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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

For the transition period from _____ to _____

Commission file number: 001-38541

Magenta Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**81-0724163**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
100 Technology Square Cambridge, Massachusetts	**02139**
(Address of principal executive offices)	**(Zip Code)**

(857) 242-0170
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 Par Value	**MGTA**	**The Nasdaq Global Market**

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of Common Stock held by non-affiliates of the registrant computed by reference to the price of the registrant's Common Stock as of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $436.0 million (based on the last reported sale price on the Nasdaq Global Market as of such date). For this computation, the registrant has excluded the market value of all shares of Common Stock reported as beneficially owned by its executive officer and directors; such exclusion shall not be deemed to constitute an admission that any such person is an affiliate of the registrant.

As of January 31, 2022, there were 58,799,157 shares of the registrant's Common Stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2022 Annual Meeting of Stockholders, which the registrant intends to file with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2021, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Magenta Therapeutics, Inc.
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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K of Magenta Therapeutics, Inc. (the "Company") contains or incorporates statements that constitute forward-looking statements within the meaning of the federal securities laws. Any express or implied statements that do not relate to historical or current facts or matters are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "could," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "seeks," "endeavor," "potential," "continue" or the negative of these terms or other comparable terminology. Forward-looking statements appear in a number of places in this Annual Report on Form 10-K and include, but are not limited to, statements about:

- our expectation that our existing capital resources will be sufficient to enable us to fund our planned development of MGTA-117, MGTA-145 and any other product candidates we may identify and pursue;
- the initiation, timing and success of clinical trials of MGTA-117, MGTA-145 and any other product candidates;
- our ability to commence and enroll patients in our clinical trials at the pace that we project;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- the outcomes of our preclinical studies;
- our ability to manufacture MGTA-117, MGTA-145 or any other product candidate in conformity with the U.S. Food and Drug Administration's requirements and to scale up manufacturing of our product candidates to commercial scale, if approved;
- whether the results of our trials will be sufficient to support domestic or foreign regulatory approvals for MGTA-117, MGTA-145 or any other product candidates we may develop;
- our reliance on third parties to conduct our clinical trials;
- our reliance on third-party contract development and manufacturer organizations to manufacture and supply our product candidates for us;
- our ability to establish clinical programs moving forward in multiple indications, with a rapidly advancing portfolio and sustainable platform;
- our ability to obtain, including on an expedited basis, and maintain regulatory approval of MGTA-117, MGTA-145 or any other product candidates we may develop;
- the level of expenses related to any of our product candidates or clinical development programs;
- the benefits of the use of MGTA-117, MGTA-145 or any other product candidate, if approved;
- our ability to successfully commercialize MGTA-117, MGTA-145 or any other product candidates we may identify and pursue, if approved;
- the rate and degree of market acceptance of MGTA-117, MGTA-145 or any other product candidates we may identify and pursue;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to obtain and maintain intellectual property protection for MGTA-117, MGTA-145 or any other product candidates we may identify and pursue;
- our ability to obtain orphan drug designation for any of our product candidates we may identify and pursue;
- our ability to successfully build a specialty sales force and commercial infrastructure;

- our ability to compete with companies currently producing or engaged in the clinical development of treatments for the disease indications that we pursue and treatment modalities that we develop;
- our ability to successfully find collaborators for E478 or any of our current and future programs and product candidates;
- our ability to retain and recruit key personnel;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- our expectations regarding the time during which we will continue to be an emerging growth company or smaller reporting company as defined in federal securities regulations;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, and involve known and unknown risks, uncertainties and other factors including without limitation, risks, uncertainties and assumptions regarding the continuing impact of the novel coronavirus, or COVID-19, pandemic on our business, operations, strategy, goals and anticipated timelines, our ongoing and planned preclinical activities, our ability to initiate, enroll, conduct or complete ongoing and planned clinical trials, our timelines for regulatory submissions and our financial position that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. You are urged to carefully review the disclosures we make concerning these risks and other factors that may affect our business and operating results under "Item 1A. Risk Factors" in this Annual Report on Form 10-K, as well as our other reports filed with the Securities and Exchange Commission (the "SEC"). Any public statements or disclosures by us following this Annual Report on Form 10-K that modify or impact any of the forward-looking statements contained in this Annual Report on Form 10-K will be deemed to modify or supersede such statements in this Annual Report on Form 10-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this document. The Company does not intend, and undertakes no obligation, to update any forward-looking information to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events, unless required by law to do so.

RISK FACTOR SUMMARY

The risk factors detailed in Item 1A entitled "Risk Factors" in this Annual Report on Form 10-K are the risks that we believe are material to our investors and a reader should carefully consider them. Those risks are not all of the risks we face and other factors not presently known to us or that we currently believe are immaterial may also affect our business if they occur. The following is a summary of the risk factors detailed in Item 1A:

- We are a clinical stage company with a limited operating history, have incurred significant losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future.
- We have no products approved for commercial sale and have not generated any revenue from product sales. If we are unable to raise additional capital when needed or on terms acceptable to us, we could be forced to significantly delay, scale back or discontinue our development or commercialization efforts.
- Although we have initiated and conducted clinical trials for some of our product candidates, including MGTA-117 and MGTA-145, we have not yet demonstrated the ability to successfully advance our clinical trials for our product candidates through the final regulatory processes and obtain marketing approvals for such products, or to conduct sales and marketing activities necessary for successful commercialization of such products.

- If we are unable to obtain regulatory approval for MGTA-117, MGTA-145 or any other product candidates that we may identify or develop, our business will be substantially harmed.
- We have not yet demonstrated an ability to manufacture or process drug product on a commercial-scale and may not be able to do so for any of our product candidates.
- The results of earlier studies and interim data from our ongoing studies may not be predictive of future clinical trial results, and we may fail to establish an adequate safety or efficacy profile to conduct advanced clinical trials or obtain regulatory approval for MGTA-117, MGTA-145 or any other product candidates that we may pursue.
- Stem cell transplant is a high-risk procedure that may result in complications or adverse events for patients in our clinical trials or for patients that use any of our product candidates, if approved. If serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any of our product candidates, we may need to limit, delay or abandon our further clinical development of those product candidates, even if such events, effects or characteristics were the result of stem cell transplant or related procedures generally, and not directly or specifically caused or exacerbated by our product candidates.
- If we are not able to identify a safe and effective dose for any of our antibody-drug conjugates, or ADCs, we may need to delay, abandon or limit our development of any potential product candidates.
- We rely, and expect to continue to rely, on third parties to manufacture our clinical product supplies, and we intend to rely on third parties to produce and process our product candidates, if approved.
- We are highly dependent on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection. If we are unable to obtain and maintain sufficient intellectual property protection for MGTA-117, MGTA-145 or any of our other current or any future product candidates, or our technologies, we may not be able to compete effectively in our markets.
- If we are unable to successfully develop our current programs into a comprehensive portfolio of product candidates, or experience significant delays in doing so, we may not realize the full commercial potential of our current and future product candidates.
- The commercial success of any of our product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.
- We face substantial competition, including from companies with greater financial, technical, research, manufacturing, marketing, distribution and other resources than us, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We have entered into collaborations and may enter into additional collaborations, strategic alliances or additional licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.
- We are developing E478 specifically to partner with gene therapy and genome editing companies, and if we are unable to find willing collaborators, this may adversely affect the development of E478 and our business.
- The coronavirus, or COVID-19, pandemic or any future pandemic, epidemic or outbreak of any other highly infectious disease could have a material adverse effect on our business, financial condition and results of operations.
- Our future success depends in part upon our ability to attract and retain highly skilled personnel, including the members of our executive team and key scientific and medical personnel employees.
- Changes in tax law could adversely affect our business and financial condition.

This section contains forward-looking statements. You should refer to the explanation of the qualifications and limitations on forward-looking statements beginning on page three.

PART I

Except where the context otherwise requires or where otherwise indicated, the terms "Magenta," "we," "us," "our," "our company," "the company," and "our business" refer to Magenta Therapeutics, Inc. and its consolidated subsidiary.

ITEM 1. BUSINESS

Overview

Magenta Therapeutics, Inc. is a clinical-stage biotechnology company developing novel medicines designed to bring the curative power of stem cell transplants to more patients with blood cancers, genetic diseases and autoimmune diseases.

Magenta's drug development pipeline includes multiple clinical and preclinical product candidates designed to improve stem cell transplants. We are developing product candidates that are designed to deplete targeted cells in the bone marrow to make space for the bone marrow to receive newly transplanted stem cells, a process known as conditioning. Our targeted conditioning programs are intended to enhance the efficacy of and/or reduce the dosing levels, intensity or, in some cases, even the need for chemotoxic agents. Our first targeted conditioning program, MGTA-117, has entered clinical development in a Phase 1/2 trial, and our second program, a CD45-antibody drug conjugate, or CD45-ADC, is advancing in preclinical development. In addition to our conditioning programs, we are also developing a product candidate, MGTA-145, to improve the process by which stem cells are stimulated out of the bone marrow and into the bloodstream so they are available for collection for future reinfusion, known as mobilization, which is required for all transplants and gene therapy applications. MGTA-145 is a Phase 2 clinical stage program intended to enable rapid, reliable, predictable and safe mobilization and collection of high numbers of functional stem cells for transplant.

Stem cell transplant is a well-established and potentially curative medical procedure that can reset a patient's blood and immune system after the patient has received treatment for certain blood cancers, genetic diseases, or autoimmune diseases. Over 90,000 patients globally received a stem cell transplant in 2020. Stem cell transplants involve a three-step process: (i) stem cells are mobilized out of the patient's or donor's bone marrow and collected from the blood (or, in rare cases, surgically extracted from their bone marrow); (ii) the patient's bone marrow is cleared of any remaining stem cells in order to make space to receive new transplanted stem cells; and (iii) the stem cells are transplanted into the patient via infusion where they fasten to, or engraft in, the bone marrow and grow into the blood cells and platelets that form the basis of a reset and rebuilt blood and immune system. All transplants are categorized as either autologous or allogeneic depending on the source of the new stem cells for the transplant. In an autologous transplant, the patient's own stem cells are used. In an allogeneic transplant, patients receive cells from a stem cell donor.

Stem cell transplant, whether autologous or allogeneic, has broad applicability across disease settings, including blood cancers, gene therapies for genetic diseases and autoimmune diseases. It is the current standard of care for certain blood cancers such as acute myeloid leukemia, or AML, myelodysplastic syndromes, or MDS, multiple myeloma and non-Hodgkin's lymphoma.

Hematopoietic stem cell, or HSC, based gene therapies also rely on the same steps of the stem cell transplant process with an additional step where collected stem cells are gene-corrected or modified to address the underlying disease prior to transplant. Such gene therapy approaches that leverage the stem cell transplant procedure are being investigated by numerous companies in a variety of diseases, including sickle cell disease, beta-thalassemia and lysosomal storage disorders. Autoimmune diseases such as multiple sclerosis and systemic sclerosis may also benefit from resetting the immune system through stem cell transplant.

In addition to our product candidates, Magenta's research efforts are evaluating several early-stage targets that include a program for targeted lymphodepletion prior to therapies such as chimeric antigen receptor T-cells

or CAR-T. We also have a cell therapy program, E478, which is a small molecule aryl hydrocarbon receptor, or AHR, antagonist designed to increase the numbers of gene-modified HSCs for stem cell-based gene therapy and genome editing.

Magenta intends to become a fully integrated discovery, development, and commercial company in the field of stem cell transplant. We are developing our product candidates to be used individually or, in some cases, in combination with each other or together with other therapies. As a result, our portfolio could be tailored to the patient's disease, such that a patient may receive more than one Magenta therapy as part of his or her individual stem cell transplant.

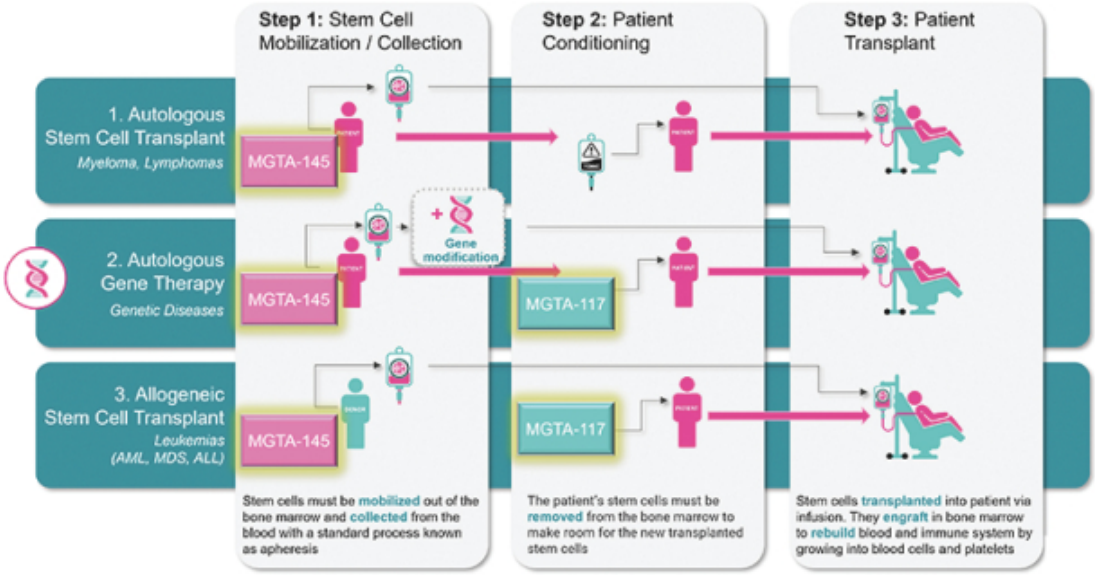
Our goal is to advance our product candidates through regulatory approval and bring them to the commercial market based on the data from our clinical trials and communications with regulatory agencies and payer communities. We expect to continue to advance our portfolio and innovate through our productive research programs.

Stem Cell Transplant: The Process and Current Opportunities

A stem cell transplant procedure involves three main steps: (i) stem cells are mobilized out of the patient's or donor's bone marrow and collected from the blood (or, in rare cases, surgically extracted from their bone marrow); (ii) the patient's bone marrow is cleared of any remaining stem cells in order to make space to receive new transplanted stem cells; and (iii) the stem cells are transplanted into the patient via infusion where they fasten to, or engraft in, the bone marrow and grow into the blood cells and platelets that form the basis of reset and rebuilt blood and immune systems. All transplants are categorized as either autologous or allogeneic, depending on the source of the new stem cells for the transplant.

In an autologous transplant—used for conditions such as multiple myeloma, non-Hodgkin's lymphoma and autoimmune diseases—the patient's own stem cells are used. In the case of autologous stem cell gene therapy and genome editing in certain non-malignant diseases such as sickle cell disease, beta-thalassemia, and severe combined immunodeficiencies, the cells are collected from the patient and are modified to insert a functioning gene or correct a defective gene within the cell. Modified cells are then transplanted into the patient via infusion.

In an allogeneic transplant—used for conditions such as acute leukemias and myelodysplastic syndromes—patients receive cells from a stem cell donor. The preferred source of stem cells for an allogeneic transplant is a donor from a biological relative who has a well-matched immune system. Patients without a matched related donor have the option of finding a matched unrelated donor identified through a bone marrow donor registry. For patients without a matched related or unrelated donor, other options include mismatched donors, who can either be unrelated or related; however, transplant outcomes are not optimal with these donor types.



Our Strategy

Magenta's mission and culture are centered around the goal of enabling more patients with severe or life-threatening diseases to have access to the transformative benefit of stem cell transplant. We intend to provide transplant physicians with a tailored, multi-product treatment regimen based on the disease setting and the individual needs of patients. Our strategic priorities are as follows:

***Bring the curative power of blood and immune reset through stem cell transplant to all patients who can benefit by advancing an integrated product portfolio*:** We believe we are the only company that is committed to addressing both conditioning and mobilization opportunities in stem cell transplant and HSC-based gene therapies. We are focused on creating a comprehensive portfolio of therapies to optimize the blood and immune reset process. Our initial focus is on blood cancers, genetic diseases, and autoimmune diseases, and we also plan to address other diseases for which blood and immune reset could represent a one-time, curative treatment.

***Build on our deep expertise in stem cell biology to lead a new era in blood and immune reset through stem cell transplant*:** We have assembled a group of experts in the fields of stem cell biology, biotherapeutics and transplant medicine. With this team, we plan to convert recent scientific breakthroughs into a pipeline of product candidates for blood and immune reset therapies.

***Create a fully integrated patient-focused biotechnology company*:** We are building a fully integrated biotechnology company with end-to-end capabilities in research, development, and commercialization, and we believe the broad and synergistic nature of our portfolio will allow us to address many of the significant limitations of stem cell transplant and transplant-based therapies.

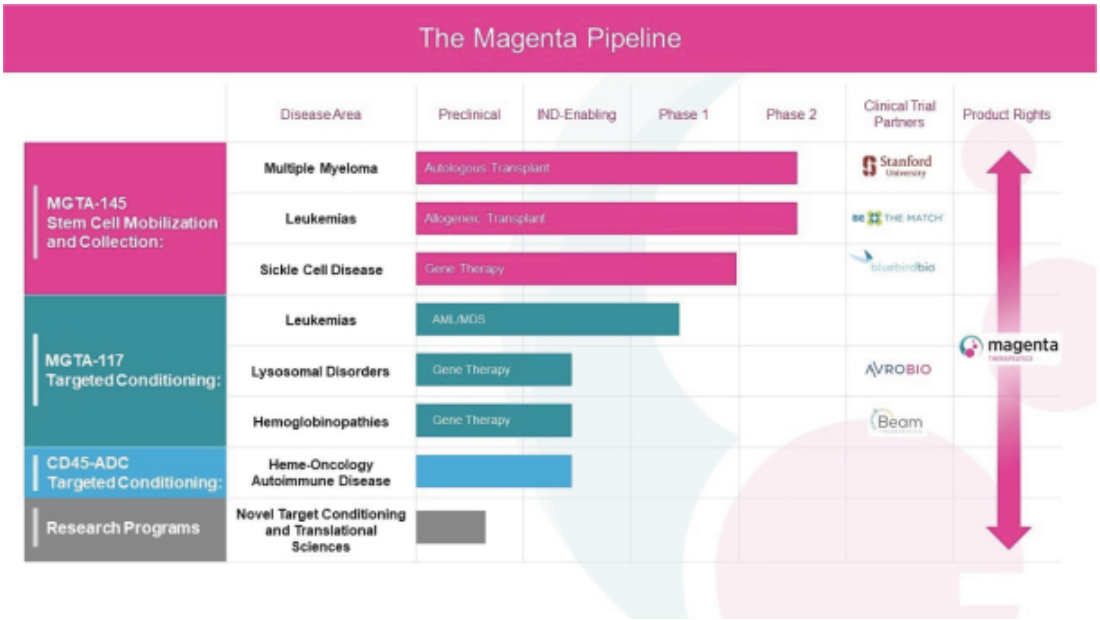
***Commercialize our drug products to bring tailored blood and immune reset solutions to patients and physicians*:** Our commercial planning centers around hospital-based prescribers, and this is consistent across all product candidates in our portfolio. Stem cell transplants are performed in approximately 450 accredited medical centers in the U.S. and Europe, with more than half of the U.S. procedures performed at 20% of transplant centers. We have established relationships with key stakeholders within many of these top transplant centers. We believe the synergies among our programs and the well-defined structure of the current stem cell transplant provider network will allow us to commercialize our therapeutics through a focused, targeted commercial and medical affairs organization.

***Strategically collaborate to realize the full potential of our portfolio*:** We own all product rights across our conditioning and mobilization programs, including MGTA-117 and MGTA-145. We will evaluate additional collaborations when available to:

- maximize the patient impact of our portfolio by finding value-creating partnerships to enable gene and cell therapies, including stem cell-based gene therapies, genome editing and CAR-T therapies;
- build relationships with partners to access complementary expertise and capabilities to bring our therapies as quickly as possible to all patients who can benefit; and
- opportunistically bring in preclinical or clinical assets that fit with our integrated portfolio.

Our Pipeline of Product Candidates

We are developing a portfolio of novel product candidates that we believe have the potential to meaningfully improve stem cell transplant for patients with blood cancers, genetic diseases, and autoimmune diseases. Additionally, we believe our product candidates have the potential to allow more patients with debilitating or life-threatening diseases to access a one-time, transformative blood and immune reset through stem cell transplant with better outcomes and reduced risk of toxicities and mortality.



We are applying our expertise in stem cell biology and biotherapeutics discovery to bring innovative product candidates to the stem cell transplant field through our programs, specifically designed to address each of the key opportunities in the stem cell transplant journey for patients:

- ***Targeted Conditioning Programs***: Our MGTA-117 program is focused on selectively depleting stem cells from patients prior to transplant or HSC-based gene therapy to lessen the need for high-dose or high-intensity chemotherapeutic agents or, in the case of gene therapy applications, to potentially eliminate the need for chemotherapeutic agents altogether. Our second targeted conditioning program, CD45-ADC, is focused on depleting both stem and immune cells to enable transplant as a single agent in autologous autoimmune disease and allogenic blood cancer transplants.
- ***Stem Cell Mobilization & Collection Program***: Our MGTA-145 program is focused on enabling rapid, reliable, predictable and safe mobilization and collection of high numbers of functional blood stem cells for transplant.
- ***Research Programs***: Our current research efforts are focused on expanding the utilization of targeted conditioning by targeting the removal of additional specific cell types with an approach that is tailored to a patient's disease and transplant requirements.

Targeted Conditioning Programs

Targeted conditioning refers to agents that can selectively deplete stem and/or immune cells. These product candidates are designed to lessen the need for high-dose or high-intensity chemotherapeutic agents or, in the case of gene therapy applications, potentially eliminate the need for chemotherapeutic agents altogether, and make stem cell transplant more effective.

Opportunity

After a sufficient number of stem cells have been mobilized and collected, patients must be prepared, or conditioned, for transplant. Conditioning is intended to remove the disease-causing cells and make room for the new stem cells that will rebuild the healthy blood and immune system.

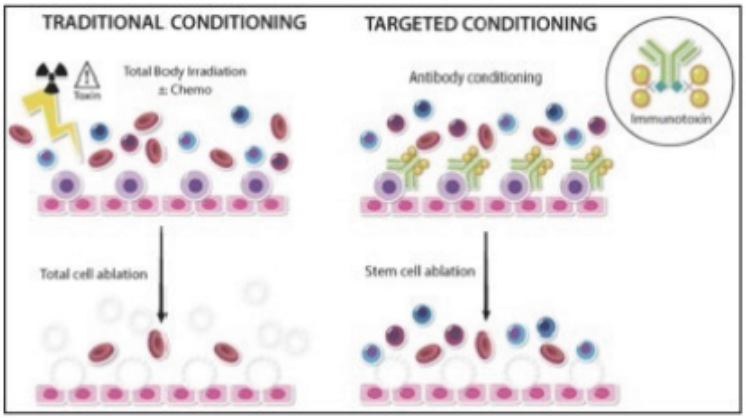
Conditioning for stem cell transplant and gene therapy is currently burdensome and risky for both pediatric and adult patients. The agents used today are non-targeted and involve high doses of systemic, toxic chemotherapy and/or radiation, which are known carcinogens and cause cancer. Most of these chemotherapy agents, including derivatives of mustard gas, were discovered more than 50 years ago, and were never intended for stem cell transplant conditioning. The current treatments eradicate the stem cells, immune cells, and diseased cells but also indiscriminately damage DNA and kill normal, healthy cells in the body. These conditioning regimens can cause long-term lung injury and liver toxicity, serious infections, organ failure, infertility, secondary cancers and even death. Nearly all transplant patients experience complications as a result of current conditioning treatments, and conditioning toxicity is responsible for up to 35% of mortality following allogeneic transplants.

