition a court of competent jurisdiction for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by the court or by such other person as the court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 9(d) of this Agreement. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 9(f) of this Agreement, Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing). Any expenses incurred by or in connection with the appointment of Independent Counsel shall be borne by the Company (irrespective of the Determination of Indemnitee's entitlement to indemnification) and not by Indemnitee.

(f) Consequences of Determination; Remedies of Indemnitee. The Company shall be bound by and shall have no right to challenge a Favorable Determination. If an Adverse Determination is made, or if for any other reason the Company does not make timely indemnification payments or advances of Expenses, Indemnitee shall have the right to commence a Proceeding before a court of competent jurisdiction to challenge such Adverse Determination and/or to require the Company to make such payments or advances (and the Company shall have the right to defend its position in such Proceeding and to appeal any adverse judgment in such Proceeding). Indemnitee shall be entitled to be indemnified for all Expenses incurred in connection with such a Proceeding and to have such Expenses advanced by the Company in accordance with Section 8 of this Agreement. If Indemnitee fails to challenge an Adverse Determination within twenty (20) business days, or if Indemnitee challenges an Adverse Determination and such Adverse Determination has been upheld by a final judgment of a court of competent jurisdiction from which no appeal can be taken, then, to the extent and only to the extent required by such Adverse Determination or final judgment, the Company shall not be obligated to indemnify Indemnitee under this Agreement.

Section 10. Presumptions; Burden and Standard of Proof. The parties intend and agree that, to the extent permitted by law, in connection with any Determination with respect to Indemnitee's entitlement to indemnification hereunder by any person, including a court:

(i) it will be presumed that Indemnitee is entitled to indemnification under this Agreement (notwithstanding any Adverse Determination), and the Company will have the burden of proof to overcome that presumption in connection with the making any determination contrary to that presumption;

(ii) the termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, had reasonable cause to believe that Indemnitee's conduct was unlawful;

(iii) Indemnitee will be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Company, including financial statements, or on information supplied to Indemnitee by the officers, employees, or committees of the Board of Directors of the Company, or on the advice of legal counsel or other advisors (including financial advisors and accountants) for the Company or on information or records given in reports made to the Company by an independent certified public accountant or by an appraiser or other expert or advisor selected by the Company; and

(iv) the knowledge and/or actions, or failure to act, of any director, officer, agent or employee of the Company will not be imputed to Indemnitee in a manner that limits or otherwise adversely affects Indemnitee's rights hereunder.

The provisions of this Section 10 shall not be deemed to be exclusive or to limit in any way the other circumstances in which Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

Section 11. Remedies of Indemnitee.

(a) Subject to Section 11(e), in the event that (i) a determination is made pursuant to Section 10 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 8 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 9 of this Agreement within twenty (20) days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to Section 4, 5 or 6 of this Agreement within ten (10) days after receipt by the Company of a written request therefor, (v) payment of indemnification pursuant to Section 2, 3 or 8 of this Agreement is not made within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification, or (vi) in the event that the Company or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or Proceeding designed to deny, or to recover from, the Indemnitee the benefits provided or intended to be provided to the Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of Indemnitee's entitlement to such indemnification or advancement of Expenses. Alternatively, Indemnitee, at Indemnitee's option, may seek an award in arbitration to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. The Company shall not oppose Indemnitee's right to seek any such adjudication or award in arbitration.

(b) In the event that a determination shall have been made pursuant to Section 9 of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding or arbitration commenced pursuant to this Section 11 shall be conducted in all respects as a de novo trial, or arbitration, on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this Section 11 the Company shall have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) If a determination shall have been made pursuant to Section 9 of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding or arbitration commenced pursuant to this Section 11, absent (i) proof of a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) The Company shall, to the fullest extent not prohibited by law, be precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 11 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court or before any such arbitrator that the Company is bound by all the provisions of this Agreement. It is the intent of the Company that, to the fullest extent permitted by law, the Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to the Indemnitee hereunder. The Company shall, to the fullest extent permitted by law, indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Company of a written request therefor) advance, to the extent not prohibited by law, such Expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advancement of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company if, in the case of indemnification, Indemnitee is wholly successful on the underlying claims; if Indemnitee is not wholly successful on the underlying claims, then such indemnification shall be only to the extent Indemnitee is successful on such underlying claims or otherwise as permitted by law, whichever is greater.

