Marker Therapeutics, Inc.
Form 10-K
March 15, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-K

x 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	**77027**

Houston, Texas
(Address of principal executive offices) (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 x

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 x

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 x 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. x

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 x Accelerated filer
¨ Non-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 x

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.

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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”, “anticipat “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.

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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.

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· **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.

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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;

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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

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- 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;

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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 120th 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	**F-2**
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of

Marker Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Marker Therapeutics, Inc. (the “Company”) as of December 31, 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 audits 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				