Whenever possible, physicians use the most aggressive conditioning regimens, known as myeloablative conditioning, or MAC, to generate optimal efficacy outcomes for oncology and gene therapy patients. For oncology patients who can tolerate these high-intensity conditioning regimens to prepare them for stem cell transplant, over 50% are alive and without disease relapse, known as relapse-free survival, at five years post-transplant, an impressive survival rate in these high-risk patient populations. However, approximately 20% of patients receiving MAC regimens die from complications related to the transplant procedure, known as transplant-related mortality, and a significant majority experience serious short- and long-term side effects.

For the many patients that cannot tolerate such intense and toxic regimens due to advanced age or co-morbidities, such as decreased organ function, recent efforts have focused on reducing chemotherapy doses in

regimens known as reduced intensity conditioning, or RIC. While significantly better tolerated, these RIC regimens, when used alone, lack the potency to adequately deplete a sufficient number of leukemic cells and therefore RIC regimens have significantly poorer disease outcomes (due to relapse) at five years post-transplant. Over 50% of patients receiving RIC relapse and only approximately 30% of patients are alive without relapse at five years following stem cell transplant. Therefore, physicians and patients must currently choose between either the superior long-term efficacy of MAC or the improved safety and tolerability of RIC.

Multiple clinical trials, including multi-center Phase 3 trials, have also shown that certain autoimmune diseases can be cured with an immune system reset through autologous stem cell transplant, with data in multiple sclerosis and scleroderma. When compared to the standard of care in relapsing remitting multiple sclerosis, clinical trials have shown that the proportion of patients with clinical benefit at two years appears to be double that of the next best treatment and that transplant prolongs the time to disease progression compared with disease modifying therapies. However, the toxicity of the required conditioning regimens has historically led many physicians to conclude that the risks of transplant in these patient populations outweigh the benefits. Currently only approximately 6% of eligible patients with multiple sclerosis and scleroderma receive a stem cell transplant, in part due to these significant risks. Magenta believes we can significantly expand the number of autoimmune patients who can benefit from immune reset with effective and safe targeted conditioning.



Our Targeted Conditioning Programs

Our targeted conditioning programs are designed to selectively eliminate stem cells and/or immune cells from a patient prior to transplant or gene therapy, and to be far less toxic than the current radiation and chemotherapy-based treatments. These programs focus on developing targeted products that remove specific cell types, with an approach that is tailored to the patient's disease and transplant requirements.

We are developing a suite of novel ADCs for targeted conditioning. While ADCs are an established treatment for certain cancers, we believe this is the first time that ADC technology has been harnessed for transplant medicine. ADCs are a technology developed over the past 20 years where a monoclonal antibody specific for a cell surface protein is coupled to a payload via a molecule known as a linker. The ADC binds the receptor on the target cell, is internalized and degraded to release the payload into the target cell. Coupling the payload to the antibody increases the specificity of payload delivery to the target cell, reducing systemic exposure and increasing the safety and efficacy compared to delivering the payload alone or the antibody without the payload attached. Today, most ADCs are directed toward treating cancer cells expressing specific target receptors enriched on tumor cells. Our programs build on this clinically validated modality and adapt it for preparing patients for blood and immune reset through stem cell transplant.

In our development of ADCs for use in conditioning, we are seeking to optimize several key parameters:

- First, the antibody component of the ADC must specifically target a receptor that is expressed on the cells of interest.
- Second, to comply with typical stem cell transplant conditioning timelines, the ADC must have suitable potency to ensure that the agent is able to remove the target cells rapidly, in days rather than weeks or months.
- Third, the ADC clearance from the body needs to be accelerated so that it is eliminated by the time the transplanted cells are infused into the patient, typically within a week of starting conditioning. This requirement stems from the fact that the target receptor is expressed on cells present in the patient but also on the newly transplanted cells which should not be targeted for depletion in order for the transplant to be successful.
- Finally, the drug must be well-tolerated for patients at dose levels where stem cells are effectively removed. We designed the ADC with a stable linker-payload which is intended to ensure that the payload used for cell depletion is primarily released intracellularly following internalization by target cells.

We are addressing each of these requirements through careful selection of the appropriate target receptor as well as antibody properties, including binding site, affinity, half-life and linker-payload chemistry.

Our targeted conditioning programs include both our ADC programs and earlier-stage research programs that leverage alternate modalities for targeted cell depletion. This is achieved by tuning the antibodies to specific cellular markers or receptors that are expressed on the particular cell types. These drugs are designed to specifically remove only the cell types required for a successful transplant, with an approach that is tailored to the patient's disease and transplant requirements:

- **MGTA-117:** targets HSCs and genetically mutated stem cells that cause acute myeloid leukemia and myelodysplastic syndromes.
- **CD45-ADC:** targets both HSCs and immune cells and is currently in Investigational New Drug application, or IND enabling studies for potential use as a single-agent in autoimmune diseases and hematology-oncology transplants.

MGTA-117 Clinical Candidate

Our most advanced conditioning product candidate, MGTA-117, has entered a Phase 1/2 clinical trial in patients with relapsed/refractory AML or MDS. MGTA-117 is an anti-CD117 antibody conjugated to an amanitin payload, and it targets CD117, also known as c-Kit, which is highly expressed on HSCs and leukemia cells. If clinically proven to target and safely deplete these types of cells, MGTA-117 could improve conditioning across broad sets of diseases where stem cell transplant is either already the standard of care or could be expanded to benefit more patients.

For stem cell transplant in AML/MDS, we believe that MGTA-117, in combination with RIC, has the potential to demonstrate clinical outcomes that preserve the safety and tolerability of RIC while achieving the efficacy of MAC. Likewise, gene therapy is a promising approach to treat a variety of non-malignant diseases, including inherited metabolic disorders, sickle cell disease and beta-thalassemia, but the risks and toxicity associated with current chemotherapy-based conditioning approaches (e.g. busulfan) may limit the utility of this approach. In gene-therapy stem cell transplant, MGTA-117 may enable single-agent conditioning and replace the use of busulfan.

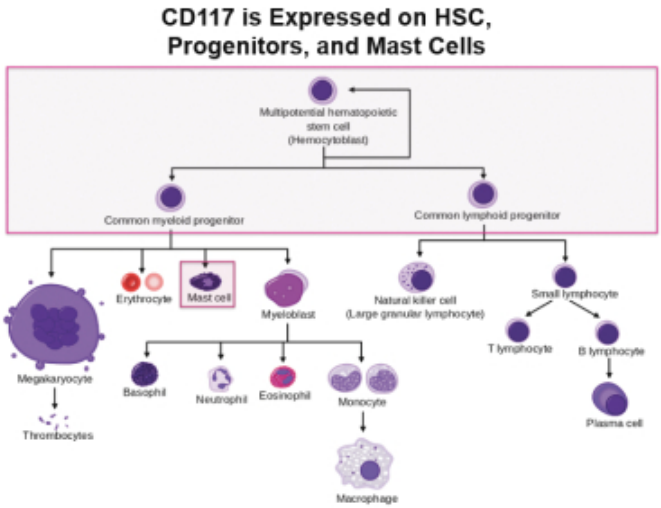
Preclinical Data Supporting Clinical Development

We believe that it is critical for successful clinical development and commercialization of MGTA-117 that we demonstrate selective target engagement, robust cell depletion and rapid clearance from the body with an

acceptable safety profile. Our preclinical experiments have supported each of these concepts and informed our clinical trial plans.

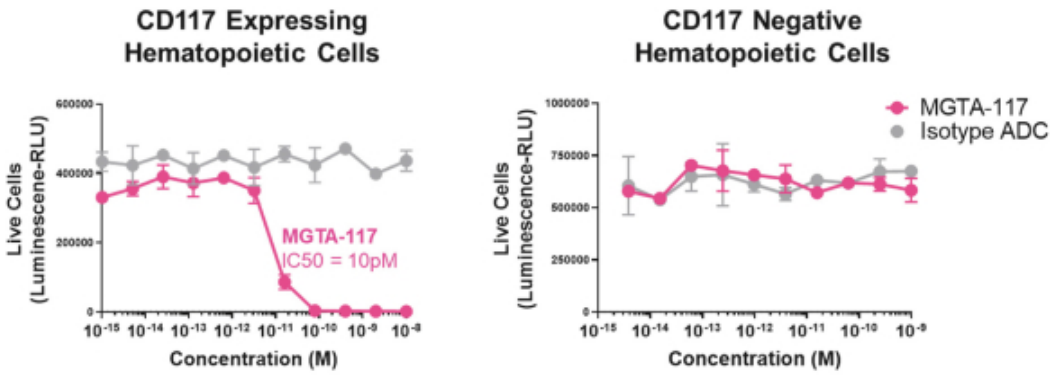
Selective Target Engagement and Cell Depletion

In the hematopoietic system, CD117 is primarily expressed on HSC/progenitor, or HSPC, cells and mast cells but not expressed on mature immune cells such as B cells or T cells. We have demonstrated this selectivity in vitro by incubating cells with increasing concentrations of MGTA-117. Cells expressing CD117 were dose-dependently depleted by MGTA-117, while it had no depletion effect on cells lacking CD117, demonstrating the selectivity of MGTA-117.



Based on: Nobili et.al., Long non-coding RNAs in normal and malignant hematopoiesis. Oncotarget (2016)

CD117 is expressed on stem cells and their progenitors and mast cells only within the hematopoetic system.

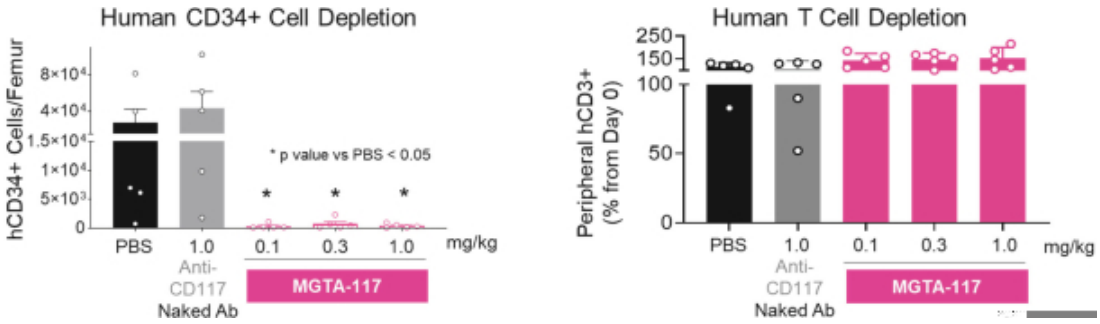


CD117-expressing cells are selectively depleted when cultured with increasing concentrations of MGTA-117, while CD117-negative cells are unaffected.

Cell Depletion

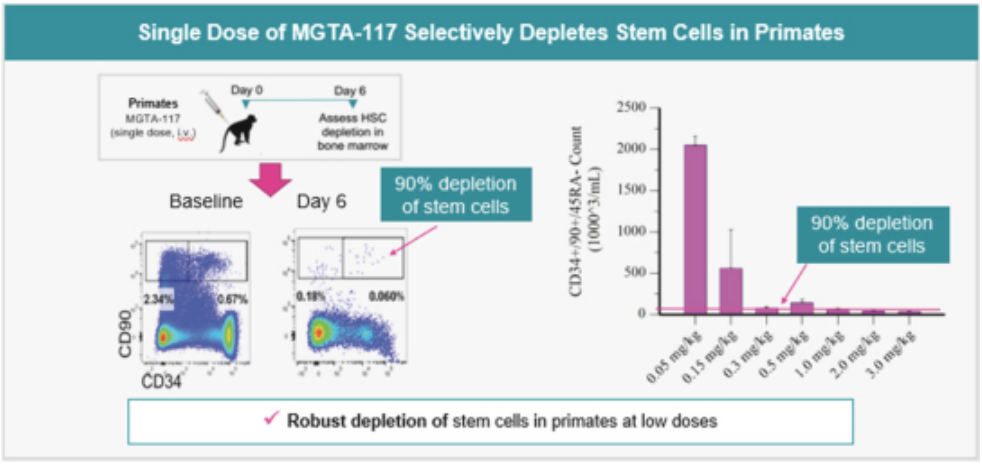
In humanized mice, single dose administration of MGTA-117 engaged CD117-expressing cells with on-target depletion of human stem and progenitor (CD34+) cells in the bone marrow. Importantly, cells that did

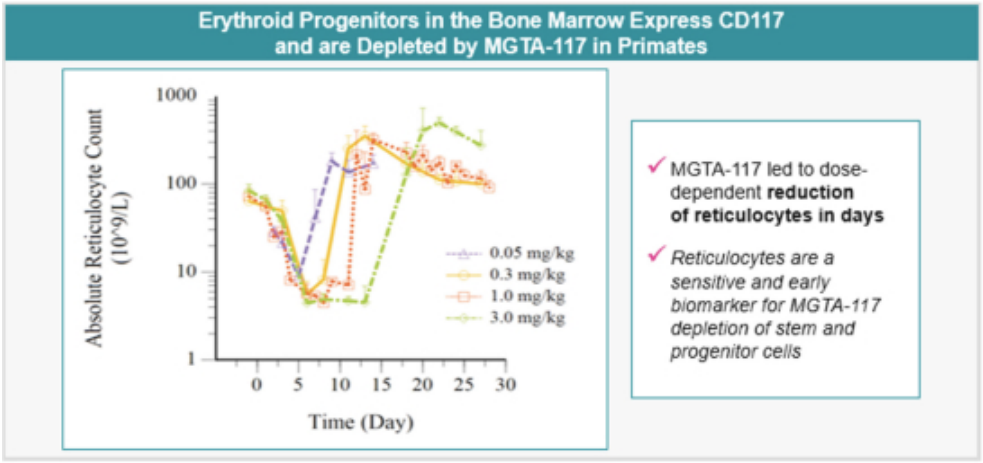
not express CD117, for example T cells, were not depleted and functional immunity was preserved. Additionally, cell depletion was payload dependent because the stand alone, or naked, antibody was shown to have no effect in the same experiment. These data collectively demonstrate that MGTA-117 selectively engages the CD117 receptor on stem cells and their progenitors and once internalized the release of the amanitin payload results in effective potent targeted HSC depletion, while sparing non CD117 expressing cells of the immune system.



Administration of a single dose of MGTA-117 to humanized mice results in significant depletion of CD117-positive HSC/HSPC but is without effect on CD117-negative T-cells. The monoclonal or naked antibody is ineffective in depleting stem cells.

In healthy primate studies, a single dose of MGTA-117 showed dose-dependent HSC depletion in the bone marrow at seven days post-dosing with doses ≥ 0.3 mg/kg achieving ≥ 90% HSC depletion as measured by CD34+CD90+CD45RA- cells. These data demonstrate that in normal healthy primates, MGTA-117 selectively targeted and depleted bone marrow stem cells and their progenitors. In the same studies, we observed dose-dependent depletion of peripheral blood reticulocytes. Reticulocytes do not express CD117 and therefore this sensitive depletion of these red blood cell precursors indicates the sensitivity of bone marrow erythro-progenitor cells to MGTA-117. Peripheral reticulocytes in the blood may therefore serve as a sensitive biomarker of MGTA-117 effectiveness in depleting HSC/HSPC in the bone marrow compartment.

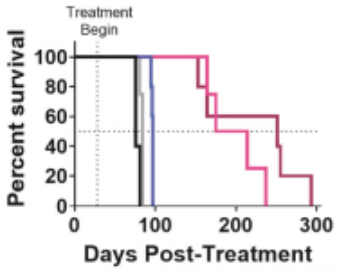




MGTA-117 has also been shown to be effective in killing human acute myeloid leukemia cells *in vitro*. To extend these data, we assessed the ability of MGTA-117 to reduce tumor burden and therefore extend survival in mice bearing two different human AML tumor types. We selected patient-derived AML tumor cells from a patient prior to treatment and compared that with human tumor cells from a recurrent/relapsed AML that was resistant to multiple lines of therapy. Tumor-bearing mice treated with a single dose of MGTA-117 showed improved survival regardless of tumor-type, compared to mice left untreated or those treated with isotype control ADC (which does not bind to CD117) or multiple doses of standard aracytidine chemotherapy.

AML PDX 1

AML, M4; no previous treatment

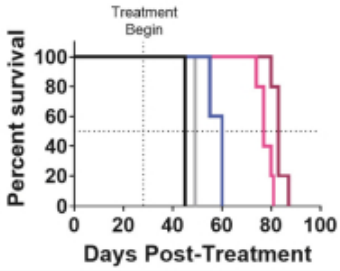


Treatment Groups		Median Survival (Days Post Implant)
PBS		76
ARA-C 30 mg/kg QDx5		97^$
2.6 mg/kg	MGTA-117	194.5^%$
8.7 mg/kg	MGTA-117	251^%$
8.9 mg/kg	Isotype-AM	84^#

Log-rank test $p \leq 0.05$ compared to *PBS, ^ Isotype-AM or # ARA-C

AML PDX 2

AML recurrent/Relapse



Treatment Groups		Median Survival (Days Post Implant)
PBS		45
ARA-C 30 mg/kg QDx5		60^$
2.6 mg/kg	MGTA-117	77^%$
8.7 mg/kg	MGTA-117	83^%$
8.9 mg/kg	Isotype-AM	49^#

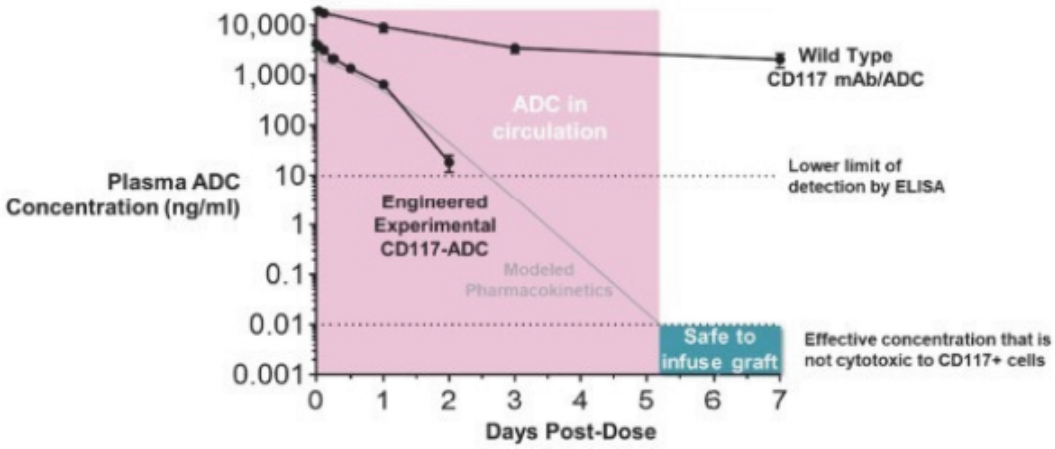
Log-rank test $p \leq 0.05$ compared to *PBS, ^ Isotype-AM or # ARA-C

Mice bearing human tumor explants from naïve patients (PDX1) or from recurrent/relapsed patients (PDX2) showed improved survival following treatment with MGTA-117 compared with either the isotype-control antibody or aracytidine.

Rapid Clearance

In preclinical studies, we utilized an experimental CD117-ADC with a full length human IgG1 antibody that had been engineered to have rapid clearance from the body which enables safe graft infusion within five days after dosing. As shown in the graphic below, the engineered half-life experimental CD117-ADC (that has the

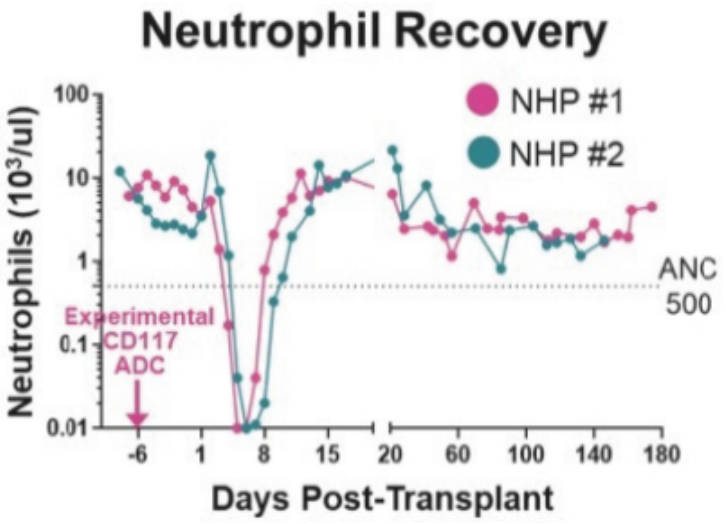
same engineered antibody as MGTA-117 with a different non-amanitin payload) demonstrated rapid clearance in non-human primates with a half-life suitable for transplant (n=3/group). The half-life of the wild type CD117 antibody is approximately three days. The experimental CD117-ADC drops below limit of detection for the assay after two days and modeled pharmacokinetics (gray line) predicts the ADC will be below cytotoxic concentrations after five days.



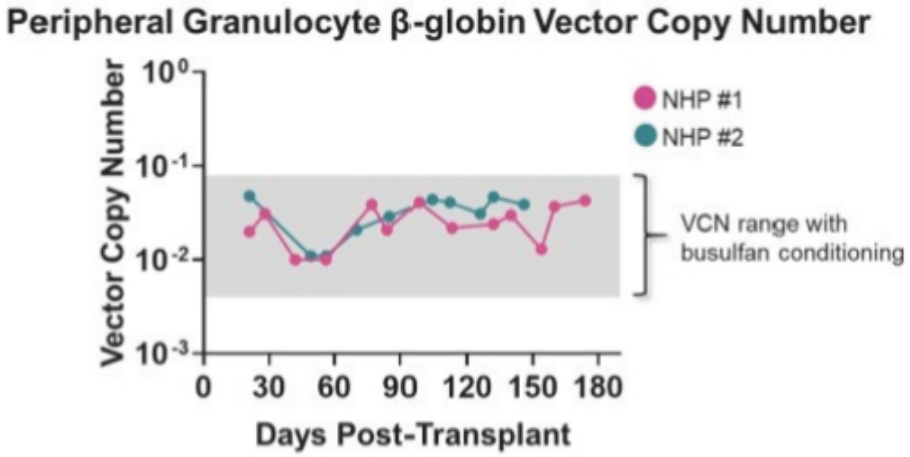
An Experimental CD117-ADC Successfully Supports Transplant in a Gene Therapy Model

HSC-based gene therapies also require conditioning of the transplant recipient prior to infusion with stem cells that have been gene-corrected or modified to address the underlying disease prior to transplant. Such gene therapy approaches that leverage the stem cell transplant procedure are being investigated by numerous companies in a variety of diseases, including sickle cell disease, beta-thalassemia and lysosomal storage disorders.

In a preclinical study, an experimental CD117-ADC that has the same engineered antibody with a different non-amanitin payload, enabled engraftment of autologous gene-modified HSCs in a non-human primate, or NHP, model. CD34+ cells were harvested from two rhesus NHPs and transduced with a lentiviral vector encoding beta-globin. The transduced cells were transplanted into the same animals six days after a single dose of experimental CD117-ADC. The neutrophil counts before and after transplantation of the transduced cells are shown for animal #1 (magenta line) and animal #2 (teal line). The animals recovered their neutrophils on day eight (animal #1) and day ten (animal #2) demonstrating that (1) the conditioning regiment was successful in depleting stem cells reflected by the severe depletion of neutrophils and (2) that the neutrophil count recovered demonstrating recovery from the conditioning and transplant.