(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement of Indemnitee to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

Section 12. Non-exclusivity; Survival of Rights; Insurance; Subrogation.

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, the Bylaws, any agreement, a vote of stockholders or a resolution of directors, or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by Indemnitee in Indemnitee's Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in Delaware law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Bylaws, Certificate of Incorporation and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents of any Marker Entity, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any such director, officer, employee or agent under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Company has director and officer liability insurance in effect, the Company shall give prompt notice of such claim or of the commencement of a Proceeding, as the case may be, to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies. The Company shall continue to provide such insurance coverage to Indemnitee for a period of at least ten (10) years after Indemnitee ceases to serve as a director or an officer or in any other Corporate Status.

(c) In the event of any payment made by the Company under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

(d) The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable (or for which advancement is provided hereunder) hereunder if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

(e) The Company's obligation to indemnify or advance Expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, trustee, partner, managing member, fiduciary, employee or agent of any other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of Expenses from such other corporation, limited liability company, partnership, joint venture, trust or other enterprise.

Section 13. Duration of Agreement; Successors.

(a) This Agreement shall continue until and terminate upon the later of: (i) ten (10) years after the date that Indemnitee shall have ceased to serve as a director, officer, employee or agent of the Company or, at the request of the Company, as a director, officer, employee, agent or fiduciary of another corporation, partnership, joint venture, trust or other enterprise or (ii) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding commenced by Indemnitee pursuant to Section 11 of this Agreement relating thereto. For the avoidance of doubt, this Agreement shall provide for rights of indemnification and advancement of Expenses as set forth herein for any event or occurrence related to Indemnitee's service for the Company, regardless of whether such events or occurrences occurred before or after the date of this Agreement.

(b) The indemnification and advancement of expenses rights provided by or granted pursuant to this Agreement shall be binding upon and be enforceable by the parties hereto and their respective successors and assigns (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), shall continue as to an Indemnitee who has ceased to be a director, officer, employee or agent of the Company or of any other Marker Entity, and shall inure to the benefit of Indemnitee and Indemnitee's spouse, assigns, heirs, devisees, executors and administrators and other legal representatives. The Company shall require and cause any successor (whether direct or indirect by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company, by written agreement, in form and substance reasonably satisfactory to Indemnitee, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no such succession had taken place.

Section 14. Severability. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

Section 15. Definitions. For purposes of this Agreement:

(a) "Corporate Status" describes the status of a person by reason of such person's past, present or future service as a director, officer, employee, fiduciary, trustee, or agent of the Company (including, without limitation, one who serves at the request of the Company as a director, officer, employee, fiduciary, trustee or agent of any other Marker Entity).

(b) "Determination" means a determination that either (x) there is a reasonable basis for the conclusion that indemnification of Indemnitee is proper in the circumstances because Indemnitee met a/the particular standard(s) of conduct (a "Favorable Determination") or (y) there is no reasonable basis for the conclusion that indemnification of Indemnitee is proper in the circumstances because Indemnitee met a/the particular standard(s) of conduct (an "Adverse Determination"). An Adverse Determination shall include the decision that a Determination was required in connection with indemnification and the decision as to the applicable standard of conduct.

(c) "Disinterested Director" means a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee and does not otherwise have an interest materially adverse to any interest of the Indemnitee.