The success of the transplants in both animals were confirmed by measurement of vector copy number, or VCN, in the immune cells which are derived from the infused gene modified stem cells. The VCN was stable beyond three months, the longest time point in the study, demonstrating that the gene-modified cells persisted in the body indicating the gold-standard of a durable transplant. This was comparable to historical data with four doses of busulfan conditioning, but without observation of the side effects associated with busulfan such as veno-occlusive disease, weight loss, diarrhea, mucositis, vomiting, pulmonary fibrosis or seizures.



Conditioning Regimen	Animal Number	CD34 dose (x10⁶ cells/kg)	VCN of infused cells	Peripheral VCN @ 1-6 months
Experimental CD117-ADC	NHP #1	3.3	5	0.01-0.04
	NHP #2	1.1	4	0.01-0.05
Busulfan	Busulfan Cohort *Uchida et al. Mol Ther 2019	4.1-4.2	8-10	0.004-0.08

The graphic above shows that the VCN in the peripheral neutrophils (granulocytes) was equivalent with conditioning with one dose of the experimental CD117-ADC versus four doses of toxic busulfan even though the transduced CD34+ cell dose and VCN infused for the experimental CD117-ADC conditioned animals was lower compared to the busulfan conditioned animals**.** This indicates the conditioning with the experimental CD117-ADC is sufficient to enable engraftment of gene modified HSCs.

Well-Tolerated

A critical characteristic of our next generation conditioning agent MGTA-117 is that it demonstrates safety and tolerability that supports advancement into human testing. We determined the safety of MGTA-117 by conducting a four-week good laboratory practices, or GLP, toxicology study in primates where a no observable adverse event level dose level was identified. There were only two target organs identified. At lower doses the target organ identified was the bone marrow with the intended pharmacological effect of stem cell depletion. At higher doses the target organ identified was the liver with transient enzyme elevations and transient histopathological changes observed. No histopathological changes were observed in kidney, reproductive organs and any other major organ. The GLP toxicology study enabled the advancement of MGTA-117 into a Phase 1/2 clinical trial.

Clinical development of MGTA-117

We have an ongoing Phase 1/2 clinical trial to evaluate MGTA-117 in a multi-center, open-label, single-ascending-dose trial with patients with relapsed/refractory AML and MDS-excess blasts, or MDS-EB Dose escalation in the trial will be determined in accordance with a modified Fibonacci sequence. The primary outcomes for the clinical trial will be the evaluation of the safety profile, pharmacokinetics and pharmacodynamics of MGTA-117 as a single dose.

The dosing cohorts expected to enroll in 2022 will allow for evaluation of MGTA-117's ability to:

- selectively target CD117 as measured by receptor occupancy;
- potently deplete CD117-expressing cells such as stem cells, progenitors, and tumor cells; and
- rapidly clear from the body with a well-tolerated profile as determined by pharmacokinetic analysis and clinical chemistry tests, respectively.

Magenta will assess data from each cohort and, after collection of adequate safety, pharmacokinetic and pharmacodynamic data, Magenta intends to engage with the U.S. Food and Drug Administration, or FDA, to transition to the primary target population of patients eligible for stem cell transplantation. In addition, Magenta plans to explore MGTA-117 as a targeted conditioning agent for stem cell gene therapies.

We have entered into two research and clinical collaborations to evaluate the potential utility of MGTA-117 for conditioning of patients prior to stem cell-based gene therapies:

- **Lysosomal Storage Disorders.** We entered into an agreement with AVROBIO, Inc. to evaluate the potential utility of MGTA-117 for conditioning of patients receiving one or more of AVROBIO, Inc.'s investigational lentiviral gene therapies.
- **Hemoglobinopathies.** We entered into an agreement with Beam Therapeutics, Inc. to evaluate the potential utility of MGTA-117 for conditioning of patients with sickle cell disease and beta-thalassemia receiving Beam Therapeutics, Inc.'s base editing gene therapies.

CD45-ADC Program

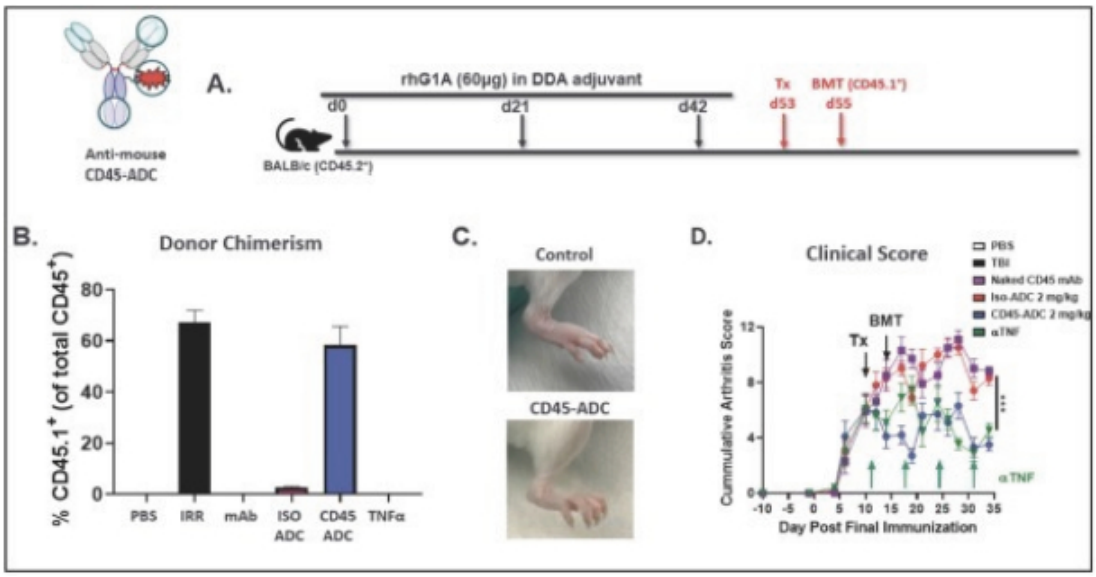
Our second ADC-based conditioning program is CD45-ADC, which targets the CD45 receptor that is expressed on both HSCs and disease-causing immune cells. For many stem cell transplant applications, it is

important to eliminate both HSCs and immune cells in the patient prior to transplant. This is especially important as immune cell depletion is a key feature of the use of autologous stem cell transplant in patients with severe autoimmune disease. In this case, our goal is to eliminate the disease-causing auto-reactive immune cells that perpetuate the underlying autoimmune disease. Similarly, in the allogeneic blood cancer transplant setting, host immune cells must be depleted because they can elicit an immune-mediated rejection of the incoming foreign stem cells. Lastly, for cancer patients with tumors expressing CD45, there may also be a direct anti-tumor effect providing additional therapeutic benefit. For these reasons, we are developing a CD45-ADC product candidate that simultaneously targets both HSCs and immune cells.

Preclinical Data Supporting Development

Mouse Models of Autoimmune Disease

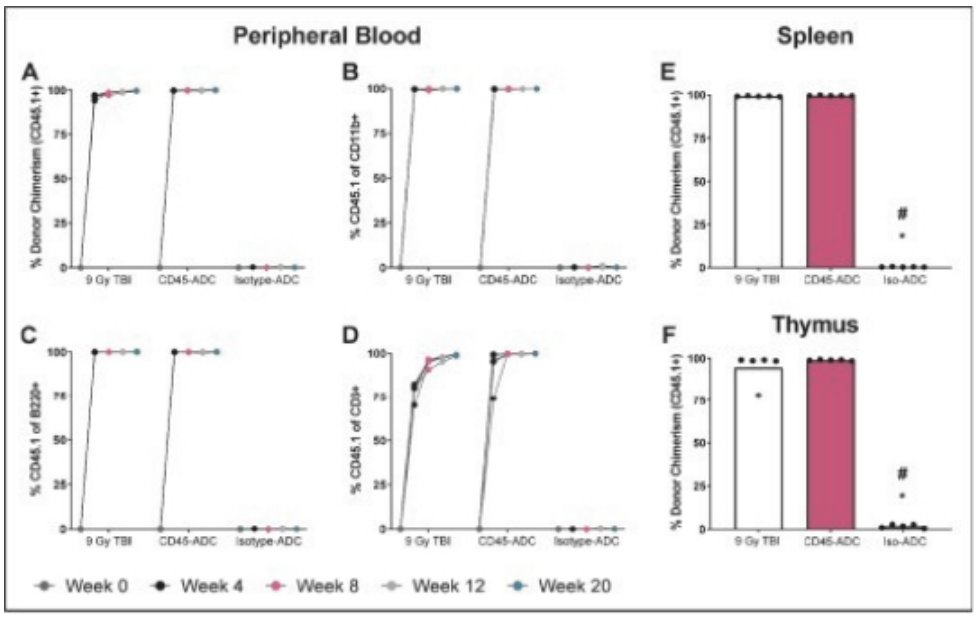
Data presented at the Transplant and Cellular Therapy, or TCT, and the European League Against Rheumatism, or EULAR, annual meetings in 2020 showed that a single dose of an experimental CD45-ADC removed disease-causing reactive T cells, enabled successful blood and immune reset, and rebuild of the immune system and was well tolerated in a reliable murine model of autoimmune disease, proteoglycan-induced arthritis. Further, a single dose of the CD45-ADC significantly reduced disease incidence and delayed disease onset in this model that has successfully provided preclinical proof of concept for many clinically validated standard-of-care therapies.



Conditioning with CD45-ADC Enables Immune Reset via Bone Marrow Transplant and results in halt of disease progression in a murine model of Rheumatoid Arthritis. BALB/c mice (CD45.2$^+$) were given three immunizations (study day 0, 21, and 42) with recombinant human core G1 aggrecan (60 µg in 2 mg DDA) to trigger rheumatoid arthritis (**A**). Animals were treated on day 11 post the final immunization (study day 53) and conditioned animals were transplanted with Balb/c CD45.1$^+$ congenic bone marrow 48 hours later (study day 55). Animals treated with a neutralizing monoclonal antibody to murine TNF α received 500 µg/mouse IP weekly starting on study day 53. Treatment with 2 mg/kg of CD45-ADC, but not Isotype-ADC, enabled full congenic donor chimerism in peripheral blood (**B**) at three weeks post-transplant. Representative paws from control and CD45-ADC –treated animals are shown in (**C**). Scores for the treatment groups over time are graphed in (**D**).

Mouse Models of Allogeneic Transplant

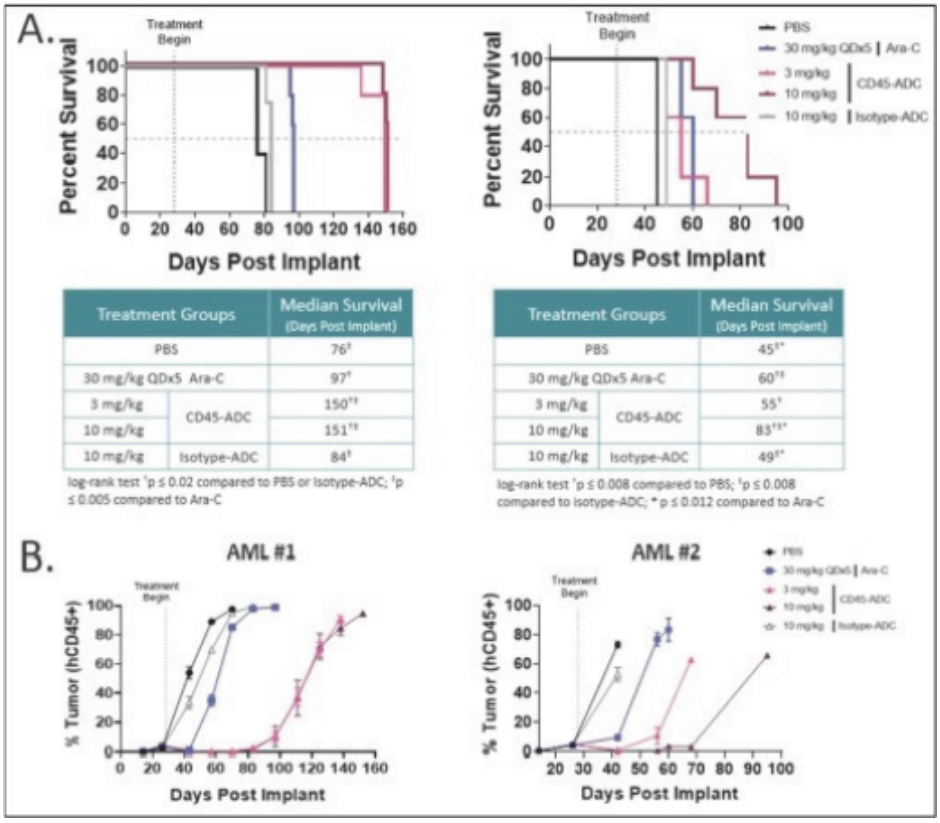
Data presented at the European Society for Blood and Marrow Transplantation, or EMBT, and American Society of Hematology, or ASH, annual meetings in 2020 and at the TCT annual meeting in February 2021 showed that a single dose of CD45-ADC is fully myeloablative and enables complete chimerism in a full mismatch allogeneic stem cell transplant model without the need for additional conditioning agents.



A single dose of 5 mg/kg CD45-ADC is sufficient to enable allogeneic transplant of Balb/c CD45.1 donor cells into C57BL/6 recipients. (A-D) C57BL/six mice were conditioned with 5 mg/kg Isotype-ADC or CD45-ADC. CD45-ADC enables ≥ 95% donor chimerism **(A)** and peripheral donor engraftment is multilineage through week 20. **(B-D)**. Terminal splenic **(E)** and thymic **(F)** chimerism in CD45-ADC conditioned mice were similar to TBI. *p<0.05 versus TBI; #p<0.05 versus CD45-ADC; ANOVA with post hoc Tukey's multiple comparisons test.

Oncology Model Results

Data presented at the TCT annual meeting in 2020 demonstrated that a single dose administration of a short half-life CD45-ADC is well tolerated and is capable of reducing tumor burden by potently targeting leukemia cells in xenograft models. It significantly prolonged the median survival of animals harboring an established AML cell line and patient derived tumor cells as compared to both untreated controls and a multi-dose regimen of aracytidine, or ARA-C, a standard-of-care chemotherapy.



A single dose of a short half-life CD45-ADC increases survival (A) and effectively decreases tumor burden (B) of human acute myeloid leukemia cells in two patient derived xenograft models compared to vehicle (PBS) or isotype-ADC, and comparable to a multi-dose regimen of ARA-C, a standard-of-care chemotherapy. Treatment began when 2-16% tumor blasts were detected in the periphery (n=3-5 mice/group/AML PDX model). Mice were treated with a single intravenous dose of anti-human CD45-ADC, isotype-ADC, or vehicle (PBS). ARA-C chemotherapy was administered intravenously once daily for five consecutive days. (A) Survival of CD45+CD117+ PDX AML mice treated with a single intravenous dose of CD45-ADC was significantly increased as compared to PBS or isotype-ADC controls (B). CD45-ADC significantly delayed tumor burden (expressed as %hCD45) in the peripheral blood of treated mice compared to PBS, isotype-ADC and standard of care controls.

Development plans

We plan to develop CD45-ADC for use in patients with autoimmune diseases, such as multiple sclerosis and scleroderma, and patients with leukemias and myelodysplastic syndromes. We have identified a lead antibody and progressed this program into IND-enabling studies. Magenta expects to have preclinical data from a dose ranging toxicology study in the second half of 2022.

Stem Cell Mobilization & Collection Program

Stem cell mobilization is a process by which stem cells are stimulated out of the bone marrow and into the bloodstream so they are available for collection for future reinfusion. The cells are then preserved, frozen, and stored until the time of transplant. We are developing MGTA-145 as a new medicine intended to transform the process of mobilization and collection of stem cells.

Opportunity

Once the patient and physician agree that stem cell transplant is the best treatment option, the source of stem cells must be identified and then the cells are collected. There are three methods of collecting stem cells from either patients or healthy donors for transplant:

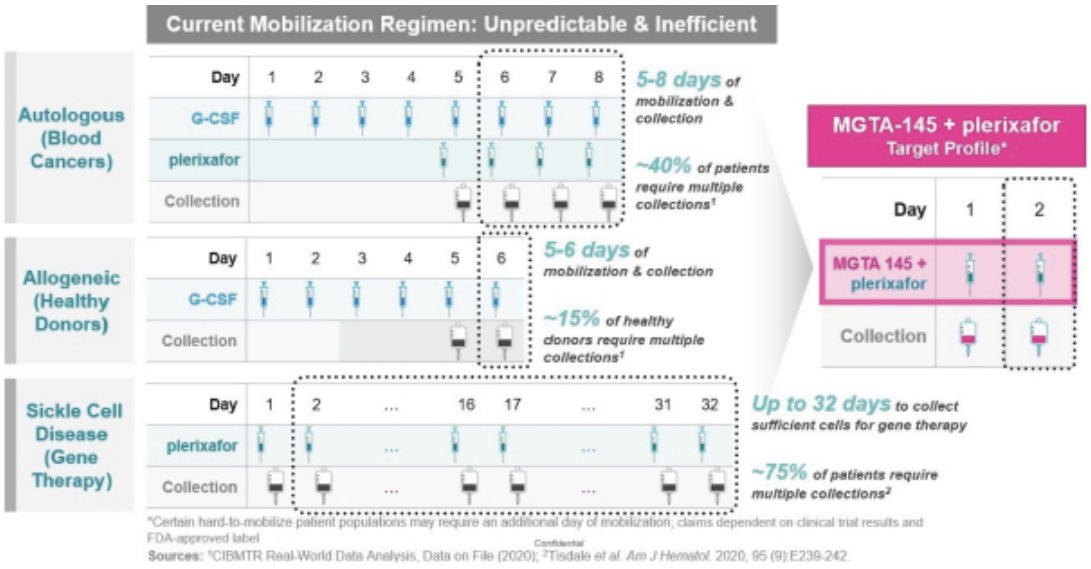
- mobilization into the peripheral blood, which typically requires several days of injections of a drug or combination of drugs to mobilize the cells, or move them from the bone marrow into the bloodstream, where they are then collected through a process called apheresis;
- extraction from the bone marrow in a process known as bone marrow harvest, which requires a procedure performed under general anesthesia where cells are withdrawn directly from the bone marrow with needle aspirates; or
- harvesting from umbilical cord blood units, which are stored in cord blood banks.

Successful stem cell transplant requires collection of HSCs in both sufficient number and functionality, whether from the patient or a donor, to allow for robust engraftment and rebuilding of the blood and immune systems. Higher cell doses are associated with better outcomes and are especially important for gene therapy applications, which require processing of the stem cells following collection.

Mobilizing stem cells from the bone marrow to the blood has been shown to be an effective way to collect stem cells for transplant. Approximately 85% of the approximately 90,000 stem cell transplants performed globally each year use mobilized peripheral blood from either donors or patients as a source of stem cells.

Current approaches for stem cell mobilization include granulocyte colony-stimulating factor, or G-CSF, which mobilizes stem cells indirectly, requires repeated daily injections and is associated with significant side effects, including bone pain and, in some cases, splenic rupture and death. The multi-day regimen requires at least five days of injections of G-CSF, and side effects can be disruptive for both patients having their cells collected for autologous transplants and for healthy volunteers donating their cells for allogeneic transplants. For patients who are unable to mobilize a sufficient number of functional stem cells with G-CSF, physicians may add another drug, known as plerixafor. Plerixafor is a small molecule CXCR4 antagonist that blocks a pathway that otherwise plays an essential role in attracting and retaining HSCs in the bone marrow. It is approved for use in combination with G-CSF for multiple myeloma, and non-Hodgkin’s lymphoma patients who fail to achieve sufficient mobilization of stem cells with G-CSF alone. G-CSF can mobilize stem cells as a single agent but not to sufficient levels to be effective as a standalone agent in most disease settings.

The current unpredictability and inefficiency of stem cell mobilization and collection can also pose a significant logistical burden on transplant and apheresis centers. When planning for a patient’s transplant, transplanting physicians cannot reliably predict at the outset how long it will take to collect the number of cells required. In addition, each day scheduled for attempted mobilization and collection can cause an accumulation of both the direct costs associated with the repeated use of mobilization agents and other healthcare resources, including personnel time, and the indirect costs associated with the need to block time in the limited number of chairs in transplant centers that are used to collect stem cells. It is difficult to predict whether mobilization with G-CSF will be successful, especially in heavily treated blood cancer patients. Many patients require multiple collections, including approximately 40% of blood cancer patients. Finally, patients with sickle cell disease can have severe side effects with G-CSF, including potentially fatal complications, and therefore, plerixafor is the only available mobilization option for sickle cell disease patients. However, because of its poor efficacy as a standalone agent and the high number of stem cells required for a transplant in sickle cell disease, multiple doses of plerixafor and collections are needed in approximately 75% of sickle cell disease patients.

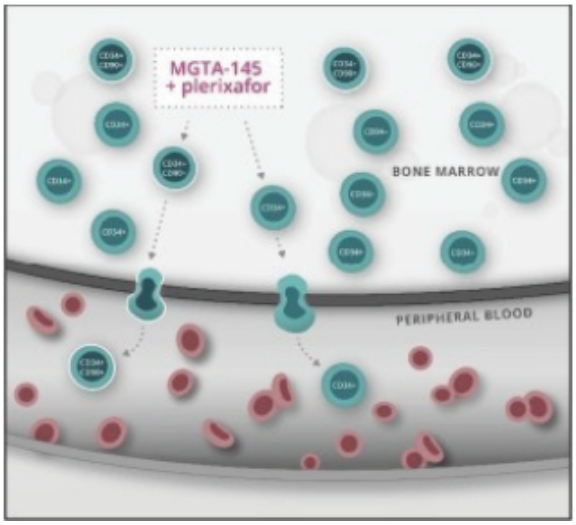


Our MGTA-145 Product Candidate

Magenta is developing MGTA-145 as a potential first-line standard of care for stem cell mobilization in a broad range of diseases, for both autologous and allogeneic transplants. MGTA-145, a CXCR2 agonist, works in combination with plerixafor, a CXCR4 antagonist, to harness the physiological mechanism of stem cell mobilization. Our goal is for MGTA-145 is to be the preferred first-line mobilization option for all patients and donors through rapid, reliable, predictable and safe mobilization and collection of high numbers of functional stem cells. We received Orphan Drug Designation from the FDA, for MGTA-145 for the mobilization of HSCs to the peripheral blood for collection and subsequent transplant.

Mechanism of action

CXCR2 is a chemokine receptor expressed on the surface of neutrophils. Binding of MGTA-145 to the receptor results in neutrophil activation. Published data from Magenta founders and scientists show that a key event for mobilization of stem cells is the MGTA-145-mediated release of proteases from activated neutrophils, which together with the actions of the CXCR4 antagonist, plerixafor, results in the rapid release of HSCs from the bone marrow into the blood. Blocking CXCR4 using plerixafor and activating neutrophils with MGTA-145 has been shown clinically to produce an effective and synergistic untethering and release of HSCs from bone marrow into the blood, resulting in rapid, reliable, predictable and well-tolerated mobilization of HSCs.