(d) "Expenses" shall mean all direct and indirect costs, fees and expenses of any type or nature whatsoever and shall specifically include, without limitation, all reasonable attorneys' fees, retainers, court costs, transcript costs, fees and costs of experts, witness fees and costs, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, any federal, state, local or foreign taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, ERISA excise taxes and penalties, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness, in, or otherwise participating in, a Proceeding or an appeal resulting from a Proceeding, including, but not limited to, the premium for appeal bonds, attachment bonds or similar bonds and all interest, assessments and other charges paid or payable in connection with or in respect of any such Expenses, and shall also specifically include, without limitation, all reasonable attorneys' fees and all other expenses incurred by or on behalf of Indemnitee in connection with preparing and submitting any requests or statements for indemnification, advancement, contribution or any other right provided by this Agreement. Expenses, however, shall not include amounts of judgments or fines against Indemnitee.

(e) "Independent Counsel" means, at any time, any law firm, or a member of a law firm, that (a) is experienced in matters of corporation law and (b) is not, at such time, or has not been in the five years prior to such time, retained to represent: (i) any Marker Entity or Indemnitee in any matter material to either such party (other than with respect to matters concerning Indemnitee under this Agreement, or of other indemnities under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agree to pay the reasonable fees and expenses of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto and to be jointly and severally liable therefor.

(f) "Marker Entity" means the Company, any of its subsidiaries and any other corporation, partnership, limited liability company, joint venture, trust, employee benefit plan or other enterprise with respect to which Indemnitee serves as a director, officer, employee, partner, representative, fiduciary, trustee, or agent, or in any similar capacity, at the request of the Company.

(g) "Proceeding" includes any actual, threatened, pending or completed action, suit, arbitration, alternate dispute resolution mechanism, investigation (formal or informal), inquiry, administrative hearing or any other actual, threatened, pending or completed proceeding, whether brought by or in the right of the Company or otherwise and whether civil, criminal, administrative or investigative in nature, in which Indemnitee was, is, may be or will be involved as a party, witness or otherwise, by reason of Indemnitee's Corporate Status or by reason of any action taken by Indemnitee or of any inaction on Indemnitee's part while acting as director, officer, employees, fiduciary, trustee or agent of any Marker Entity (in each case whether or not he is acting or serving in any such capacity or has such status at the time any liability or expense is incurred for which indemnification or advancement of Expenses can be provided under this Agreement). If the Indemnitee believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, this shall be considered a Proceeding under this paragraph.

Section 16. Construction. Whenever required by the context, as used in this Agreement the singular number shall include the plural, the plural shall include the singular, and all words herein in any gender shall be deemed to include (as appropriate) the masculine, feminine and neuter genders.

Section 17. Reliance. The Company expressly confirm and agree that they have entered into this Agreement and assumed the obligations imposed on each of them hereby in order to induce Indemnitee to serve as a director and/or an officer of one or more of the Company, and the Company acknowledge that Indemnitee is relying upon this Agreement in serving as a director and/or an officer of one or more of the Company.

Section 18. Modification and Waiver. No supplement, modification or amendment of this Agreement shall be binding unless executed in a writing identified as such by all of the parties hereto. Except as otherwise expressly provided herein, the rights of a party hereunder (including the right to enforce the obligations hereunder of the other parties) may be waived only with the written consent of such party, and no waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions hereof (whether or not similar) nor shall such waiver constitute a continuing waiver.

Section 19. Notice Mechanics. All notices, requests, demands or other communications hereunder shall be in writing and shall be deemed to have been duly given if (i) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (ii) mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed, (iii) mailed by reputable overnight courier and receipted for by the party to whom said notice or other communication shall have been directed or (iv) sent by facsimile transmission, with receipt of oral confirmation that such transmission has been received:

(a) If to Indemnitee to:

[_____]

(b) If to the Company, to:

Marker Therapeutics, Inc.
5 West Forsyth Street
Suite 200
Jacksonville, FL 32202

or to such other address as may have been furnished (in the manner prescribed above) as follows: (a) in the case of a change in address for notices to Indemnitee, furnished by Indemnitee to the Company and (b) in the case of a change in address for notices to the Company, furnished by the Company to Indemnitee.