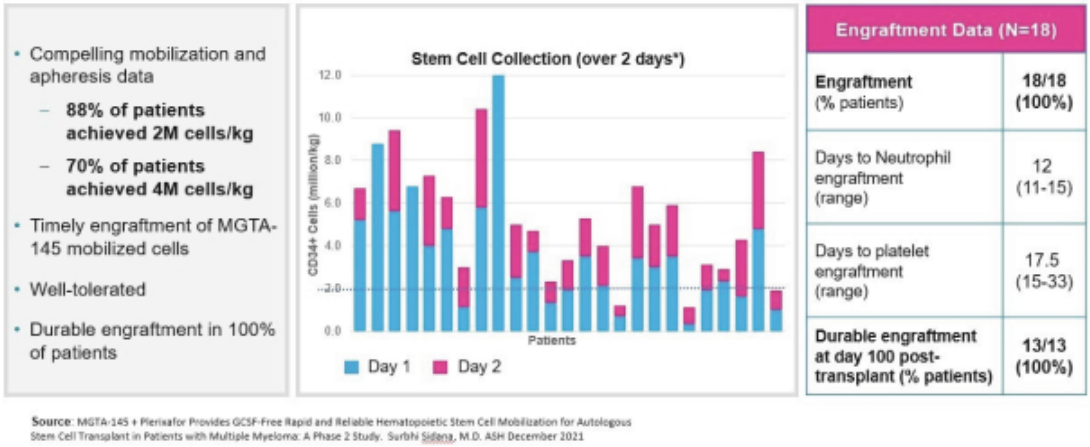
MGTA-145 in combination with plerixafor harnesses the natural mechanism of stem cell mobilization.

MGTA-145 Phase 1 Clinical Data – Healthy Subjects

We have completed a Phase 1 clinical trial of MGTA-145 plus plerixafor in healthy subjects. The trial met all primary and secondary endpoints. Clinical endpoints included safety and tolerability, pharmacokinetics, target engagement and pharmacodynamic effects. Data from the trial presented at the ASH annual meeting in December 2020 showed that MGTA-145 was safe and well tolerated as a single agent and in combination with plerixafor, and that MGTA-145 in combination with plerixafor demonstrated rapid, single-day mobilization and collection of sufficient numbers of functional stem cells. MGTA-145 was shown to engage CXCR2 on neutrophils to mobilize CD34+ stem cells into peripheral blood with limited neutrophil activation, which may minimize risk of vaso-occlusive crises in patients with sickle cell disease.

MGTA-145 Phase 2 Clinical Data – Phase 2 Investigator-Initiated Trial in Multiple Myeloma

A Magenta supported Phase 2 investigator-initiated clinical trial at Stanford University with 25 multiple myeloma patients showed that MGTA-145, in combination with plerixafor, mobilized a sufficient number of stem cells for transplantation and met the trial's primary endpoint in 88% of patients (22/25). In addition, all patients transplanted with cells mobilized by MGTA-145 plus plerixafor as of the data cut-off date had successful engraftment (18/18 patients) with prolonged durability through the 100-day follow-up period (13/13 patients) which were two key exploratory endpoints. The regimen was generally well-tolerated.



Source: MGTA-145 + Plerixafor Provides GCSF-Free Rapid and Reliable Hematopoietic Stem Cell Mobilization for Autologous Stem Cell Transplant in Patients with Multiple Myeloma: A Phase 2 Study. Surbhi Sidana, M.D. ASH December 2021

MGTA-145 Clinical Data Confirms Potential Clinical Benefit, as Demonstrated in Multiple Myeloma from Single-Center Phase 2 Investigator-Initiated Trial (n=25 patients)

Next Steps in MGTA-145 Clinical Development

Phase 2 Dosing and Administration Optimization Clinical Trial. Building upon the encouraging cell collection data from the Phase 2 investigator-initiated clinical trial in multiple myeloma patients, Magenta plans to pursue a company-sponsored Phase 2 clinical trial to evaluate identified possible adjustments in the dosing and administration regimen that are expected to further increase the number of stem cells mobilized for collection. This evaluation will be performed in healthy subjects which we believe will enable expedited enrollment and reduced patient variability. This clinical trial approach is intended to inform our clinical development plans in autologous transplant, including multiple myeloma, and allogeneic stem cell transplant.

Phase 2 Sickle Cell Disease Stem Cell Mobilization and Collection (Cell Characterization; Pre-Clinical Gene Modification Model). We entered into a Phase 2 clinical collaboration with bluebird bio, Inc. to evaluate the safety and potential utility of MGTA-145, in combination with plerixafor, for the mobilization and collection of stem cells in patients with sickle cell disease. Under the agreement, the companies will co-fund the clinical trial. Each party will characterize the collected cells and Magenta plans to gene- modify the cells and transplant them into established pre-clinical models to evaluate engraftment. Data from this clinical trial could provide proof-of-concept for MGTA-145, in combination with plerixafor, as the preferred mobilization regimen for patients with sickle cell disease and, more broadly, across all HSC gene therapy applications.

Phase 2 Allogeneic Donor Stem Cell Mobilization and Collection for Stem Cell Transplant in AML, ALL and MDS Patients. We entered into a clinical trial collaboration with National Marrow Donor Program (as successor in interest to Be the Match Biotherapies, LLC, or Be the Match, to evaluate the potential utility of MGTA-145, in combination with plerixafor, to mobilize and collect stem cells from allogeneic donors for transplant in patients with AML, acute lymphocytic leukemia, or ALL, and MDS. The clinical trial commenced in 2021 and, after review of initial clinical data from the trial in parallel with the review of the multiple myeloma clinical data, we decided to close the allogeneic donor clinical trial in favor of exploring the dosing and administration adjustments described above. We decided that the dosing and administration optimization clinical trial would be more beneficial to the overall MGTA-145 program due to its applicability to both allogeneic and autologous mobilization.

Research Programs

Our research efforts currently focus on future ADC-based conditioning programs. Our most advanced research program targets a receptor that is expressed on T cells, a type of immune cell. T cell depletion is

currently performed with highly toxic, non-specific drugs which can lead to immune deficiency, infections and other complications, including secondary autoimmune reactions. We are pursuing targets expressed on the surfaces of T cells with the goal of offering a safer and more optimized targeted conditioning approach through T cell depletion before cell therapy such as CAR-T for blood cancers, prevention of stem cell rejection prior to allogeneic stem cell transplant or achievement of immune system reset through autologous stem cell transplant in patients with autoimmune diseases.

E478: AHR antagonist for expansion of gene-modified stem cells

Opportunity

Stem cell transplant with gene-modified HSCs, which is referred to as gene therapy, stem cell gene therapy or genome editing, is a promising treatment approach for many diseases. We believe this approach can be enhanced by (1) increasing the number of gene-modified HSCs that retain the ability to durably engraft in patients and (2) reducing the cost and complexity of manufacturing viral vectors for gene modification of cells. These constraints could increase the commercial viability of stem cell gene therapy.

E478 product candidate

We developed the E478 program in response to the unmet technological need recognized in the field of stem cell gene therapy – the challenge of achieving sufficiently high doses of gene-modified stem cells. E478 is a novel and proprietary small molecule AHR antagonist that was developed to increase the number of gene-modified HSCs *ex vivo* for stem cell based-gene therapy. AHR antagonism is a clinically validated mechanism to increase the number of HSCs, most recently having been studied in patients with hematologic malignancies and inherited metabolic diseases.

We believe that E478 could represent a key component for unlocking the full value of gene therapy by providing each patient with an optimal dose of gene-modified HSCs for rapid and successful engraftment. In addition to addressing cell dose limitations, the ability to expand long-term repopulating HSCs *ex vivo* has the potential to reduce manufacturing costs for these therapies by requiring less viral vector for gene modification of the stem cells.

Preclinical data

We have shown that E478 can generate higher numbers of long-term engrafting human HSCs compared to other technologies. We have presented *in vitro* and *in vivo* data demonstrating successful increases in the number of gene-modified HSCs from both bone marrow and mobilized blood cell sources with E478 and showed that *ex vivo* incubation with E478 leads to higher and durable levels of engraftment in NSG mice compared to conventional culture approaches. Our data demonstrate that HSCs modified via lentiviral transduction, CRISPR/Cas9 and other gene-modifying approaches can be expanded *in vitro* by E478 and engraft *in vivo* in NSG mice.

Development plan

We are developing E478 to partner with gene therapy, genome editing and cell therapy companies. E478 would be integrated into our potential partners' cell-based products, leading to newly defined cell/gene therapies.

Commercialization Plans

We plan to establish sales, marketing and commercial product distribution capabilities. As our product candidates advance in clinical development, we are building upon our existing relationships with transplant centers and thought leaders, furthering our understanding of the influences on the transplant decision-making process, refining our market research into reimbursement and market access and leveraging our partnership with

Be the Match. Transplants are currently conducted in a small number of specialist sites worldwide. There are approximately 180 transplant centers in the U.S. that are accredited, of which approximately 36 collectively account for over 50% of transplant volume. In Europe, approximately 275 transplant centers are accredited through the Joint Accreditation Committee ISCT-Europe-EMBT. All of our product candidates are focused on the transplant physician as the key prescriber and decision maker.

As we advance our development programs, we will evaluate our sales and marketing resource needs and develop plans to build out a dedicated transplant center-focused medical affairs, sales and marketing organization. We intend to leverage any infrastructure developed for our most advanced product candidate, MGTA-145, to support commercialization of any additional product candidates in our portfolio for which we gain approval. In addition, we expect to build upon physicians' familiarity with MGTA-145 to accelerate adoption of our other potential products. As additional product candidates advance through our pipeline, our commercial plans may change. In particular, some of our discovery-stage pipeline assets target autoimmune disease indications, which could potentially require additional commercial resources in order to engage with referring physicians outside of transplant centers and clinical trial sites.

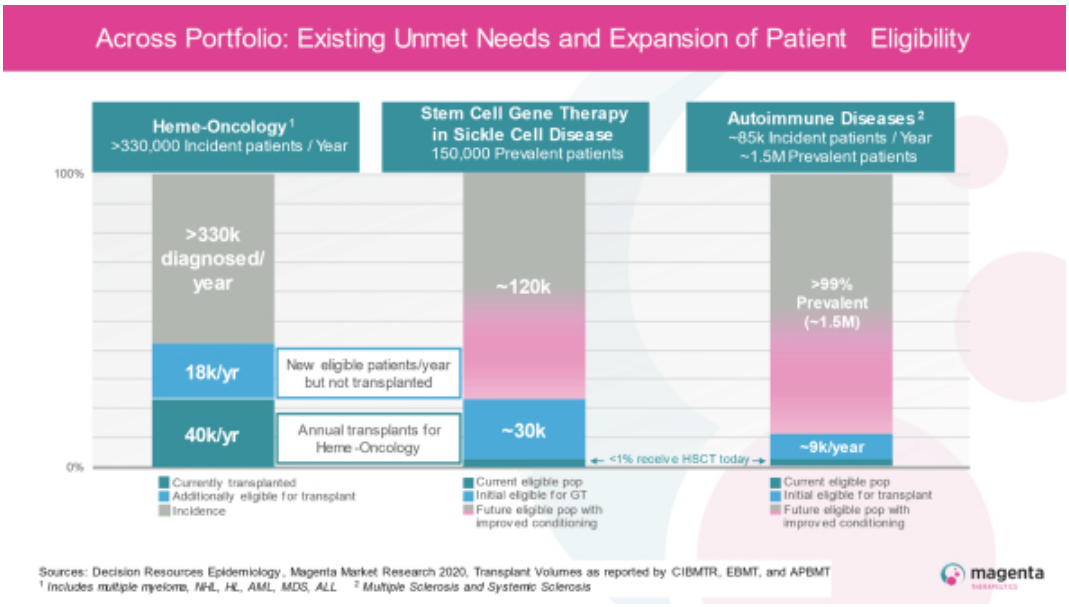
Our commercial strategy in the U.S., Europe, and Asia may include the use of strategic partners, distributors, a contract salesforce and/or the establishment of our own commercial structure.

Stem Cell Transplant Commercial Market Opportunity

Stem cell transplant is currently a large commercial market opportunity and approximately 90,000 patients annually have a stem cell transplant in the U.S., Europe and Asia. This is a significant existing potential market for Magenta medicines. However, this number represents only approximately 50% of the patient population that is eligible for stem cell transplant given the existing barriers and risks that can prevent eligible patients from proceeding to transplant.

We believe our portfolio of product candidates could not only improve upon existing approaches but also extend the curative power of stem cell transplant to more patients. Each of our product candidates is designed to address distinct unmet needs in the stem cell transplant patient journey. By using multiple Magenta products, physicians would be able to tailor the transplant procedure, thereby improving patient outcomes and increasing the potential for every eligible patient to benefit from stem cell transplant.

Across diseases where transplant has been shown to result in improved patient outcomes, only a fraction of eligible patients currently receives a transplant because the current risks and challenges associated with the drug products used to prepare patients often outweigh the potential for a cure. Depending on the disease, the barriers for treatment currently include the risk of morbidity and mortality associated with current conditioning regimens, efficiently obtaining an adequate cell dose to complete the transplant and finding a matched donor. We believe that by removing some of the major barriers to transplant with Magenta's programs, we can potentially enable safe and effective stem cell transplant for more of the 175,000 eligible patients worldwide. Today 90,000, or approximately 50%, of eligible patients worldwide undergo stem cell transplant. Further, by optimizing the benefit versus risk tradeoff, we believe the eligible patient populations could increase beyond the current numbers.



We have assessed the existing stem cell transplant market and potential eligible patient population in major global markets: U.S., Germany, France, U.K., Italy, Spain and Japan on a per-indication basis to estimate the potential number of patients that could benefit from Magenta's product candidates.

Blood Cancers: *Stem cell transplant is an existing standard of care for many diseases, however outcomes can be impacted by many factors, including lack of a matched donor or poor mobilization, and a significant number of eligible patients do not receive a transplant because of the toxicity of conditioning:*

Our targeted conditioning programs, including our MGTA-117 product candidate, have the potential to provide more effective targeted conditioning for blood cancer patients, particularly allogeneic transplant candidates, who currently weigh the tradeoffs of long-term efficacy and toxicity with current conditioning regimens that impact patient outcomes. Our MGTA-145 product candidate has the potential to address the challenges in mobilizing and collecting stem cells faced by patients and healthy donors for autologous and allogeneic transplant in blood cancer patients.

Multiple myeloma, a cancer arising from plasma cells, is diagnosed in approximately 64,000 patients annually in the major global markets. Multiple myeloma represents the second most common blood cancer treated by autologous stem cell transplant. Following diagnosis, patients typically undergo treatment with one or more therapeutic classes which may include chemotherapy, immunotherapy, targeted agents, and/or corticosteroids. After one or more courses of initial treatment, patients may proceed to a stem cell transplant depending on whether they are considered an appropriate candidate depending on several patient- and disease-related factors. Currently, approximately 15,300 multiple myeloma patients receive a stem cell transplant annually in the major global markets.

Non-Hodgkin's and Hodgkin's lymphomas, cancers arising from lymphocytes or white blood cells, are diagnosed in approximately 200,000 patients annually in the major global markets. Non-Hodgkin's lymphoma, or NHL, is the most common group of blood cancers, the largest of which is Diffuse Large B-Cell Lymphoma, comprising approximately 33% of cases. Both major types of lymphomas can be treated by autologous stem cell transplant. Following diagnosis, patients typically undergo treatment with one or more therapeutic classes which may include chemotherapy, immunotherapy, cell therapy, targeted agents, and/or corticosteroids. After one or more courses of initial treatment, patients may proceed to a stem cell transplant depending on whether they are

considered an appropriate candidate depending on several patient- and disease-related factors. Currently, approximately 10,500 lymphoma patients receive a stem cell transplant annually in the major global markets.

AML is a cancer arising from myeloid cells, an immature white blood cell found in the bone marrow, is diagnosed in approximately 36,000 patients annually in the major global markets. Eligibility for a stem cell transplant is determined by several criteria including patient fitness (including age and comorbidities), cytogenetic risk status and response to induction therapy. Approximately 40% of newly diagnosed AML patients become eligible for transplant to achieve a more durable remission based on the criteria outlined. However, the current challenges of stem cell transplant, including highly toxic chemotherapy conditioning regimens, limit transplant to approximately 60% of those patients who are otherwise eligible. Currently, approximately 8,400 patients with AML receive a stem cell transplant annually in the major global markets.

MDS occurs when the blood-forming cells in the bone marrow become abnormal, leading to low numbers of one or more types of blood cells. It is diagnosed in approximately 46,000 patients annually in the major global markets. Approximately 35% of newly diagnosed MDS patients have intermediate- to high-risk disease and one-third of those are eligible for stem cell transplant based on patient fitness (including age and comorbidities) and blast count. However, the current challenges of stem cell transplant, including highly toxic chemotherapy conditioning regimens, limit transplant to approximately 60% of those MDS patients who are otherwise eligible. Currently, approximately 2,900 patients with MDS receive a stem cell transplant annually in the major global markets.

ALL is a cancer that develops from immature white blood cells and is common in children. It is diagnosed in approximately 11,000 patients annually in the major global markets. Currently, approximately 3,800 patients with ALL receive a stem cell transplant annually in the major global markets.

Hematopoietic Stem Cell-Based Gene Therapies: *Stem cell gene therapy is a promising treatment option but is limited by the same conditioning challenges as standard stem cell transplant, as the current standard of care, busulfan, has many risks including long-term infertility and secondary cancers. Additionally, all HSC-based gene therapy patients require a high dose of stem cells for gene modification, and sickle cell patients specifically have limited options and experience significant safety risks with current mobilization regimens.*

Our MGTA-117 conditioning program has the potential to provide safer, targeted conditioning for patients who are eligible to receive autologous stem cell gene therapies, including, but not limited to, patients with sickle cell disease, beta thalassemia, and lysosomal storage disorders. MGTA-117 may also further expand the number of patients who are eligible for these currently investigational gene therapy product candidates. Our MGTA-145 product candidate has the potential to address patients with sickle cell disease who cannot receive G-CSF because of the risk of triggering sickle cell crises, as well as other patients requiring collection of stem cells prior to HSC-based gene therapy.

Sickle cell disease affects over 150,000 patients in major global markets. Approximately 20%, or 30,000, of these patients have severe disease (based on annualized sickle cell crises) and are therefore eligible for stem cell transplant or gene therapy once the current risks of the transplant are factored in.

Beta-thalassemia affects approximately 7,500 patients in the U.S., 7,000 patients in Italy, and 2,600 patients in Germany, France, U.K., Spain and Japan annually. Approximately 70% of these patients, or 12,500 patients, have severe disease, or beta-thalassemia major, and are therefore eligible for stem cell transplant.

Autoimmune Diseases: *emerging data support use of stem cell transplant as a one-time therapy, however the high morbidity and mortality associated with current conditioning regimens limit the uptake of transplant as a therapeutic option.*

MGTA-145 product candidate has the potential to be the first product specifically indicated for the mobilization of autoimmune disease patients, without the risks associated with G-CSF. In addition, our CD45

conditioning program has the potential to provide safer, targeted conditioning for autoimmune disease patients eligible to receive autologous transplant. We are developing targeted conditioning approaches to grow the use of transplant in autoimmune disease significantly.

Multiple sclerosis affects over 1 million patients worldwide and approximately 62,000 new patients are diagnosed annually in the major global markets. To assess current eligibility in this population, we focused on the patients with active relapsing-remitting disease and relapsing secondary progressive multiple sclerosis patients who are not adequately treated by current therapies. We believe this population represents more than 6,000 diagnosed severe multiple sclerosis patients annually who are eligible for stem cell transplant under current guidelines. Given stem cell transplant's proven ability to durably eliminate relapses and disease activity in multiple sclerosis patients, we believe a safe blood and immune reset would be a viable option for those patients with highly active disease beyond what therapeutics can manage. Currently fewer than 10% of eligible multiple sclerosis patients receive a stem cell transplant because the risk of the process outweighs the benefits of a potential cure, and we believe we can significantly expand this number.

Systemic sclerosis, or scleroderma, is a chronic connective tissue disease that is characterized by thickening of the skin. It affects over 245,000 patients and approximately 21,000 new patients are diagnosed annually in the major global markets. Although 35% of scleroderma patients suffer from diffuse cutaneous disease and are therefore eligible for stem cell transplant today, currently fewer than 10% of eligible scleroderma patients receive a stem cell transplant. However, with the recent addition of stem cell transplant into the EULAR treatment guidelines for scleroderma and with the opportunity for a safer transplant procedure, we believe transplant would be a viable option for the severe scleroderma patient population who have no other therapeutic options available.

Manufacturing

We do not own or operate, and have no plans to establish, any manufacturing facilities. We currently depend on third-party contract development and manufacturing organizations, or CDMOs, for all of our requirements of raw materials, drug substance and drug product for our preclinical research and our ongoing clinical trials of MGTA-145, MGTA-117 and CD45-ADC. We have not entered into long-term agreements with our current CDMOs.

We intend to continue to rely on CDMOs for later-stage development and commercialization of MGTA-145, as well as the development and commercialization of MGTA-117, and CD45-ADC, and other product candidates that we may identify. Although we rely on CDMOs, we have personnel and consultants with extensive process, product development and manufacturing experience to oversee the development, manufacturing and overall relationships with our CDMOs.

In the case of MGTA-145, we have manufactured, and released for clinical use, drug substance and drug products which have been manufactured by our CDMOs to satisfy our immediate and near term clinical and preclinical needs. We expect to refine, scale, and optimize the process, including the final product formulation, for our development and commercial supply needs. The late-stage development efforts are underway for MGTA-145 and our ability to manufacture phase appropriate product quality and purity at a favorable yield is still to be determined.

In the case of MGTA-117, we have developed, manufactured, and released for early clinical use, drug substance and drug product which have been manufactured by our CDMOs to satisfy our immediate and near term clinical and preclinical needs. We expect to refine, scale, and optimize the process, including the final product formulation, for our development and commercial supply needs.

In the case of CD45-ADC, we are developing a process to produce preclinical and early clinical trial material manufactured by our CDMOs to satisfy our immediate and near term clinical and preclinical needs. We expect to refine, scale, and optimize the process, including the final product formulation, for our development and commercial supply needs.

As our product candidates advance through development and commercialization, we expect to enter into longer-term commercial supply agreements with key suppliers and manufacturers to fulfill and secure the ongoing and planned preclinical, clinical, and, if our product candidates are approved for marketing, commercial supply needs for ourselves and our collaborators.

Manufacturing of any product candidate is subject to extensive regulations that impose various procedural and documentation requirements, which govern recordkeeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. We expect that all of our CDMOs will manufacture MGTA-145, MGTA-117 and CD45-ADC under current Good Manufacturing Practice, or cGMP, conditions. cGMP is a regulatory standard for the production of pharmaceuticals to be used in humans.

Competition

The biotechnology industry is extremely competitive in the race to develop new products and treatment modalities. While we believe we have significant competitive advantages with our expertise in transplant medicine, preclinical and clinical development expertise, our comprehensive approach to patient care and intellectual property position, we may face competition for our development programs from companies focused on traditional therapeutic modalities, such as small molecules and antibodies, as well as companies developing next-generation cell therapies. Competition is likely to come from multiple sources, including larger pharmaceutical companies, biotechnology companies and academia. For any products that we may ultimately commercialize, not only will we compete with any existing therapies and those therapies currently in development, we will also have to compete with new therapies that may become available in the future. We believe we are the only company that is committed to addressing multiple major opportunities in stem cell transplant to revolutionize an entire field of medicine. We are building a portfolio of novel therapeutic development programs to address multiple major unmet medical needs inherent to the existing stem cell transplant process, which distinguishes us from our competition.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals, and product marketing than we currently do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Stem cell transplant is used to treat a range of diseases and indications. We are aware of many companies that are developing therapeutics, including biologics, small molecules, and cell and gene therapies that are directed to the treatment of blood cancers, genetic diseases and autoimmune diseases that overlap with current stem cell transplant indications.