Section 20. Contribution. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the Company (and its other directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

Section 21. Governing Law; Submission to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. The Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Court of Chancery of the State of Delaware (the "Delaware Court"), and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (iv) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum.

Section 22. Headings. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

Section 23. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement.

[Remainder of Page Intentionally Blank]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

Company:

MARKER THERAPEUTICS, INC.

By: _____
Name:
Title:

Indemnitee:

By: _____
Name: [_____]

[Signature Page to Indemnification Agreement]

Exhibit 10.40

AMENDMENT TO EMPLOYMENT AGREEMENT

THIS AMENDMENT TO EMPLOYMENT AGREEMENT (this "Amendment") is made on this 14th day of March, 2019, by and between Marker Therapeutics, Inc., a Delaware corporation (formerly known as TapImmune Inc. the "Company"), and Peter L. Hoang, an individual (the "Executive"), and amends that certain Employment Agreement between the Company and the Executive, dated September 22, 2017 (the "Employment Agreement").

RECITALS:

WHEREAS, the Company and the Executive entered into the Employment Agreement on September 22, 2017; and

WHEREAS, the Company and Executive desire to amend the Executive's Employment Agreement, as provided herein.

NOW THEREFORE, the Executive and the Company for themselves, their heirs, successors and assigns, in consideration of their mutual promises contained herein, intending to be legally bound, hereby agree that the Employment Agreement is hereby amended as follows:

1. Section 4 of the Employment Agreement - Compensation and Benefits is hereby deleted and replaced in its entirety with the following:

4. **COMPENSATION AND BENEFITS**.

(a) Base Salary. Upon the Effective Date, the Executive's annual rate of base salary commencing effective January 1, 2019, shall be three hundred eighty thousand dollars ($380,000) per year, which shall be paid by the Company to the Executive bi-weekly in accordance with the Company's customary payroll practices, and subject to customary withholding as required by applicable law. This annual base salary shall be reviewed by the Board periodically, and the Board may increase the Executive's annual base salary from time to time as the Board deems to be appropriate subject to performance and market conditions. The Executive's salary will not be reduced without Executive's prior written consent except that the Board may, in its sole discretion, reduce Executive's base salary in connection with a salary reduction applicable to all Company senior executive officers in substantially the same proportions.

(b) Annual Incentive Compensation. During the Term, the Executive shall be eligible for an annual performance bonus of up to fifty percent (50%) of the Executive's annual base salary, based on goals and other conditions as the Board shall determine in its sole discretion on an annual basis (the "Annual Performance Bonus"). The Annual Performance Bonus will be payable in the form of cash or fully-vested shares of the Company's common stock, or a combination thereof, at the Board's discretion, in any case to be paid or delivered as soon as practicable after the end of the year in which it is earned and in any event not more than ninety (90) days after the end of such year. Payment of the Annual Performance Bonus shall be expressly conditioned upon Executive's employment with the Company on the date that the Annual Performance Bonus is paid, except as provided in Section 9(b) and Section 10(a) below

Any such Annual Performance Bonus, as well as any equity awards which are granted to the Executive or which become vested as a result of the satisfaction of financial performance goals of the Company, shall be subject to the Company's Policy on Recoupment of Executive Incentive Compensation, and that the Executive shall be obligated to repay to the Company, any and all amounts received with respect to the Annual Performance Bonus or performance-based equity awards, to the extent such a repayment is required by the terms of the Policy on Recoupment of Executive Incentive Compensation, as such policy may be amended from time to time.