The following overview is focused on companies that are developing technologies to improve the distinct steps of stem cell transplant.

Competitors for our targeted conditioning programs include the following:

MGTA-117:

- Medexus Pharmaceuticals, Inc., which is developing treosulfan (reduced intensity conditioning alkylating agent used in allogeneic stem cell transplant) to replace busulfan; and
- Jasper Therapeutics, Inc., which is developing an antibody to CD117 that is not conjugated to a payload.

CD45-ADC:

- Actinium Pharmaceuticals, Inc., which is developing an antibody to CD45 that is linked to radioisotope iodine-131; and
- Molecular Templates Inc., which is developing an antibody to CD45 that is conjugated to engineered Shiga-toxin.

Competitors for our stem cell mobilization and collection program include the following:

- BioLineRx Ltd., which is developing BL-8040, a peptide that functions as a high-affinity antagonist for CXCR4. They have Phase 3 data in multiple myeloma patients;
- Yifan Pharmaceutical Co., Ltd., which is developing YF-H-2015005, a peptide that functions as a high-affinity antagonist for CXCR4 (in China); and
- TaiGen Biotechnology Co., Ltd. & GPCR Therapeutics, Inc., which are developing burixafor, a CXCR4 receptor antagonist.

Competitors for our research programs include the following:

- Allogene Therapeutics, Inc., which is developing an antibody to CD52 that is not conjugated to any toxin;
- Telix Pharmaceuticals Ltd, which is developing a CD66-radioconjugate;
- Cellectis S.A., which is developing an anti-CD52 monoclonal antibody for lymphodepletion; and
- Precision Biosciences, Inc., which is developing foralumab, a humanized anti-CD3 monoclonal antibody (Phase 1).

Licenses and Collaborations

Harvard University License Agreement

In November 2016, we entered into a license agreement with Harvard University, or Harvard, pursuant to which Harvard granted us the worldwide exclusive, subject to Harvard's retained right solely for research and educational purposes, sublicensable, right, to research, develop and commercialize licensed products under certain conditioning-related and mobilization-related patents. The license granted to us under the Harvard Agreement is also subject to any retained rights of the U.S. government in the licensed patents. Under the terms of the agreement, which we refer to as the Harvard Agreement, we will be responsible for all research, development, regulatory and commercialization activities related to licensed products. We are obligated to use commercially reasonable efforts to commercialize at least two licensed products under the Harvard Agreement, including one for conditioning and one for mobilization. The license from the Harvard Agreement relates to our conditioning and mobilization programs.

Pursuant to the Harvard Agreement, we made an upfront payment to Harvard of $85,000 and issued to Harvard and the other co-owners of the licensed patent rights (The General Hospital Corporation d/b/a Massachusetts General Hospital, and Children's Medical Center Corporation) 385,063 shares of our common stock. In addition, we reimbursed Harvard for approximately $300,000 in expenses incurred by Harvard in connection with the licensed patent rights. Harvard is also entitled to receive an annual license maintenance fee of $25,000 for each calendar year through 2019 and $50,000 for each calendar year thereafter until expiration or termination of the Harvard Agreement.

Harvard is entitled to payments upon certain development and regulatory milestones for the first two licensed products of up to $7.4 million per licensed product. In addition, we must pay Harvard low-single digit

royalties on net sales of licensed products. If we or our affiliates or sublicensees under the Harvard Agreement commence a legal action to challenge the validity, enforceability or scope of any licensed patents, the royalty rate payable to Harvard will double during the pendency of such proceeding and will remain double thereafter if such action is determined in Harvard's favor. Depending on the type of licensed product, royalties are payable on a product-by-product and country-by-country basis until the later of (i) the last to expire valid claim in the applicable country covering or claiming the composition, manufacture, sale, or use of such licensed product and (ii) 12 years from the date of the first commercial sale of such licensed product in such country.

Harvard controls the filing, prosecution, and maintenance of the licensed patent rights at our expense. We have the first right, but not the obligation, to enforce licensed patent rights against third-party infringement.

The term of the Harvard Agreement will continue until the later of (i) the expiration of the last to expire valid claim under a licensed patent, and (ii) the expiration of the royalty period. Each party has the right to terminate the Harvard Agreement due to the other party's uncured material breach or insolvency. In particular, Harvard may terminate the Harvard Agreement upon our uncured failure to meet certain development and regulatory milestone deadlines set forth therein. We have the right to terminate the Harvard Agreement for convenience upon 60 days' prior written notice to Harvard. Upon termination of the Harvard Agreement for any reason, the license granted to us by Harvard will terminate.

Exclusive Research, Development Option and License Agreement with Heidelberg Pharma Research GmbH

In March 2018, we entered into an exclusive research, development option and license agreement with Heidelberg Pharma Research GmbH, or Heidelberg Pharma. We refer to this agreement, as amended, as the Heidelberg Agreement. Heidelberg Pharma has developed a proprietary antibody targeted amanitin conjugates platform. This collaboration enables our research and development efforts across several targeted conditioning programs through the combination of our proprietary antibodies and Heidelberg Pharma's antibody targeted amanitin conjugates platform.

Under the terms of the Heidelberg Agreement, Heidelberg Pharma has granted to us a worldwide, non-exclusive research license for a one-year period with respect to certain targets set forth in an agreed-to research plan. We have the option to extend such license for up to an additional three years. We also have an option to obtain an exclusive target-specific research license, which would expire two years after the exercise of such option. In addition, we will have an option to obtain a target-specific exclusive license for global development and commercialization rights to each of the product candidates resulting from the research collaboration. We may obtain such exclusive target-specific rights to up to four targets. We are required to use commercially reasonable efforts to perform our research activities under the Heidelberg Agreement and, if we exercise our right to obtain a development and commercialization license, we are required to use commercially reasonable efforts to pursue development and commercialization of a product directed to the applicable target.

In addition, we granted Heidelberg Pharma a worldwide, non-exclusive license under all of our patents and know-how, and any improvements of the foregoing developed under the Heidelberg Agreement, that are reasonably necessary or useful for Heidelberg Pharma to perform its research activities under the Heidelberg Agreement. In addition, we grant Heidelberg Pharma a worldwide, royalty-free, non-exclusive license under all joint improvements developed under the Heidelberg Agreement for non-clinical research purposes only.

Payment terms to Heidelberg Pharma include an upfront technology access fee, research exclusivity fees with respect to the two initial targets, and payments for research support. Heidelberg Pharma is entitled to additional fees of between $50,000 and $1.1 million in the aggregate if we extend the initial research license or if we exercise our research exclusivity options with respect to additional targets. Upon our exercise of an option for an exclusive development and commercialization license, with respect to a target, we are required to make a low single digit million-dollar payment to Heidelberg Pharma for each exercised option. In addition, we may be required to pay development, regulatory and commercial milestones totaling up to approximately $83.5 million

per target. We will pay Heidelberg Pharma mid-single digit royalties on a country-by-country and product-by-product basis, on worldwide net product sales of licensed products. Royalties are payable on a licensed product-by-licensed product and country-by-country basis until the later of (i) expiration of the last valid claim of a licensed patent right that covers the use, import, offering for sale, or sale of such licensed product in such country, and (ii) ten years following the first commercial sale of such licensed product in such country. We have the option to buy-down royalties at certain points during the development path of each product.

Heidelberg Pharma will own all improvements solely related to the intellectual property rights Heidelberg Pharma licensed to us under the Heidelberg Agreement. We will own all improvements solely related to the intellectual property rights that we licensed to Heidelberg Pharma and all other intellectual property rights developed under the Heidelberg Agreement for which ownership is not otherwise allocated.

Heidelberg Pharma controls the filing, prosecution, maintenance and enforcement of the intellectual property that it licenses to us under the Heidelberg Agreement. We have the right to enforce such licensed intellectual property against infringement if the infringement is competitive with our licensed products and Heidelberg Pharma does not pursue enforcement. We control the filing, prosecution, maintenance and enforcement of the intellectual property we license to Heidelberg Pharma under the Heidelberg Agreement.

The term of the Heidelberg Agreement will continue until the last to expire royalty term unless terminated earlier by either party. Each party has the right to terminate the Heidelberg Agreement due to the other party's uncured material breach on a product-by-product or target-by-target basis. We have the right to terminate the Heidelberg Agreement for convenience in its entirety or on a product-by-product, target-by-target or country-by-country basis upon 60 days' prior written notice to Heidelberg Pharma if terminating before the first commercial sale of a product in a country or upon six months' prior written notice to Heidelberg Pharma if terminating after the first commercial sale of any product directed to such target in such country. Furthermore, each party has the right to terminate the Heidelberg Agreement if the other party experiences an insolvency event (as such term is defined in the Heidelberg Agreement), provided that, in the case of any involuntary bankruptcy proceeding, such right to terminate is only effective if the party that is subject to the insolvency event consents to the involuntary bankruptcy proceeding or such proceeding is not dismissed within a certain time-period after filing thereof. Upon termination of the Heidelberg Agreement in its entirety or with respect to a product or target, all applicable licenses granted to us will terminate immediately.

Master Services Agreement with Heidelberg Pharma

In May 2019 and in connection with the Heidelberg Agreement, we entered into a master services agreement with Heidelberg Pharma. We refer to this agreement as the Heidelberg MSA. Under the terms of the Heidelberg MSA, Heidelberg Pharma agrees to perform, and cause certain of its subcontractors to perform, certain services related to development, synthesis, analytical purification, formulation, packaging, storage, stability, release testing, quality control and other related services for the purpose of supplying us with certain targeted amanitin conjugates for use in our preclinical and clinical trials. Payment terms to Heidelberg Pharma include the payment of service fees set forth in applicable work orders.

The term of the Heidelberg MSA is indefinite unless terminated earlier by either party. We have the right to terminate the Heidelberg MSA for convenience in its entirety upon 60 days' prior written notice to Heidelberg Pharma. In addition, each party has the right to terminate the Heidelberg MSA (i) if the agreement between Heidelberg Pharma and certain of its subcontractors relating to the work to be performed under the Heidelberg MSA is terminated, (ii) upon a general assignment by one of the parties for the benefit of creditors or if a petition in bankruptcy or under any insolvency law is filed by or against the other party and such petition is not dismissed within a certain time-period after it has been filed, or (iii) upon a material uncured breach of the other party that relates to the Heidelberg MSA as a whole (subject, in the case of (iii), to a cure period).

Bachem Master Development and Manufacturing Agreement

In February 2018, we entered into a Master Development and Manufacturing Agreement with Bachem Americas, Inc., or Bachem. This agreement, which we refer to as the Bachem Agreement, governs several projects related to the development and manufacture of CXCR2 agonists, including MGTA-145, each pursuant to a separate project plan. The active pharmaceutical ingredient of MGTA-145 is a 69 amino acid protein. We selected Bachem as our contract manufacturer for this program based on their deep expertise in the synthesis and production of proteins. Financial terms related to this agreement will be determined on a project-by-project basis. Bachem has produced Phase 1/2 clinical drug substance, and we are contracted with them to perform Phase 3 process development and Phase 3 GMP manufacturing of the MGTA-145 drug substance.

The term of the Bachem Agreement is initially five years and will be automatically renewed for one-year periods unless either party provides the other with written notice of nonrenewal at least three months prior to expiry. Each party may terminate the agreement upon a material uncured breach of the other party. During the term, Bachem will be restricted from producing a pre-defined set of agonists, including MGTA-145, for clinical or commercial use by any third party without our prior written consent, as long as Bachem remains our primary supplier of CXCR2 agonists. Each project plan may be terminated independently of the agreement as a whole.

Intellectual Property

Overview

We strive to protect the proprietary product candidates and technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the composition of matter of our product candidates, their methods of use, related technologies, diagnostics, and other inventions. As of December 31, 2021, our patent portfolio was composed of more than 15 issued patents and more than 250 pending patent applications in the U.S. and foreign jurisdictions. In addition, we have licensed more than 100 issued patents and pending patent applications in the U.S. and foreign jurisdictions.

Company-Owned Patent Rights Relating to Our Targeted Conditioning and Post-Transplant Complications Programs

With regard to our targeted conditioning and post-transplant complications programs, our owned patent portfolio includes six issued U.S. patents, six issued foreign patents, and more than 200 pending patent applications in the U.S. and foreign jurisdictions. Our targeted conditioning and post-transplant complications patent portfolio includes, for example, composition of matter and methods of use claims directed to program-specific ADCs and antibodies, as well as claims directed more generally to our targeted conditioning and post-transplant complications programs that provide coverage for multiple programs.

Our CD117 patent portfolio contains patent families directed to compositions and methods for the depletion of CD117+ cells as well as patent families directed to the MGTA-117 composition of matter and methods of use. As of December 31, 2021, our CD117 patent portfolio included three issued U.S. patents, more than eight pending U.S. patent applications, more than 70 patents and pending patent applications in foreign jurisdictions, three families of pending U.S. provisional patent applications, and a pending PCT application. The issued U.S. patent would be expected to expire in 2037, absent any applicable patent term extensions. Any other patents that issue from the pending patent applications in this portfolio would be expected to expire between 2037 and 2041, absent any applicable patent term extensions.

Company-Owned Patent Rights Relating to Our Mobilization Program

Our MGTA-145 patent portfolio contains patent families directed to methods of mobilizing HSCs. As of December 31, 2021, we owned one issued U.S. patent, six pending U.S. patent applications, more than 15 pending foreign patent applications, and two pending PCT patent applications. The issued U.S. patent would be

expected to expire in 2037, absent any applicable patent term extensions. Any other patents that issue from the pending patent applications would be expected to expire between 2037 and 2042, absent any applicable patent term extensions.

Company-Owned Patent Rights Relating to Our Cell Therapy Programs

Our cell therapy patent portfolio contains patent families directed to compositions of matter for AHR antagonists, including E478, methods of using these compounds, and methods of treatment using expanded HSCs. As of December 31, 2021, we owned three issued U.S. patents, seven pending U.S. patent applications, and more than 50 pending patent applications in foreign jurisdictions. The issued U.S. patents would be expected to expire in 2038, absent any applicable patent term extensions. Any patents that issue from the pending patent applications would be expected to expire between 2038 and 2039, absent any applicable patent term extensions.

In-Licensed Harvard Portfolio

We have exclusively licensed a patent portfolio from Harvard applicable to our targeted conditioning and mobilization programs that contains patent families directed to compositions and methods for non-myeloablative conditioning, compositions, and methods for mobilizing HSCs, and highly engraftable hematopoietic stem cells and their uses. As of December 31, 2021, this patent portfolio included four issued U.S. patents, four pending U.S. patent applications, and more than 30 patents and pending patent applications in foreign jurisdictions. The issued U.S. patents would be expected to expire in 2034 and 2036, absent any applicable patent term extensions. Any patents that issue from the pending patent applications in this patent portfolio would be expected to expire between 2034 and 2037, absent any applicable patent term extensions.

In-Licensed Heidelberg Portfolio

We have licensed a patent portfolio from Heidelberg Pharma applicable to our targeted conditioning and post-transplant complications programs that contains patent families directed to amatoxin conjugates, methods of treatment, and methods of synthesizing amatoxins. As of December 31, 2021, these families included more than 90 issued patents and pending patent applications in jurisdictions worldwide. The issued patents and any other patents that issue from these families would be expected to expire between 2030 and 2040, absent any applicable patent term extensions.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries in which we have filed, including the U.S., the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the U.S., a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting a patent or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted for a portion of the term effectively lost as a result of the FDA regulatory review period, subject to certain limitations and provided statutory and regulatory requirements are met. Any such patent term extension can be for no more than five years, only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. We may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. In the future, if and when our product candidates receive approval from the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents we may obtain in the future covering those products, depending upon the length of the clinical trials for each product and other factors. There can be no assurance that any of our pending patent applications will issue or that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our owned and licensed pending patent applications, and any patent applications that we may in the future file or license from third parties may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. Any issued patents that we may receive in the future may be challenged, invalidated, infringed, or circumvented. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide. For more information, see the section entitled "Item 1A. Risk Factors – Risks Related to Intellectual Property."

Other IP Rights

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors, and non-competition, non-solicitation, confidentiality, and invention assignment agreements with our employees and consultants. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties, such agreements will not be breached, or that these agreements will afford us adequate protection of our intellectual property and proprietary rights. For more information, see the section entitled "Item 1A. Risk Factors—Risks Related to Intellectual Property."

Trademarks

We have filed and obtained trademark protection for the MAGENTA THERAPEUTICS character mark and service mark logo for pharmaceutical research and development services and biochemical research and development services. We have also filed for trademark protection for the #THECOLOROFCURE character mark for promoting public awareness of medical disorders and their treatment, promoting public awareness of bone marrow diseases, cancer, tumors, infectious diseases, autoimmune diseases and related diseases and disorders, providing a website featuring medical information, and providing medical information. We plan to register trademarks in connection with our future products.

Governmental Regulation

Compliance with various governmental regulations has an impact on our business, including our capital expenditures and competitive position, which can be material. We incur costs to monitor and take actions to comply with governmental regulations that are applicable to our business, which include, among others, federal securities laws and regulations, applicable stock exchange requirements, tax laws and regulations, environmental and health and safety laws and regulations and the regulations that govern our products and drug discovery efforts. Government authorities in the U.S. at the federal, state and local level and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, such as MGTA-117, MGTA-145 and any other current or future product candidates. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

In addition to the discussion below, see “Item 1A. Risk Factors” for a discussion of material risks to us, including, to the extent material, to our competitive position, relating to governmental regulations, and see “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” together with our consolidated financial statements, including the related notes included therein, for a discussion of material information relevant to an assessment of our financial condition and results of operations, including, to the extent material, the effects that compliance with governmental regulations may have upon our capital expenditures.

U.S. drug and biologic development

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

MGTA-117, MGTA-145 and any other current or future product candidates must be approved by the FDA through either a New Drug Application, or NDA, or a Biologics License Application, or BLA, process before they may be legally marketed in the U.S. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice, or GLP, requirements;
- submission to the FDA of an application for an IND application, which must become effective before human clinical trials may begin;
- approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA or BLA;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug or biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug or biologic’s identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA or BLA;
- payment of user fees for FDA review of the NDA or BLA; and
- FDA review and approval of the NDA or BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug or biologic in the U.S.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and the regulatory scheme for drugs and biologics is evolving and subject to change at any time. We cannot be certain that any approvals for MGTA-117, MGTA-145 and any other current or future product candidates will be granted on a timely basis, or at all.

Preclinical studies and IND

Before testing any drug or biological candidate in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess safety and, in some cases, to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP regulations for safety/toxicology studies.

An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA unless, before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside of the U.S. may, but often need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials are generally conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.

- Phase 2 clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the product candidate's safety and effectiveness for its intended use, and to establish the overall benefit/risk relationship of the product candidate and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators 15 days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Phase 1, Phase 2, Phase 3 and other types of clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies, must develop additional information about the chemistry and physical characteristics of the drug or biologic and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

NDA/BLA and FDA review process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA or BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. The NDA or BLA is a request for approval to market the drug or biologic for one or more specified indications and must contain proof of safety and efficacy for a drug or safety, purity and potency for a biologic. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of

alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of an NDA or BLA must be obtained before a drug or biologic may be marketed in the U.S.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA or BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs and BLAs before it accepts them for filing and may request additional information rather than accepting the NDA or BLA for filing. The FDA generally makes a decision on accepting an NDA or BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA targets ten months from the filing date to complete its initial review of a new molecular entity NDA or original BLA and respond to the applicant, and six months from the filing date of a new molecular entity NDA or original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs or BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving an NDA or BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, withdraw the application, or request an opportunity for a hearing. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or 200,000 or more individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety, provision of a major contribution to patient care, or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity could also block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Expedited development and review programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria. Specifically, new drugs and biologics are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. For a fast track-designated product, the FDA may consider sections of the NDA or BLA for review on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. The sponsor can request that the FDA designate the product for fast track status any time before receiving NDA or BLA approval, but ideally no later than the pre-NDA or pre-BLA meeting.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biologic designated for priority review in an effort to facilitate the review.

A product may also be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and demonstrates an effect on either 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, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. The FDA may also withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Additionally, a drug or biologic may be

eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation plus intensive guidance from the FDA to ensure an efficient drug development program.

As part of the 21st Century Cures Act, Congress amended the FDCA to facilitate an efficient development program for, and expedite review of, RMATs which include cell and gene therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. RMATs do not include those human cells, tissues, and cellular and tissue based products regulated solely under section 361 of the PHSA and 21 CFR Part 1271. This program is intended to facilitate efficient development and expedite review of RMATs, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such disease or condition. A sponsor may request that the FDA designate a product candidate as an RMAT concurrently with, or at any time after, submission of an IND. The FDA has 60 calendar days to determine whether the product candidate meets the criteria, including whether there is preliminary clinical evidence indicating that the product candidate has the potential to address unmet medical needs for a serious or life-threatening disease or condition. A BLA for a regenerative medicine therapy that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with the FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A product candidate with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence from clinical studies, patient registries, or other sources of real world evidence, such as electronic health records, the collection of larger confirmatory data sets, or post-approval monitoring of all patients treated with such therapy prior to its approval.

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

Pediatric information

Under the Pediatric Research Equity Act, or PREA, certain NDAs and BLAs and certain supplements to an NDA or BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The FDCA, as amended, requires that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 trial. The initial PSP must include an outline of the pediatric trial or trials that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric trials along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials, and/or other clinical development programs.

Post-marketing requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of

adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations, or off-label use, and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing or if the FDA determines that the product is no longer safe or effective.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including recall.

Companion diagnostics and complementary diagnostics

We believe that the success of our product candidates may depend, in part, on the development and commercialization of either a companion diagnostic or complementary diagnostic. Companion diagnostics and complementary diagnostics can identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics and complementary diagnostics are regulated as medical devices by the FDA and, as such, require either clearance or approval prior to commercialization. The level of risk combined with available controls to mitigate risk determines whether a companion diagnostic device requires Premarket Approval Application approval or is cleared through the 510(k) premarket notification process. For a novel therapeutic product for which a companion diagnostic device is essential for the safe and effective use of the product, the companion diagnostic device should be developed and approved or 510(k)-cleared contemporaneously with the therapeutic. The use of the companion diagnostic device will be stipulated in the labeling of the therapeutic product. This is also true for a complementary diagnostic, although it is not a prerequisite for receiving the therapeutic.

Other regulatory matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the U.S. in addition to the FDA, including the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, or HHS, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with third party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. In the U.S., these laws include: the federal Anti-Kickback Statute, the False Claims Act, laws and regulations related to the reporting of payments to physicians and teaching hospitals, and the Health Insurance Portability and Accountability Act of 1996, or HIPAA.

The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer, pay or provide any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties for each violation, plus up to three times the renumeration involved, and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it.

The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalty laws impose civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and the potential implication of various federal criminal statutes. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The government may deem manufacturers to have “caused” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. The federal False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, as well as the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law.

HIPAA imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or knowingly and willfully making false statements, and concealing or covering up by any trick or device a material fact or making any materially false statement relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, also imposes obligations, including mandatory contractual terms and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," those independent contractors or agents of covered entities that create, receive, maintain, transmit or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

The Physician Payments Sunshine Act of 2010, as amended by the Health Care and Education Reconciliation Act, requires applicable manufacturers of covered drugs, biologics, and medical supplies (those paid for by a federal healthcare program) to report annually to CMS information related to any payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners.