(c) Benefits. The Executive shall be entitled to participate in all group insurance, vacation, retirement and other employee benefits established by Company for its senior level executives, on terms comparable to those provided to such executives from time to time by the Company. Nothing in this Agreement will preclude the Company from terminating or amending any employee benefit plan so as to change eligibility or other requirements or eliminate, reduce or otherwise change any benefit, *provided* that such termination or amendment applies equally to the Executive and other senior level executives of the Company.

(d) Paid Time off. The Executive shall be entitled to twenty-one (21) days paid vacation per calendar year plus such sick leave as he may reasonably and actually require. Accrued and unused vacation shall be paid at termination of employment in accordance with payroll practices applicable to all employees.

(e) Reimbursement of Business Expenses. The Executive shall be entitled to receive reimbursement for all appropriate business expenses incurred by him in connection with his duties under this Agreement in accordance with the written policies of the Company as in effect from time to time.

(f) D&O Insurance. The Company shall use its commercially reasonable efforts to maintain a Directors and Officers Insurance policy with no less than $2.0 million coverage, and to list the Executive as one of the covered management employees under such policy.

2. Section 7 of the Employment Agreement - Non-Competition and Non-Solicitation Covenants, particularly the sentence in Section7(a) providing the meaning of the Company Products and Services is hereby deleted and replaced with the following:

> "For purposes hereof, "Company Products and Services" means (i) the generation and/or commercialization of T cells targeting non-viral tumor-associated antigens and/or cancer testis antigens and related applications or any cancer immunotherapy T-Cell vaccines and directly related applications (a) which the Applicable Entities currently anticipate developing, producing, designing, providing, marketing, distributing or selling as of the date of termination of Executive's employment with the Company, (ii) which the Applicable Entities develop, produce, design, provide, market or distribute while Executive is employed by the Applicable Entities or is otherwise providing services to the Applicable Entities, or (iii) that compete with any of the products and services of the Applicable Entities referenced in (i) or (ii) above."

3. Section 12 of the Employment Agreement - Notices, particularly Section 12(b) thereof is hereby deleted and replaced with the following:

(b) if to the Company, to:

Marker Therapeutics, Inc.,
3200 Southwest Freeway, Suite 2240,
Houston, TX 77027,
Attention: Chairman of the Board.

4. Section 17 of the Employment Agreement - General Provisions, particularly Section 17(a) thereof, is hereby deleted and replaced with the following:

(a) This agreement shall be governed by the laws of the State of Texas, without giving effect to any principles of conflicts of law that would result in application of the law of any other jurisdiction.

5. Except as expressly amended by this Amendment, the Employment Agreement shall continue and remain in full force and effect.

[SIGNATURE PAGE TO FOLLOW]

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the date first written above for the purposes herein contained.

COMPANY –Marker Therapeutics, Inc.	**EXECUTIVE**
By: /s/ Anthony Kim	/s/ Peter L. Hoang
Name: Anthony Kim	Name: Peter L. Hoang
Title: Chief Financial Officer	

[Signature Page to Amendment to Employment Agreement]

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 Statements of Marker Therapeutics, Inc. on Form S-1 (File No. 333-205757), on Form S-3 (File Nos. 333-215258, No. 333-220538 and 333-228059) and on Form S-8 (File. Nos. 333-223900 and 333-228056) of our report dated March 15, 2019, with respect to our audits of the consolidated financial statements of Marker Therapeutics, Inc. as of December 31, 2018 and 2017 and for the two years in the period ended December 31, 2018 and our report dated March 15, 2019 with respect to our audit of the effectiveness of internal control over financial reporting of Marker Therapeutics, Inc. as of December 31, 2018, which reports are included in this Annual Report on Form 10-K of Marker Therapeutics, Inc. for the year ended December 31, 2018.

/s/ Marcum LLP
New York, NY
March 15, 2019

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 15, 2019

/s/ Peter 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 15, 2019

/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, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Peter 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 15, 2019

/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, 2018 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 15, 2019

/s/ Anthony Kim
Anthony Kim
Chief Financial Officer