Federal government price reporting laws require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs. Additional federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

Analogous state and foreign fraud and abuse 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. Such laws are generally broad and are enforced by various state agencies and private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Certain state and local laws require the registration of pharmaceutical sales representatives.

State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts. For example, in California, the California Consumer Protection Act, or CCPA, which went into effect on January 1, 2020, establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Further, the CCPA creates a private right of action for certain data breaches that result in the loss of personal information of California residents, and this private right of action may increase the likelihood of, and risks associated with, data breach litigation. Currently, clinical trial data and information governed by HIPAA are exempt from the current version of the CCPA, but possible changes to the CCPA may broaden its scope. In addition, a new California ballot initiative, the California Privacy Rights Act, or CPRA, was passed in November 2020. Effective starting on January 1, 2023, the CPRA imposes additional obligations on companies covered by the legislation and will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. Similar laws have been proposed, and likely will be proposed, in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging. For example, on March 2, 2021, the Virginia Consumer Data Protection Act, or CDPA, was signed into law. The CDPA becomes effective January 1, 2023 and contains provisions that, in

addition to other mandates, require businesses subject to the legislation to conduct data protection assessments in certain circumstances and that require opt-in consent from Virginia consumers to process certain sensitive personal information. Further data privacy and security laws and regulations in foreign jurisdictions may be more stringent than those in the U.S. (such as the European Union, which adopted the GDPR, which became effective in May 2018). Analogous state laws may additionally govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

Current and Future Legislation

In the U.S. and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

In March 2010, the Congress enacted the ACA, which, among other things:

- created an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount, which was increased to 70% by the Bipartisan Budget Act of 2018 (as of January 1, 2019), off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial

challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact our business. Prior to the Biden administration, on October 13, 2017, former President Trump signed an executive order terminating the cost-sharing subsidies that reimburse insurers under the ACA. The Trump administration concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it would discontinue these payments immediately until those appropriations were made. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On August 14, 2020, the U.S. Court of Appeals for the Federal Circuit ruled in two separate cases that the federal government is liable for the full amount of unpaid CSRs for the years preceding and including 2017. For CSR claims made by health insurance companies for years 2018 and later, further litigation will be required to determine the amounts due, if any. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued the payments were owed to them. On April 27, 2020, the United States Supreme Court reversed the U.S. Court of Appeals for the Federal Circuit's decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. It is unclear what impact these rulings will have on our business. In addition, CMS has published a final rule that gives states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The Right to Try Act, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Packaging and Distribution in the U.S.

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and requirements to notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the U.S.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result

in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other U.S. environmental, health and safety laws and regulations

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

U.S. patent term restoration and marketing exclusivity

Depending upon the timing, duration and specifics of FDA approval of MGTA-117, MGTA-145 and any other current or future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Marketing exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 as part of the ACA. This amendment to the PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Complexities associated with the larger, and often more complex, structure of biological products as compared to small molecule drugs, as well as the processes by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted four- and twelve-year exclusivity periods from the time of first licensure of the product. The FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and the FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the U.S. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the “first licensure” of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Pediatric exclusivity is another type of regulatory marketing exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods. This six-month exclusivity may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

European Union drug development

In the European Union, our future products also may be subject to extensive regulatory requirements. As in the U.S., medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which replaced the previous Clinical Trials Directive 2001/20/EC on January 31, 2022. It overhauls the current system of approvals for clinical trials in the European Union, and is aimed at harmonizing and streamlining clinical-trial authorization (for example, by providing for a streamlined application procedure via a single entry point and strictly defined deadlines for the assessment of clinical trial applications), simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. The new Clinical Trials Regulation also ensures that the rules for conducting clinical trials in the European Union will be identical, as no national implementing legislation in each European Union Member State will be required.

European Union drug marketing

Much like the Anti-Kickback Statue prohibition in the U.S., the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union and the U.K. The provision of benefits or advantages to induce or reward improper performance generally is typically governed by the national anti-bribery laws of European Union Member States, and the Bribery Act 2010 in the U.K. Infringement of these laws could result in substantial fines and imprisonment. European Union Directive 2001/83/EC, which is the European Union Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the U.K. despite its departure from the European Union.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

European Union drug review and approval

In the European Union, medicinal products can only be commercialized after obtaining a marketing authorization, or MA. There are two types of marketing authorizations.

- The centralized MA is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medical Agency, or EMA, and is valid throughout the European Union. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and medicinal products containing a new active substance indicated for the treatment of

HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the European Union, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union. Under the centralized procedure the maximum timeframe for the evaluation of a marketing authorization application, or MAA, by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

- National MAs, which are issued by the competent authorities of the European Union Member States and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a European Union Member State, this national MA can be recognized in other European Union Member States through the mutual recognition procedure. If the product has not received a national MA in any European Union Member State at the time of application, it can be approved simultaneously in various European Union Member States through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the European Union Member States in which an MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SmPC, and a draft of the labeling and package leaflet, which are sent to the other European Union Member States (referred to as the Concerned Member States) for their approval. If the Concerned Member States raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the European Union Member States (i.e., in the RMS and the Concerned Member States).

Under the above described procedures, before granting a MA, the EMA or the competent authorities of the European Union Member States make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Now that the U.K. (which comprises Great Britain and Northern Ireland) has left the European Union, Great Britain is no longer covered by centralized MAs (under the Northern Ireland Protocol, centralized MAs will continue to be recognized in Northern Ireland). All medicinal products with a current centralized MA were automatically converted to Great Britain MAs on January 1, 2021. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, the U.K. medicines regulator, may rely on a decision taken by the European Commission on the approval of a new MA in the centralized procedure, in order to more quickly grant a new Great Britain MA. A separate application will, however, still be required. The MHRA also has the power to have regard to MAs approved in the European Union Member States through decentralized or mutual recognition procedures with a view to more quickly granting an MA in the U.K. or Great Britain.

European Union market and data exclusivity

In the European Union, innovative medicinal products qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the European Union. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on a marketing authorization application with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

European Union orphan designation and exclusivity

In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions and either (i) such condition affects not more than 5 in 10,000 persons in the European Union or (ii) it is unlikely that the development of the medicine would generate sufficient return to justify the necessary investment in its development. In either case, the applicant must also demonstrate that no satisfactory method of diagnosis, prevention or treatment for the condition has been authorized (or, if a method exists, the product would be a significant benefit to those affected compared to the product available).

In the European Union, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following medicinal product approval. During this market exclusivity period, neither the EMA nor the European Commission nor any of the competent authorities in the European Union Members States can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. This period may be reduced to six years if the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Market exclusivity may also be revoked in very select cases, such as if (i) it is established that a similar medicinal product is safer, more effective or otherwise clinically superior to an authorized orphan product; (ii) the marketing authorization holder for the authorized orphan product consents to such revocation; or (iii) the marketing authorization holder for the authorized orphan product cannot supply enough orphan medicinal product. Orphan designation must be requested before submitting an application for marketing approval. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

From January 1, 2021, a separate process for orphan designation will apply in Great Britain. There will be no pre-marketing authorization orphan designation (as there is in the European Union) and the application for orphan designation will be reviewed by the MHRA, at the time of the marketing authorization application. The criteria are the same as in the European Union, save that they apply to Great Britain only (e.g., there must be no satisfactory method of diagnosis, prevention or treatment of the condition concerned in Great Britain).

The aforementioned European Union rules are generally applicable in the European Economic Area (comprising the European Union Member States plus Norway, Iceland and Liechtenstein).

Brexit and the Regulatory Framework in the U.K.

On June 23, 2016, the electorate in the U.K. voted in favor of leaving the European Union (commonly referred to as Brexit) and the U.K. formally left the European Union on January 31, 2020. A transition period began on February 1, 2020, during which European Union pharmaceutical law remained applicable to the U.K., which ended on December 31, 2020. However, the European Union and the U.K. have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of good manufacturing practice, inspections of manufacturing facilities for medicinal products and good manufacturing practice documents issued, but does not foresee wholesale mutual recognition of U.K. and European Union pharmaceutical regulations. At present, Great Britain has implemented European Union legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the European Union regulatory framework will continue to apply in Northern Ireland). The regulatory regime in Great Britain therefore currently aligns with European Union regulations, however it is possible that these regimes will diverge in future now that Great Britain's regulatory system is independent from the European Union and the TCA does not provide for mutual recognition of U.K. and European Union pharmaceutical legislation. It remains to be seen how Brexit will impact regulatory requirements for medicinal products and devices in the U.K. in the long-term.

European and United Kingdom Data Collection

The collection and use of personal health data in the European Union is governed, as of May 2018, by the General Data Protection Regulation, or GDPR. The GDPR imposes several requirements on companies that process personal data, including requirements relating to the processing of health and other sensitive data, the consent of the individuals to whom the personal data relates, the information provided to the individuals regarding data processing activities, the notification of data processing obligations to the competent national data protection authorities and certain measures to be taken when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data out of the European Economic Area, including to the U.S. Failure to comply with the requirements of the GDPR, and the related national data protection laws of the European Union Member States, may result in fines and other administrative penalties, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules, including as implemented by individual countries. In addition, further to the U.K.'s exit from the European Union on January 31, 2020, the GDPR ceased to apply in the U.K. at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the U.K.'s European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain U.K. specific amendments) into U.K. law (referred to as the U.K. GDPR). The U.K. GDPR and the U.K. Data Protection Act 2018 set out the U.K.'s data protection regime, which is independent from but aligned to the European Union's data protection regime. Non-compliance with the U.K. GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. In addition, on June 28, 2021, the European Commission adopted an adequacy decision in respect of transfers of personal data to the U.K. for a four-year period (until June 27, 2025). Similarly, the U.K. has determined that it considers all of the European Economic Area to be adequate for the purposes of data protection. This ensures that data flows between the U.K. and the European Economic Area remain unaffected.

Rest of the world regulation

For other countries outside of the European Union and the U.S., such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and

reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Additional laws and regulations governing international operations

If we further expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the U.S., no uniform policy of coverage and reimbursement for drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. For example, the ACA contains provisions that subject biological products to potential competition by lower-cost biosimilars and may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, creating a new methodology by which rebates owed are calculated for drugs that are inhaled, infused, instilled, implanted or injected, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate

data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. An increasing emphasis on cost containment measures in the U.S. has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In recent years, additional laws have resulted in direct or indirect reimbursement reductions for certain Medicare providers.

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022. Then, a 1% payment reduction will occur beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction will resume on July 1, 2022.
- The American Taxpayer Relief Act of 2012, among other things, 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 Middle Class Tax Relief and Job Creation Act of 2012 required that the Centers for Medicare & Medicaid Services reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting.

In addition, there has recently been heightened governmental scrutiny of the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, proposed and enacted legislation and executive orders issued by the former Trump administration designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. The likelihood of success of these and other measures initiated by the former Trump administration is uncertain, particularly in light of the Biden administration.

At the federal level, President Biden signed an executive order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, imposing inflation caps and supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the executive order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, to enhance the domestic drug supply chain, to reduce the price that the federal government pays for drugs, and to address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. The FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs

from Canada. Further, on November 20, 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. On December 29, 2021 CMS rescinded the Most Favored Nations rule. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. On May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization for Medicare Part B drugs, beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019.

Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden Administration may reverse or otherwise change these measures, both the Biden Administration and Congress have indicated that it will continue to seek new legislative measures to control drug costs.

The Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be.

At the state level, legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Some of these measures include price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce

prices. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other trials that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world, but have been most drastic in the European Union.

Human Capital Resources

As of December 31, 2021, we had 75 full-time employees, 25 of our employees have Ph.D. or M.D. degrees and 56 of our employees are engaged in research and development activities.

Our human capital resource objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our employees with the common purpose of helping more patients live free from disease. At Magenta, we celebrate our differences and value the power of a diverse array of people who bring all of themselves to their work. We embrace cultural, racial, gender, cognitive, social and professional diversity because we know that the only way we are going to make new cures possible is by working together. We prioritize employee development and seek to align employees' goals with Magenta's overall strategic direction. We use our equity incentive plan to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards to achieve short- and long-term results that are in the best interests of investors, Magenta's mission and our patients. For additional information on the impact of COVID-19 on our employees, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Impact of the Ongoing COVID-19 Pandemic."

Our Corporate Information

We were incorporated under the laws of the State of Delaware on June 17, 2015 under the name HSCTCo Therapeutics, Inc. In February 2016, we changed our name to Magenta Therapeutics, Inc.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, as defined in Rule 12b-2 under the Securities and Exchange Act of 1934, as amended, or the Exchange Act, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

Our principal executive offices are located at 100 Technology Square, Cambridge, MA 02139, and our telephone number is (857) 242-0170. Our website address is *www.magentatx.com*. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K.

Available Information

Our Internet address is *www.magentatx.com*. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act are available through the "Investors" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, our filings with the SEC may be accessed through the SEC's Electronic Data Gathering, Analysis and Retrieval system at *http://www.sec.gov*. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

ITEM 1A. RISK FACTORS

Set forth below are the risks that we believe are material to our investors and they should be carefully considered. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and other factors not presently known to us or that we currently believe are immaterial may affect our business, prospects, financial condition and results of operations if they occur. This section contains forward-looking statements. You should refer to the explanation of the qualifications and limitations on forward-looking statements beginning on page three of this Annual Report on Form 10-K.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.

We are a clinical-stage biotechnology company developing novel medicines to bring the curative power of stem cell transplant to more patients and have a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in June 2015. For the years ended December 31, 2021 and 2020, we reported net losses of $71.1 million and $74.9 million, respectively. As of December 31, 2021, we had an accumulated deficit of $325.6 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development costs and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require additional capital to fund our operations and if we fail to obtain necessary financing, we will not be able to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts of cash (including the net proceeds from our initial public offering, or IPO, and our subsequent public and private equity offerings) to conduct further research and development and preclinical testing and clinical trials of our product candidates, to seek regulatory approvals for our product candidates and to launch and commercialize any product candidates for which we receive regulatory approval, including potentially building our own commercial organization to address the U.S., the European Union and certain other markets. As of December 31, 2021, we had approximately $176.9 million in cash, cash equivalents and marketable securities. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with successful development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of research, preclinical studies and clinical trials for our product candidates;

- the costs to develop, maintain, and enhance a sustainable, scalable, reproducible, and transferable manufacturing process for our product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we develop or may in-license;
- the cost of milestone or other payments under any current or future license, acquisition, collaboration or other strategic transaction agreements;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the European Medical Agency, or EMA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- the cost of seeking to attract, hire and retain skilled personnel; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholder's ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect our stockholder's rights. 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.

Our company has a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We are a clinical-stage company. We were founded and commenced operations in June 2015. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates, and undertaking preclinical studies and clinical trials. Although we have initiated clinical trials for certain of our product candidates, we have not yet demonstrated an ability to successfully complete clinical trials of our product candidates; obtain marketing approvals; manufacture a commercial-scale medicine, or arrange for a third party to do so on our behalf; or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes about 10 to 15 years to develop a new medicine from the time it is discovered to when it is available for treating patients. Consequently, any predictions we make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We will need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, product candidates we may identify for development. We may not generate revenues from product sales for the next several years, if ever. Our ability to generate future revenues from product sales depends heavily on our, or our collaborators', ability to successfully:

- identify product candidates and complete research and preclinical and clinical development of any product candidates we may identify;
- seek and obtain regulatory and marketing approvals for any of our product candidates for which we complete clinical trials;
- launch and commercialize any of our product candidates for which we obtain regulatory and marketing approval by establishing a sales force, marketing, and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- qualify for adequate coverage and reimbursement by government and third-party payors for any of our product candidates for which we obtain regulatory and marketing approval;
- develop, maintain, and enhance a sustainable, scalable, reproducible, and transferable manufacturing process for the product candidates we may develop;
- establish and maintain supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for any of our product candidates for which we obtain regulatory and marketing approval;
- obtain market acceptance of any product candidates we may develop as viable treatment options;
- address competing technological and market developments;
- implement internal systems and infrastructure, as needed;
- negotiate favorable terms in any collaboration, licensing, or other arrangements into which we may enter and perform our obligations in such collaborations;
- maintain, protect, and expand our portfolio of intellectual property rights, including patents, trade secrets, and know-how;

- avoid and defend against third-party interference or infringement claims; and
- attract, hire, and retain qualified personnel.

Even if one or more of the product candidates we may develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the EMA, or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

Risks Related to Product Development and Regulatory Approval

We are early in our development efforts. If we are unable to advance our product candidates to obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts for our product candidates, including MGTA-145 and MGTA-117. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any product, and we may never be able to develop or commercialize a marketable product.

Each of our programs and product candidates will require additional preclinical and clinical development; regulatory approval, potentially in multiple jurisdictions; obtaining manufacturing supply, capacity and expertise; building of a commercial organization; substantial investment and significant marketing efforts before we generate any revenue from product sales. Our product candidates must be authorized for marketing by the FDA, or certain other foreign regulatory agencies, such as the EMA, before we may commercialize our product candidates in the U.S. or other countries.

The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and successful enrollment and completion of clinical trials, including toxicology studies, biodistribution studies and minimally efficacious dose studies in animals, where applicable, under the FDA's current Good Clinical Practices, or cGCPs, and the FDA's current Good Laboratory Practices;
- effective IND applications or Clinical Trial Authorizations that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- positive results from our preclinical and clinical programs that support a finding of safety and effectiveness and an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt of regulatory approvals from applicable regulatory authorities;
- establishment of arrangements with third-party manufacturers for clinical supply and, where applicable, commercial manufacturing capabilities;
- successful development of our internal or external manufacturing processes or transfer to larger-scale facilities operated by either a third-party contract development and manufacturing organization, or CDMO, or by us;
- establishment and maintenance of patent and trade secret protection or regulatory exclusivity for our product candidates;

- commercial launch of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effective competition against other therapies;
- establishment and maintenance of healthcare coverage and adequate reimbursement;
- enforcement and defense of intellectual property rights and claims; and
- maintenance of a continued acceptable safety profile of our product candidates following approval.

If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

The successful development of biopharmaceuticals and cell-based therapies is highly uncertain.

Successful development of biopharmaceuticals and cell-based therapies is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Blood and immune reset and cell-based therapies that appear promising in the early phases of development may fail to reach the market for several reasons including:

- preclinical study results may show the therapies to be less effective than desired or to have harmful or problematic side effects;
- clinical trial results may show the therapies to be less effective than expected (e.g., the trial failed to meet its primary endpoint or the results are not competitive compared to other therapeutic alternatives) or to have unacceptable side effects or toxicities;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals, which delays may be caused by, among other things, slow enrollment in clinical trials, delays due to investigations concerning safety, length of time to achieve study endpoints, additional requirements for data by regulatory agencies, additional time requirements for data analysis, or biologics license application, or BLA, preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the therapy uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent the therapy from being commercialized.

Success in preclinical studies and early clinical trials do not ensure that large-scale clinical trials will be successful. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one therapy to the next, and may be difficult to predict.

Even if we are successful in getting market approval, third-party payers 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.

In addition, if one of our product candidates 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 the FDA's current Good Manufacturing Practices, or cGMP, and cGCP requirements 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.

Our ongoing and planned clinical trials or those of our collaborators may reveal significant adverse events not seen in our preclinical and clinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. 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. 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 commence clinical trials are never approved as products.

It is impossible to predict when or if any product candidates we may develop will prove safe in humans. If any product candidates we develop are associated with serious adverse events, or undesirable side effects, or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations, and prospects. It is possible that product candidates that initially showed promise in early-stage testing will later have been found to cause side effects that prevent further clinical development of the product candidates.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trial, patients may drop out of our trial, or we may be required to abandon the trial or our development efforts of that product candidate altogether. We, the FDA or other applicable regulatory authorities, or an institutional review board, or IRB, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Stem cell transplant is a high-risk procedure with curative potential that may result in complications or adverse events for patients in our clinical trials or for patients that use any of our product candidates, if approved.

Stem cell transplant can cure patients across multiple diseases, but its use carries with it risks of toxicity, serious adverse events and death. Because many of our therapies are used to prepare or treat patients undergoing stem cell transplant, patients in our clinical trials or patients that use any of our product candidates may be

subject to many of the risks that are currently inherent to this procedure. In particular, stem cell transplant involves certain known potential post-procedure complications that may manifest several weeks or months after a transplant and which may be more common in certain patient populations. If serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any of our product candidates, we may need to limit, delay or abandon our further clinical development of those product candidates, even if such events, effects or characteristics were the result of stem cell transplant or related procedures generally, and not directly or specifically caused or exacerbated by our product candidates.

In addition, patients who are in our clinical studies or undergoing stem cell transplant typically have underlying disorders or compromised immune systems that make them vulnerable or fragile for undergoing additional clinical studies. For example, we began patient enrollment for our Phase 1/2 clinical trial of MGTA-117 in patients with acute myeloid leukemia, or AML, and myelodysplastic syndrome, or MDS; however, the patients who we expect to enroll in the initial phase of that trial are subject to underlying disorders that may cause negative outcomes for those patients that could slow down or even suspend the study. As a result, the FDA could put the trial on hold until we can satisfy any potential FDA concerns. If any FDA clinical hold is not lifted or if the process takes an extended period of time, our business and prospects may suffer material adverse consequences.

All serious adverse events or unexpected side effects are continually monitored per the clinical trial's approved protocol. If serious adverse events are determined to be directly or specifically caused or exacerbated by our product candidates, we would follow the trial protocol's requirements, which call for our data safety monitoring committee to review all available clinical data in making a recommendation regarding the trial's continuation.

If we are not able to identify a safe and effective dose for any of our antibody drug conjugates, or ADCs, including MGTA-117 utilizing an amanitin toxin not previously tested in humans, we may need to delay, abandon or limit our development of any potential product candidates.

ADCs utilize toxins to kill cells, and we may not be able to identify a safe and effective dose for some of our potential product candidates. ADCs, including those that have received marketing approval, have dose-dependent safety findings that can include liver toxicity, depending on the target of the ADC and the drug used in the conjugate. In addition, ADCs may have other adverse side effects including fatalities. Although our CD117-ADC, which was designed to deplete hematopoietic stem cells, or HSCs, was generally well tolerated at efficacious doses in non-human primate studies, we may not be able to ultimately show that MGTA-117 can deplete HSCs at a safe and effective dose in humans and we may need to delay, abandon or limit these development efforts. Further, MGTA-117 utilizes an amanitin toxin that has not been previously tested as an ADC toxin in humans. Other companies, for example Heidelberg Pharma (whether alone or with third parties), are developing ADCs with amanitin toxins and are expected to enter clinical trials. If such other trials encounter safety or efficacy issues, especially if related to the amanitin toxin, then our MGTA-117 program may be adversely affected.

Clinical development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates.

Our product candidates are in the preclinical development and clinical trial stages, and their risk of failure is high. It is impossible to predict when or if any of our programs will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of any of our future product candidates in humans. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider

clinically meaningful, and a clinical trial can fail at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

Successful completion of clinical trials is a prerequisite to submitting a BLA, or a new drug application, or NDA, to the FDA, a Marketing Authorization Application to the EMA and similar approval filings to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We do not know whether any of our clinical trials will begin or be completed on schedule, if at all.

We may experience delays in completing our preclinical studies and initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any current or future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators, IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organization, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of patients required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require, that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of preclinical studies and clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other blood and immune reset and cell-based therapies that raise safety or efficacy concerns about our product candidates.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board for such trial or FDA or

other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including 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 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 or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our preclinical or future clinical development programs may harm our business, financial condition and prospects significantly.

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

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including impacts that have resulted, or may in the future result, from the COVID-19 pandemic. 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. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient 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;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

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. Since 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 in such clinical trial site.

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.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials, and such results do not guarantee approval of a product candidate by regulatory authorities.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in the results of completed clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for their product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial procedures and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidate, and, correspondingly, our business and financial prospects would be negatively impacted.

Additionally, several of our past, planned and ongoing clinical trials utilize an “open-label” trial design. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

Even if we complete clinical development of MGTA-145, MGTA-117 or any other product candidates, there can be no assurance that the FDA, EMA, or other regulatory authorities will approve MGTA-145, MGTA-117 or any other product candidates for marketing. Additionally, as of May 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals, however, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and, due to the COVID-19 pandemic and travel restrictions, the FDA is unable to complete such required inspections during the review period. In 2020 and 2021, a number of companies announced receipt of Complete Response Letters due to the FDA’s inability to complete required inspections for their applications.

Interim, preliminary, and “topline” data from our clinical trials that we announce or publish from time to time may change as more patient data become available following the interim data; preliminary data are subject to audit and verification procedures, and deeper analysis of the data beyond the topline data may provide more color and context to the data, all of which could result in material or other changes in the final data.

From time to time, we may disclose interim data from our preclinical studies and clinical trials, which are based on an interim analysis of then-available data from ongoing studies or trials. Interim data from our

preclinical studies and clinical trials that we may complete are subject to the risk that one or more of the clinical observations may materially change as patient enrollment continues and more patient data become available from the particular study or trial. As a result, interim data should be viewed with caution until final data are available. Adverse differences between interim data and final data could significantly harm the development of our product candidates and our business prospects with respect thereto.

We may also announce or publish preliminary data from our preclinical studies or clinical trials, which are based on a preliminary analysis of final data. Preliminary data from our preclinical studies and clinical trials are subject to change following a more comprehensive review of the data from the particular preclinical study or trial. We also make assumptions, estimations, calculations and conclusions as part of our preliminary analyses of the data, and we may not have received, or had the opportunity to fully and carefully evaluate, all of the data at the time of making such assumptions, estimations, calculations and/or conclusions. As a result, preliminary data remain subject to audit and verification procedures that may result in the final data being different from the preliminary data we previously announced or published.

We may also announce or publish topline data from our preclinical studies and clinical trials, which are a subset of the total data intended to provide the important results from the study or trial. As a result, deeper analysis of the data beyond the topline data may provide more color and context to the results. Any adverse color and context provided by the broader data to the topline data could significantly harm the development of our product candidate and our business prospects with respect thereto.

Further, third parties, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our business prospects. In addition, the information we announce or publish regarding a particular preclinical study or clinical trial may represent only a portion of extensive information generated from that study or trial, and our shareholders or other third parties may not agree with what we determine is material, important or otherwise appropriate information to include in our disclosure.

If the interim, preliminary, or topline data that we report differ materially from final results, or if third parties, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business prospects, operating results or financial condition. Further, announcement of preliminary, interim or topline data by us or differences between that data and the final data could result in volatility in the price of our common stock.

We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates; these decisions may prove to be wrong and may adversely affect our business.

Although we intend to explore other therapeutic opportunities, in addition to the product candidates that we are currently developing, we may fail to identify successful product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;

- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

If we are unable to successfully develop our current programs into a comprehensive portfolio of product candidates, or experience significant delays in doing so, we may not realize the full commercial potential of our current and future product candidates.

We are developing our product candidates so that they can each be used individually or in combination with each other. In particular, we are focused on a product development strategy that includes leveraging the synergies among a comprehensive portfolio of our product candidates. Our success may depend, in part, on our ability to develop a complementary product portfolio with product candidates that, together or individually, will address the major opportunities inherent in the existing stem cell transplant process. Given our limited experience in developing product candidates that have received marketing approval, we may not be successful in developing some of our product candidates. The failure of one of our product candidates to obtain regulatory approval or market acceptance may affect our ability to expand our market opportunities for our other product candidates or programs. Although we may develop product candidates that ultimately obtain marketing approval, if we are unable to successfully develop our current programs into a comprehensive portfolio of product candidates, or experience significant delays in doing so, we may not realize the full commercial potential of our current and future product candidates.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications among many potential options. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial medicines or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable medicines. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such event could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We have no experience as a company in obtaining regulatory approval for a drug or biologic.

As a company, we have never obtained regulatory approval for, or commercialized, a drug or biologic. It is possible that the FDA may refuse to accept any or all future NDA or BLAs for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval for any current or future product candidates. If the FDA does not approve any future NDAs or BLAs, it may require that we conduct additional costly clinical, preclinical or manufacturing validation studies before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA or BLA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing MGTA-145, MGTA-117 or any other product candidate, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA, BLA or other application that we submit. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for our applications in foreign jurisdictions.

Because we are developing product candidates for the treatment of diseases in which there is little clinical experience using new technologies, there is increased risk that the FDA, the EMA, or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results, and these results may be difficult to analyze.

During the regulatory review process, we will need to identify success criteria and endpoints such that the FDA, the EMA, or other regulatory authorities will be able to determine the clinical efficacy and safety profile of any product candidates we may develop. As we are initially seeking to identify and develop product candidates to treat diseases in which there is little clinical experience using new technologies, there is heightened risk that the FDA, the EMA, or other regulatory authorities may not consider the clinical trial endpoints that we propose to provide clinically meaningful results (reflecting a tangible benefit to patients). In addition, the resulting clinical data and results may be difficult to analyze. Even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoints to a degree of statistical significance. This may be a particularly significant risk for many of the genetically defined diseases for which we plan to develop product candidates because many of these diseases have small patient populations and designing and executing a rigorous clinical trial with appropriate statistical power is more difficult than with diseases that have larger patient populations. Further, even if we do achieve the pre-specified criteria, we may produce results that are unpredictable or inconsistent with the results of the non-primary endpoints or other relevant data. The FDA also weighs the benefits of a product against its risks, and the FDA may view the efficacy results in the context of safety as not being supportive of regulatory approval. Other regulatory authorities in the European Union and other countries may make similar comments with respect to these endpoints and data. Any product candidates we may develop will be based on a novel technology that makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate we may develop, and any such approval may be for a narrower indication than we seek.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if any product candidates we may develop meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or

administrative action, or changes in regulatory authority policy during the period of product development, clinical trials, and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or distribution and use restrictions under a Risk Evaluation and Mitigation Strategy, or REMS. These regulatory authorities may require precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we may develop. Any of the foregoing scenarios could materially harm the commercial prospects for any product candidates we may develop and materially adversely affect our business, financial condition, results of operations, and prospects.

Even if we obtain regulatory approval of any of our product candidates, the approved products may be subject to post-approval studies and will remain subject to ongoing regulatory requirements. If we fail to comply, or if concerns are identified in subsequent studies, our approval could be withdrawn, and our product sales could be suspended.

If we are successful in obtaining regulatory approval for MGTA-145, MGTA-117 or any of our other product candidates, regulatory agencies in the U.S. and other countries where a product will be sold may require extensive additional clinical trials or post-approval clinical trials that are expensive and time-consuming to conduct. Alternatively, we may not be able to conduct such additional trials, which might force us to abandon our efforts to develop or commercialize certain product candidates. Even if post-approval studies are not requested or required, after our products are approved and on the market, there might be safety issues that emerge over time that require a change in product labeling, additional post market studies or clinical trials, imposition of distribution and use restrictions under a REMS, or withdrawal of the product from the market, which would cause our revenue to decline.

Additionally, any products that we may successfully develop will be subject to ongoing regulatory requirements after they are approved. These requirements will govern the manufacturing, packaging, marketing, distribution, and use of our products. If we fail to comply with such regulatory requirements, approval for our products may be withdrawn, and product sales may be suspended. We may not be able to regain compliance, or we may only be able to regain compliance after a lengthy delay, significant expense, lost revenues and damage to our reputation.

A Breakthrough Therapy Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We plan to seek a Breakthrough Therapy Designation for our product candidates if the clinical data support such a designation for one or more product candidates.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification.

The regenerative medicine advanced therapy, or RMAT, designation by the FDA for any of our product candidates may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We plan to seek an RMAT designation for our product candidates if the clinical data support such a designation for one or more product candidates.

Designation as an RMAT is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a RMAT, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of RMAT designation for our product candidates may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify for RMAT designation, the FDA may later decide that the biological products no longer meet the conditions for qualification.

Accelerated approval by the FDA, even if granted for our current or any other future product candidates, may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive regulatory approval.

We may seek accelerated approval of our current or future product candidates using the FDA's accelerated approval pathway. Even if we do receive accelerated approval, however, we may not experience a faster development, regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate FDA approval for our product candidates.

Our current product candidates and future product candidates may not be eligible for Orphan Drug status.

The FDA granted Orphan Drug designation to MGTA-145 for the mobilization of HSCs to the peripheral blood for collection and subsequent transplant in May 2020 and we plan to seek Orphan Drug designation for our other product candidates if the clinical data support such a designation. The U.S. and Europe may designate drugs for relatively small patient populations as orphan drugs. Orphan Drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, but does make the product eligible for orphan drug exclusivity, reduced filing fees and specific tax credits. Generally, if a company receives the first marketing approval for a product with an Orphan Drug designation in the clinical indication for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity means that the FDA will not approve another application to market the same drug for the same indication, except in limited circumstances, for a period of seven years in the U.S. This exclusivity, however, could block the approval of our proposed product candidates if a competitor obtains marketing approval before us. However, even if we obtain orphan drug exclusivity for any of our proposed product candidates, we may not be able to maintain it. For example, if a competitive product is shown to be clinically superior to our product candidates, any orphan drug exclusivity we have will not block the approval of such competitive product.

On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's preexisting regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The law reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. Moreover, in the Consolidated Appropriations Act of 2021, Congress did not further change this interpretation when it clarified that the interpretation codified in FDARA would apply in cases where the FDA issued an orphan designation before the enactment of FDARA but where product approval came after the enactment of FDARA. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A Fast Track Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

The FDA has broad discretion whether or not to grant a Fast Track Designation for a particular indication, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Receipt of Fast Track Designation may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not guarantee qualification for the FDA's priority review procedures. In addition, the FDA may withdraw any Fast Track Designation at any time. We may seek Fast Track Designation for our product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates.

We may seek priority review designation for our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

We may request priority review for our product candidates, however, we cannot assume that our product candidates will meet the criteria for that designation. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster development or regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory authorities, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities while local, national and international conditions warrant. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a

prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 pandemic, a number of companies announced receipt of Complete Response Letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies, such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Risks Related to Reliance on Third Parties and Manufacturing

We rely on third parties to conduct our preclinical and clinical trials and will rely on them to perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

Although we have recruited a team that has experience with clinical trials, as a company we have relied upon, and plan to continue to rely upon medical institutions, clinical investigators, contract laboratories and other third parties, or our CROs, to conduct preclinical studies and future clinical trials for our product candidates. We expect to rely heavily on these parties for execution of preclinical and future clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we will be responsible for ensuring that each of our preclinical and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs will be required to comply with regulations, including cGCPs for conducting, monitoring, recording and reporting the results of preclinical and clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with cGCPs. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements in the FDA's cGMPs requirements. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.

Although we intend to design our planned clinical trials for our product candidates, for the foreseeable future CROs will conduct all of our planned clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials will also result in less day-to-day control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any preclinical studies or clinical trials with which such CROs are associated with may be extended, delayed or terminated. In such cases, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates in the subject indication could be harmed, our costs could increase and our ability to generate revenue could be delayed.

We currently rely, and expect to continue to rely, on third parties to manufacture our clinical product supplies, and we intend to rely on third parties to produce and process our product candidates, if approved. This reliance increases the risk that we may not have sufficient quantities of our product candidates or may not be able to produce such quantities at an acceptable cost or quality level, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and, as a result, we rely, and expect to continue to rely, on third parties for the manufacture of our clinical product supplies and product candidates for our clinical development efforts, as well as for the potential commercial manufacture of our product candidates, if approved, and the related label and packaging activities involved in commercialization. We rely on these third parties to produce our clinical product supplies and product candidates at sufficient quality and quantity to support our development and commercialization efforts. Our reliance increases the risk that we will have insufficient quantities of our product candidates or that our product candidates will not be produced at an acceptable cost or quality level, which could delay, prevent or impair our development or commercialization efforts.

Additionally, even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- regulatory or judicial termination or modification of our agreement with the third party due to the third party's insolvency or winddown, a change in regulations or other reason;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

If any CDMO with whom we contract fails to or otherwise becomes unable to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities, technical knowledge or resources, or enter into an agreement with a different CDMO, which we may not be able to do on reasonable terms, if at all. In addition, if we have a dispute with any of our CDMOs or should any of our agreements with our CDMOs terminate for any reason, in particular our agreements with Bachem Americas, Inc. and Heidelberg Pharma, it could disrupt our supply and replacing these CDMOS would likely be difficult. In these scenarios, our clinical trials could be delayed significantly as we establish alternative supply sources.

In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternative supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. We cannot provide any assurance that the technology transfer to another CDMO will be successful in producing our product candidate in sufficient quantities or of acceptable quality, if at all, or that we or another CDMO will produce a comparable product to the satisfaction of the FDA or other comparable regulatory authorities, which could delay, prevent or impair the development or commercialization of our product candidates. In addition, there is typically a transition period when a new CDMO commences work. The delays associated with the verification of a new CDMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CDMO may possess technology related to the manufacture of our product candidate that such CDMO owns independently. This would increase our reliance on such CDMO or require us to obtain a license from such CDMO in order to have another CDMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacture. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

The facilities used by our CDMOs to manufacture our product candidates must be approved and may be inspected by the FDA and other comparable regulatory authorities in connection with the submission of our marketing applications to, and review by, the FDA or other comparable regulatory authorities or based on their work for other clinical trial sponsors. While we have contractual relationships with our CDMOs, our oversight of manufacturing activities is limited and we do not and will not control the manufacturing process of, and will be completely dependent on, our CDMOs for compliance with cGMPs and other regulatory requirements in connection with the manufacture of our product candidates. In addition, certain of our CDMOs may themselves rely on other third parties to produce all or a part of our product candidates. If our CDMOs (or any of the third parties upon which they rely) cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other applicable regulatory authorities in other jurisdictions, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. While we may review the compliance history and performance of our CDMOs, we have no control over the ability of our CDMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable regulatory authorities in other jurisdictions does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

Our product candidates may compete with other product candidates and approved products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Furthermore, given the limited number of available manufacturing slots and the long lead times needed to reserve them, manufacturers require monetary commitments in connection with such reservations as well as fees for changes or cancellations in the reserved manufacturing slots. As a result, we may wait to reserve manufacturing slots until we can be informed by data from the clinical trials of our product candidates, which may be several months from the time we request manufacturing slots. Any

significant delay in the supply of clinical materials for our product candidates could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates. Alternatively, we may project when we may need additional clinical material for our product candidates and reserve manufacturing time-slots "at-risk" prior to our product candidates having generated data from their then current clinical trials. Such projections involve risks and uncertainties and may result in additional costs or delays in manufacturing clinical materials for our product candidates when and if we actually need them.

Any contamination in our or our third parties' manufacturing process, shortages of raw materials or reagents or failure of any of our key suppliers to deliver necessary components of our product candidates could result in delays in our clinical development or marketing schedules.

Given the nature of biologics manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our or our third-party vendors' ability to produce our product candidates on schedule and could therefore harm our results of operations and cause reputational damage.

The raw materials required in our and our third-party vendors' manufacturing processes are derived from biological sources. We cannot assure you that we or our third-party vendors have, or will be able to obtain on commercially reasonable terms, or at all, sufficient rights to these materials derived from biological sources. Such raw materials are difficult to procure and may also be subject to contamination or recall or be of insufficient quality. A material shortage, contamination, recall, or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the clinical and commercial manufacturing of our product candidates, which could materially and adversely affect our operating results and development timelines. We rely on third-party suppliers for the supply and manufacture of certain components of our technology and product candidates, including a single supplier in some cases. Should our ability to procure the necessary components for our product candidates from our suppliers be compromised, our ability to continuously operate would be impaired until an alternative supplier is sourced, qualified and tested, which could delay or limit our ability to produce a clinical and commercial supply of our product candidates and harm our business.

Moreover, if there is a disruption to our manufacturing operations or one or more of our third-party manufacturers' or suppliers' relevant operations, such as due to the impact of the COVID-19 pandemic, including due to staffing shortages or reprioritizations, production slowdowns or stoppages or interruptions in global shipping, the supply of the related product candidate will be delayed until we or such manufacturer or supplier restores the affected facilities or we or they procure alternative manufacturing facilities or sources of supply. Our ability to progress our preclinical and clinical programs could be materially and adversely impacted if any of the third-party suppliers upon which we rely for preclinical and clinical stage product candidate supply were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues. Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

If we handle biological materials in a manner that causes injury, we may be liable for damages.

Our research and development activities involve the use of biological and hazardous materials. Although we believe our safety procedures for handling and disposing of these materials complies with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. We do not carry specific biological waste insurance coverage or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended or terminated.

Third-party manufacturers and any third-party collaborators may be unable to successfully scale-up manufacturing of our current or future product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.

In order to conduct clinical trials of MGTA-145, MGTA-117, and our other current and future product candidates, we will need to work with third-party manufacturers to manufacture them in sufficient quantities. We have not yet manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates. Our manufacturing partners or our third-party collaborators may be unable to successfully increase the manufacturing capacity of MGTA-145, MGTA-117, and our other current or future product candidates in a timely or cost-effective manner, or at all. We will make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will result in therapies that are safe and effective. The process of making these changes could delay, prevent or impair the clinical development or commercialization of our product candidates. In addition, quality issues may arise during scale-up activities. If our manufacturing partners or collaborators are unable to successfully scale up the manufacture of our current or future product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Risks Related to Commercialization, Government Regulation and Competition

We may never obtain FDA approval for any of our product candidates in the U.S., and even if we do, we may never obtain approval for or commercialize any of our product candidates in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to eventually market any of our product candidates in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding safety and efficacy. Approval by the FDA in the U.S., if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

Failure to obtain marketing approval in foreign jurisdictions would prevent any product candidates we may develop from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.

In order to market and sell any product candidates we may develop in the European Union and many other foreign jurisdictions, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these

third parties may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our medicines in any jurisdiction, which would materially impair our ability to generate revenue.

Even if we obtain marketing approvals for any product candidates we develop, the terms of approvals and ongoing regulation of our products could require the substantial expenditure of resources and may limit how we manufacture and market our products, which could materially impair our ability to generate revenue.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such medicine, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, applicable product tracking and tracing requirements, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the medicine may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine.

Accordingly, assuming we, or any collaborators we may have, receive marketing approval for one or more product candidates we develop, we, and such collaborators, and our and their contract manufacturers will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, and quality control. If we and such collaborators are not able to comply with post-approval regulatory requirements, we and such collaborators could have the marketing approvals for our products withdrawn by regulatory authorities and our, or such collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition, and prospects.

Even if our product candidates are approved by government regulators, the commercial success of any of our product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals from the FDA in the U.S., the EMA in the European Union and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, on the acceptance of physicians, patients and health care payors of our product candidates as medically necessary, cost-effective and safe. Even before receiving any potential regulatory approval for a product candidate, we may determine that the clinical trial results for a product candidate suggest that it does not have a product profile that would be competitive compared to other therapeutic options. Any product that we develop or commercialize may not have or gain acceptance by physicians, patients, health care payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy, durability and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment relative to alternative treatments;

- our ability to offer the product for sale at competitive prices;
- the clinical indications for which the product candidate is approved by the FDA or the EMA;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of physicians to prescribe new therapies;
- the willingness of the target patient population to try new therapies;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- changes in the standard of care for the targeted indications for the product; and
- sufficient third-party payor coverage and adequate reimbursement.

In addition, we analyze these factors with respect to our product candidates before they are approved by conducting market research. Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched. Any current or potential product candidate of ours that does not have a competitive product profile compared to other therapeutic options, including those that obtain regulatory approval but fail to achieve market acceptance or commercial success, would adversely affect our business prospects.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the U.S. or overseas.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates or therapies profitably.

The success of our product candidates, if approved, depends on the availability of adequate coverage and reimbursement from third-party payors. For additional information regarding laws and regulations related to

reimbursement, see “Item 1. Business – Reimbursement” in this Annual Report on Form 10-K. In addition, because our product candidates represent new approaches to blood and immune reset, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

In the U.S. and markets in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance. If government and other health care payers were not to provide adequate coverage and reimbursement levels for any of our products if approved, market acceptance and commercial success could be reduced.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor’s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Further, in the U.S., no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to maintain pricing sufficient to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Because our product candidates may have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Moreover, increasing efforts by governmental and third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect to experience pricing

pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, and reimbursement for new medicines vary widely from country to country. For additional information regarding these variations from country to country, see "Item 1. Business – Governmental Regulation" and "Item 1. Business – Reimbursement" in this Annual Report on Form 10-K. In the U.S., recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a medicine before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the medicine in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to commercialize any medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

Individual states in the U.S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Also, increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any medicine that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or similar regulatory authorities outside the U.S. Moreover, eligibility for reimbursement does not imply that any medicine will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the medicine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the U.S.

European Union drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European Member States.

We intend to seek approval to market our product candidates in both the U.S. and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of biologics is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures.

Failure to comply with the requirements under European Union and U.K. laws and regulations could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. For additional information regarding applicable government regulations, see “Item 1. Business – Governmental Regulation” in this Annual Report on Form 10-K.

Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our product candidates in those countries would be negatively affected.

Foreign governments often impose strict price controls on approved products, which may adversely affect our future profitability in those countries, and recent federal legislation and actions by federal, state and local governments may permit reimportation of drugs from foreign countries into the U.S., including foreign countries where the drugs are sold at lower prices than in the U.S., which could adversely affect our future profitability.

Frequently foreign governments impose strict price controls on newly approved therapeutic products. If we obtain regulatory approval to sell products in foreign countries, we may be unable to obtain a price that provides an adequate financial return on our investment. Furthermore, we may face competition in the U.S. for our development candidates and investigational medicines, if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the U.S., the FDA issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The market implications of the final guidance is unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability.

Ongoing healthcare legislative and regulatory reform measures may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates, and may affect the prices we may set.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (1) changes to our manufacturing arrangements; (2) additions or modifications to product labeling; (3) the recall or discontinuation

of our products; or (4) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. For additional information regarding these regulations, statutes or their interpretations, see “Item 1. Business – Governmental Regulation” in this Annual Report on Form 10-K.

Additional laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.

In the event we decide to conduct clinical trials or continue to enroll subjects in our ongoing or future clinical trials in the European Union or the U.K., we may be subject to additional privacy restrictions. The collection, use, storage, transfer, and other processing of personal data, including personal health data, regarding individuals in the European Economic Area is governed, as of May 2018, by the General Data Protection Regulation, or GDPR. Achieving and maintaining compliance with the GDPR and the U.K. GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any future European or U.K. activities. For additional information regarding GDPR, see “Item 1. Business – Governmental Regulation” in this Annual Report on Form 10-K.

In the U.S., the data protection landscape is rapidly growing and evolving, and achieving and maintaining compliance with current and future U.S. state and federal privacy laws will be similarly onerous and may adversely affect our business. For example, if we fail to comply with the CCPA, we could be subject to civil penalties. Further, if we experience a data breach that results in the loss of personal information of California residents, we may be subject to a private right of action under the CCPA. While there are currently exemptions under the CCPA for protected health information that is subject to HIPAA and for patient information subject to clinical trial regulations, the CCPA may still negatively impact our business activities. There continues to be uncertainty surrounding the enforcement and implementation of the CCPA, which exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Additionally, as recently passed U.S. state laws, such as the California Privacy Rights Act come into effect, we may become subject to or affected by new or additional data protection requirements and face increased scrutiny or attention from regulatory authorities. The effects of these laws are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and/or litigation.

We also anticipate that more states may enact legislation similar to the CCPA, which has prompted a number of proposals for new federal and state-level privacy legislation. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies.

Additionally, HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s privacy and security standards directly applicable to “business associates,” those independent contractors or agents of covered entities that create, receive, maintain, transmit or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce

the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances. These laws may differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other laws and regulations governing the processing of data by healthcare entities. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention away from the business.

Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain products outside of the U.S. and require us to develop, implement and maintain costly compliance programs.

If we further expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. We do not currently carry biological or hazardous waste insurance coverage.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities.

We are competing against numerous large, established companies that have substantially greater financial, technical, research, manufacturing, marketing, distribution and other resources than us, and our operating results will suffer if we fail to compete effectively.

The pharmaceutical and biopharmaceutical industry is characterized by intense competition and rapid and significant technological changes and advancements. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many companies, research institutions and universities are doing research and development work in a number of areas similar to those that we focus on that could lead to the development of new products which could compete with and be superior to our product candidates. We expect technological developments in the pharmaceutical and biopharmaceutical and related fields to occur at a rapid rate, and we believe competition will intensify as advances in these fields are made. Accordingly, we will be required to continue to devote substantial resources and efforts to research and development activities in order to potentially achieve and maintain a competitive position in this field. Products that we develop may become obsolete before we are able to market them or to recover all or any portion of our research and development expenses.

Most of the companies with which we compete have substantially greater financial, technical, research, manufacturing, marketing, distribution and other resources than we do, including staff, experienced marketing and manufacturing organizations, and well-established sales forces. In addition, smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. We will be competing with respect to our products with companies that have significantly more experience and expertise in undertaking preclinical testing and human clinical trials with new or improved therapeutic products and obtaining regulatory approvals of such products. A number of these companies already market and may be in advanced phases of clinical testing of various drugs that will or may compete with our

current product candidates or other future potential product candidates. Our competitors may develop or commercialize products more rapidly than we do or with significant advantages over any products we develop. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business.

In addition to larger pharmaceutical or biopharmaceutical companies that may develop different competing technologies or technologies, we will be competing with a number of smaller biotechnology companies. We are aware that collaborations between smaller companies and larger established companies may compete with our programs. Colleges, universities, governmental agencies and other public and private research organizations are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technologies that they have developed, some of which may be directly competitive with our programs and product candidates. For additional information regarding our competition, see “Item 1. Business – Competition” in this Annual Report on Form 10-K.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors’ products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

Our competitors include companies focused on developing technologies to improve the distinct steps of stem cell transplant. For additional information regarding our competition, see “Item 1. Business – Competition” In this Annual Report on Form 10-K.

Our product candidates for which we intend to seek approval may face competition from generic drugs or biosimilars sooner than anticipated.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as interchangeable based on its similarity to an existing reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product is approved under a BLA. On March 6, 2015, the FDA approved the first biosimilar product under the BPCIA. However, the law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that if any of our product candidates are approved as a biological product under a BLA it should qualify for the 12-year period of exclusivity. However, there is a risk that the FDA will not consider any of our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply

to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Finally, there has been public discussion of potentially decreasing the period of exclusivity from the current 12 years. If such a change were to be enacted, our product candidates, if approved, could have a shorter period of exclusivity than anticipated.

Risks Related to Intellectual Property

We are highly dependent on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

In November 2016, we entered into a license agreement with Harvard University, or Harvard, pursuant to which we were granted a worldwide license to research, develop and commercialize one or more therapeutic products under certain conditioning- and mobilization-related patents and patent applications owned or controlled by Harvard. We are dependent on the patents, know-how and proprietary technology, licensed from Harvard. In addition, in March 2018, we entered into a research, development option and license agreement with Heidelberg Pharma Research GmbH, or Heidelberg Pharma, pursuant to which we intend to combine our proprietary antibodies and Heidelberg Pharma's amanitin conjugates platform, including our MGTA-117 product candidate. If we commercialize any products utilizing Heidelberg Pharma's amanitin conjugates platform, we will be dependent on the intellectual property rights we license from Heidelberg Pharma. Any disputes with these licensors or termination of these licenses, or a finding that such intellectual property lacks legal effect, could result in the loss of significant intellectual property rights and could harm our ability to commercialize our current or future product candidates.

Certain of our license agreements, including our agreements with Harvard and Heidelberg Pharma, require us to use diligent efforts or meet development thresholds, to maintain the license, including establishing a set timeline for developing and commercializing products. If we fail to comply with any of the obligations under our license agreements, including payment terms and diligence terms, our licensors may have the right to terminate our agreements, in which event we may lose intellectual property rights and may not be able to develop, manufacture, market or sell the products covered by our agreements or may face other penalties under our agreements. In addition, such a termination could result in the licensor reacquiring the intellectual property rights and subsequently enabling a competitor to access the technology. Any such occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of our license agreements or reduction or elimination of our rights under them may result in our having to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all, which may mean we are unable to develop or commercialize the affected product candidate or cause us to lose our rights under the agreement.

Further, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. Accordingly, disputes may arise between us and our licensor, or our licensor and its licensors, regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights, if any, granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- whether our licensor or its licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property without their authorization;

- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of product candidates;
- our involvement in the prosecution of the licensed patents and our licensors' overall patent enforcement strategy;
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners; and
- the amounts of royalties, milestones or other payments due under the license agreement.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and commercialize the affected product candidates. If we or any such licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer. Any disputes with our licensors or any termination of the licenses on which we depend could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our commercial success depends on our ability to obtain, maintain and protect our intellectual property and proprietary technology.

Our commercial success depends in large part on our ability to obtain, maintain and protect intellectual property protection through patents, trademarks, and trade secrets in the U.S. and other countries with respect to our proprietary product candidates. If we do not adequately protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability.

To protect our proprietary position, we own and have in-licensed certain issued patents and have filed and may file provisional and non-provisional patent applications in the U.S. or abroad related to our product candidates that are important to our business. Provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of the filing of one or more of our related provisional patent applications. If we do not timely file non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. Moreover, the patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

In some instances, agreements through which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented, how claims are amended, and may not be able to secure, maintain, or successfully enforce necessary or desirable patent protection from those patent rights. We have not had and do not have primary control over patent prosecution and maintenance for certain of the patents and patent applications we license, and therefore cannot guarantee that these patents and applications will be prosecuted or maintained in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Moreover, some of our in-licensed patents and patent applications are, and our future owned and licensed patents may be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be

able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

If the scope of the patent protection we or our licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our licensed patents have, or that any of our pending owned or licensed patent applications that mature into issued patents will include, claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage, nor can we assure you that our licenses will remain in force. Other parties have developed or may develop technologies that may be related or competitive with our approach, and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or conflict with our patent applications, either by claiming the same compounds, formulations or methods or by claiming subject matter that could dominate our patent position. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Furthermore, patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. 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 patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our product candidates. In addition, the patent portfolio licensed to us is, or may be, licensed to third parties, such as outside our field, and such third parties may have certain enforcement rights. Thus, our owned and licensed patents and any patents we own or license in the future could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against another licensee or in administrative proceedings brought by or against another licensee in response to such litigation or for other reasons.

The patent protection we obtain for our product candidates may not be sufficient to provide us with any competitive advantage or our patents may be challenged.

Our owned and licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but falls outside the scope of our patent protection or license rights. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Currently, a significant portion of our patents and patent applications are in-licensed, though similar risks would apply to any patents or patent applications that we now own or may own or in-license in the future.

We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees, or licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees, or licensors, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could

be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent position of biotechnology and pharmaceutical companies carries uncertainty. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which are dependent upon the current legal and intellectual property context, extant legal precedent and interpretations of the law by individuals. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are characterized by uncertainty.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the U.S., the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we do or may license or purchase patent rights were the first to make relevant claimed inventions, or were the first to file for patent protection for them. If third parties have filed prior patent applications on inventions claimed in our patents or applications that were filed on or before March 15, 2013, an interference proceeding in the U.S. can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the U.S. can be initiated by such third parties to determine whether our invention was derived from theirs.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our owned and licensed patents or pending patent applications may be challenged in the courts or patent offices in the U.S. and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or to other patent offices around the world. Alternately or additionally, we may become involved in post-grant review procedures, oppositions, derivation proceedings, *ex parte* reexaminations, *inter partes* review, supplemental examinations, or interference proceedings or challenges in district court, in the U.S. or in various foreign patent offices, including both national and regional, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of the patent or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent application, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, 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.

Pending and future patent applications may not result in patents being issued that protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. Competitors may also be able to design around our patents. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the U.S. For example, patent laws in various jurisdictions, including significant

commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than U.S. law does. Any of these outcomes could have a material adverse effect on our ability to generate revenue.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners 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. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources 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 U.S. for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the U.S. 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.

Issued patents that we have, may obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting Abbreviated New Drug Applications to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to the protection afforded by patents, we rely upon trade secret protection, know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our contractors, collaborators, scientific advisors, employees and consultants and invention assignment agreements with our consultants and employees. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property rights under these agreements may not be self-executing or the assignment agreements may be breached, and we

may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements despite the existence of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the contractors, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. As a result, we could lose our trade secrets. Enforcing a claim against a third party that illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing or unwilling to protect trade secrets.

Moreover, our trade secrets could otherwise become known or be independently discovered by our competitors or other third parties. Competitors and other third parties could purchase our product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected or sufficient to provide an advantage over our competitors, our competitive position could be adversely affected, as could our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violations may prevent or delay our product discovery and development efforts and have a material adverse effect on our business.

Our commercial success depends in part on our avoiding infringement, misappropriation and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, under U.S. patent reform, new procedures including *inter partes* review and post grant review have been implemented.

As stated above, this reform will bring uncertainty to the possibility of challenge to our patents in the future. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. For example, we are aware of patents and a patent application owned by a third party with claims that could be construed to cover MGTA-117. The third party owner of these patents and patent application may seek to allege that our development and commercialization of MGTA-117 infringes their patent rights and file a patent infringement lawsuit against us in the future. While we believe we would have valid defenses against any such allegation or lawsuit, such defenses may be unsuccessful. In this regard, patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may also be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. Even if we obtained such a license, it may only be non-exclusive, which would permit third parties to use the same intellectual property and compete with us. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, we may be unable to commercialize our product candidates or such efforts may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. 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 have sufficient resources to bring these actions to a successful conclusion. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

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. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. 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. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which 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 earlier than would otherwise have been the case, which would have a material adverse effect on our business.

Some intellectual property that we have in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Many of the intellectual property rights we have licensed are generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the U.S. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the U.S. or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both.

In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

As is the case with other biopharmaceutical companies, our success is heavily 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. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in 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 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. For example, in the case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. In addition, the case *Amgen Inc. v. Sanofi* affects the way antibody claims are examined and litigated. We cannot predict how future decisions by the courts, the Congress or the USPTO may impact the value of our patents.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, maintaining, defending and enforcing patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. 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 U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors

may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and may export otherwise infringing drugs to territories where we have patent protection, but enforcement rights are not as strong as those in the U.S. These drugs may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents 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.

Many countries have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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, which could adversely affect our business, financial condition, results of operations, and prospects.

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 U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest filing date of a non-provisional application to which the patent claims priority. 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 for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might

otherwise be the case, and our competitive position, business, financial condition, results of operations, and prospects could be materially harmed.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information, or misappropriated trade secrets.

We employ individuals who were previously employed at universities or other biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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 interest in our owned patent rights, trade secrets or other intellectual property as an inventor or co-inventor. For example, a third party may assert claims against us arising out of conflicting obligations of employees, consultants or others who are involved in developing our product candidates or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our owned patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or own;
- we, or our current or future licensors might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own;
- we, or our current or future licensors might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could harm our business, financial condition, results of operations, and prospects.

Risks Related to Our Collaborations with Third Parties

We currently depend, and may in the future continue to depend, on collaborations with third parties for the research, development, and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates and our business may be adversely affected.

We currently depend, and may in the future continue to depend, on third-party collaborators for the research, development, and commercialization of certain of the product candidates we may develop. For example, we are working collaboratively with bluebird bio, Inc. for our planned Phase 2 trial of MGTA-145 plus plerixafor for mobilization and collection of stem cells in patients with sickle cell disease, AVROBIO, Inc., or AVROBIO, to evaluate the potential utility of MGTA-117 for conditioning patients before they receive one of AVROBIO's investigational lentiviral gene therapies, and Beam Therapeutics, or Beam, to evaluate the potential utility of MGTA-117 for conditioning of patients with sickle cell disease and beta-thalassemia receiving Beam's base editing therapies. In our current collaboration arrangements, and those we may enter into in the future, we have or will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. Our ability to develop MGTA-145 plus plerixafor for mobilization and collection of stem cells in patients with sickle cell disease, or MGTA-117 as a conditioning agent for patients before receiving gene therapy, and generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our research programs or any product candidates we may develop, pose certain risks to us, including the below.

- Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations.
- Collaborators may not pursue development and commercialization of any product candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus, available funding or external factors such as an acquisition that diverts resources or creates competing priorities.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing.
- A collaborator's product candidate may have a safety or efficacy profile that would impact the collaborator's ability to continue to pursue the development and commercialization of its product candidate, which in turn, would negatively impact our ability to continue to pursue the development and commercialization of our product candidate.

- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our medicines or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- Collaborators with marketing and distribution rights to one or more medicines may not commit sufficient resources to the marketing and distribution of such medicine or medicines.
- Collaborators may not properly obtain, maintain, enforce, or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.
- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our medicines or product candidates or that result in costly litigation or arbitration that diverts management attention and resources.
- We may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control.
- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.
- Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished, or terminated.

If our collaborations do not result in the successful development and commercialization of products, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval, and commercialization described in this Annual Report on Form 10-K apply to the activities of our collaborators.

We have in the past and may in the future decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of any product candidates we may develop. These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of several factors. If we license rights to any product candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

We are developing E478 specifically to partner with gene therapy and genome editing companies. If we are unable to find willing collaborators, this may adversely affect the development of E478 and our business.

We are developing E478 specifically to partner and collaborate with gene therapy and genome editing companies. In particular, we seek to selectively pursue collaboration arrangements with companies that have particular technology, expertise or resources for the development of E478. However, we may not be able to

execute on such collaboration and any collaboration that we may enter into may not be successful. If we are unable to identify partners whose capabilities complement and integrate well with ours and reach collaboration arrangements with such partners on a timely basis, on acceptable terms or at all, or if the arrangements we establish are unproductive for us, we may fail to meet our business and development objectives for E478, which may adversely affect our business.

We may not be successful in finding strategic collaborators for continuing development of certain of our product candidates or successfully commercializing or competing in the market for certain indications.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

In addition, any collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our product development and research programs and the potential commercialization of any product candidates we may develop will require substantial additional cash to fund expenses. For some of the product candidates we may develop, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the U.S., the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

If any party to which we have outsourced certain functions fails to perform its obligations under agreements with us, the development and commercialization of our product candidates and any future product candidates could be delayed or terminated.

To the extent that we rely on third party individuals or other companies to manage the day-to-day conduct of our clinical trials or to manufacture, sell or market our current product candidates or any future product candidates, we will be dependent on the timeliness and effectiveness of their efforts. If a clinical research management organization that we might utilize is unable to allocate sufficient qualified personnel to our trials or if the work performed by it does not fully satisfy the rigorous requirements of the FDA, we may encounter substantial delays and increased costs in completing our clinical trials. If a firm producing humanized forms of our molecular antibody product candidates or a manufacturer of the raw material or finished product for our clinical trials is unable to meet our time schedules or cost parameters, the timing of our clinical trials and development of our product candidates may be adversely affected. Any manufacturer that we select may encounter difficulties in scaling-up the manufacture of new products in commercial quantities, including problems involving product yields, product stability or shelf life, quality control, adequacy of control procedures and policies, compliance with FDA regulations and the need for further FDA approval of any new manufacturing processes and facilities. The manufacture of clinical supplies for trials and commercial quantities of our current product candidates and any future product candidates are likely to be inherently more difficult and costly than typical chemical pharmaceuticals. This could delay commercialization of any of our product candidates, if approved, or reduce the profitability of these candidates for us. If any of these occur, the development and commercialization of our product candidates could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue such development and commercialization on our own.

Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business

The COVID-19 pandemic or any future pandemic, epidemic or outbreak of any other highly infectious disease could have a material adverse effect on our business, financial condition and results of operations.

The COVID-19 pandemic, including the emergence of various variants, has caused, and could continue to cause, widespread disruptions to the U.S. and global economy and has contributed to significant volatility and

negative pressure in financial markets. The extent to which the COVID-19 pandemic, or any future pandemic, epidemic or outbreak of any highly infectious disease, impacts our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of such pandemic, the emergence and characteristics of new variants, the actions taken to contain the pandemic or mitigate its impact, including the adoption, administration and effectiveness of available COVID-19 vaccines, and the direct and indirect economic effects of the pandemic and containment measures, among others. The rapid development and fluidity of this situation precludes any prediction as to the full adverse impact of the COVID-19 pandemic. Nevertheless, the COVID-19 pandemic has affected, and may continue to adversely affect, our business, financial condition and results of operations, and it has had, and may continue to have, the effect of heightening many of the risks described in this Annual Report on Form 10-K, including but not limited to, the following:

- The COVID-19 pandemic has had, and will likely continue to have, an adverse impact on various aspects of our ongoing and planned clinical trials, and preclinical studies.
- Other potential impacts of the COVID-19 pandemic on our various clinical trials include impacts on patient dosing and study monitoring, which may be paused or delayed due to changes in policies at various clinical sites; federal, state, local or foreign laws, rules and regulations, including quarantines or other travel restrictions; the prioritization of healthcare resources toward pandemic efforts, including diminished attention from physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of our clinical trials; and interruption or delays in the operations of the U.S. Food and Drug Administration, or FDA, among other reasons related to the COVID-19 pandemic. If the COVID-19 pandemic continues, other aspects of our clinical trials will likely be adversely affected, delayed or interrupted, including, for example, site initiation, patient recruitment and enrollment, availability of clinical trial materials and data analysis. Some patients and clinical investigators may not be able to comply with clinical trial protocols and patients may choose to withdraw from our studies or we may choose to, or be required to, pause enrollment and or patient dosing in our ongoing clinical trials in order to preserve health resources and protect trial participants. It is unknown how long these pauses or disruptions could continue.
- We currently rely on third parties, including CROs, CDMOs, and other contractors and consultants to, among other things, conduct our preclinical and clinical trials, manufacture raw materials, manufacture and supply our product candidates, ship investigational drugs and clinical trial samples, perform quality testing and supply other goods and services to run our business. If any such third party is adversely impacted by restrictions resulting from the COVID-19 pandemic, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted, which could limit our ability to manufacture our product candidates for our clinical trials and conduct our research and development operations.
- We have established a work-from-home policy for all employees, as well as safety measures for those using our offices and laboratory facilities that are designed to comply with applicable federal, state and local guidelines instituted in response to the COVID-19 pandemic. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber security risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors.
- Our employees and contractors conducting non-business critical research and development activities have not been able to, and may not in the future be able to, access our laboratory for an extended period of time as a result of the current work-from-home policy and the possibility that governmental authorities further modify current restrictions. This could delay timely completion of preclinical activities, including completing Investigational New Drug, or IND, enabling studies or our ability to

select future development candidates, and initiation of additional clinical trials for our other product candidates.

- Certain government agencies, such as health regulatory agencies and patent offices, within the U.S. or internationally have experienced, and may continue to experience, disruptions in their operations as a result of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced to continue to monitor our clinical trials and, as a result, review, inspection and other timelines may be materially delayed. It is unknown how long these disruptions could continue. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates. For example, regulatory authorities may require that we not distribute a product candidate lot until the relevant agency authorizes its release. Such release authorization may be delayed as a result of the COVID-19 pandemic, which would likely result in delays to our ongoing clinical trials.
- The trading prices for our common stock and those of other biopharmaceutical companies have been highly volatile, partly due to the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2021, we had 75 full-time employees. As our development, manufacturing and commercialization plans and strategies develop, and as we continue to operate as a public company, we expect to need and are actively recruiting additional managerial, technical, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and international regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of their attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including core aspects of regulatory approval, clinical management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further

develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to identify and develop new or next generation product candidates will be impaired, which could result in loss of market opportunities or market share and could make us less competitive.

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, particularly our Chief Executive Officer, the members of our executive team, and key scientific and medical personnel employees. The loss of the services of any of our executive officers, key employees, and scientific and medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business.

We conduct our operations at our facility in Cambridge, Massachusetts. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have granted equity awards that vest over time or vest upon the achievement of certain pre-established milestones. The value to employees of equity awards may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

We expect to expand our development, regulatory, and future sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit the development and 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 in the product, negligence, strict liability

or a breach of warranties. Claims could also be asserted under state consumer protection acts. 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 products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- 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;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Although we currently carry clinical trial insurance, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any 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 corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Our internal computer systems, or those of our collaborators, other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from future 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 were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and study subjects, and company and vendor

confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

We and the third parties with whom we work are increasingly utilizing social media tools as a means of communication both internally and externally, and noncompliance with applicable requirements, policies or contracts due to social media use or negative posts or comments could have an adverse effect on our business.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. In addition, our employees or third parties with whom we contract, such as our CROs or CDMOs, may knowingly or inadvertently make use of social media in ways that may not comply with legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients and others or information regarding our product candidates or clinical trials along with the potential for litigation related to off-label marketing or other prohibited activities. For example, clinical trial patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that trial enrollment may be adversely impacted, we fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. Furthermore, negative posts or comments about us or our product candidates on social media could seriously damage our reputation, brand image and goodwill. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2021, we had net operating loss carryforwards for federal income tax purposes of $247.2 million, of which $17.5 million begin to expire in 2035 and $229.7 million can be carried forward

indefinitely. As of December 31, 2021, we had net operating loss carryforwards for state income tax purposes of $247.4 million which begin to expire in 2035. As of December 31, 2021, we also had available research and orphan drug tax credit carryforwards for federal and state income tax purposes of $10.3 million and $2.7 million, respectively, which begin to expire in 2035 and 2030, respectively. These net operating loss carryforwards and research and orphan drug tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who own at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage (by value) within a rolling three-year period. Utilization of our net operating loss carryforwards and research and orphan drug tax credit carryforwards may be subject to a substantial annual limitation under Section 382 and 383 of the Code due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. The Company has not conducted a formal study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If an ownership change has occurred or does occur in the future, the amount of net operating loss and tax credit carryforwards presented in our financial statements could be limited or expire unutilized.

Risks Related to Our Common Stock

An active trading market for our common stock may not be sustained.

In June 2018, we closed our IPO. Prior to our IPO, there was no public market for our common stock. Although we have completed our IPO and shares of our common stock are listed and trading on the Nasdaq Global Market, an active trading market for our shares may not be sustained. If an active market for our common stock does not continue, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or sell their shares at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

The trading price of our common stock has been, and will likely continue to be, highly volatile.

The trading price of our common stock may be highly volatile. The stock market in general, and the market for smaller pharmaceutical and biotechnology companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the purchase price, and you may lose some or all of your investment. The market price for our common stock may be influenced by many factors, including:

- the success of existing or new competitive products or technologies;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the timing and results of preclinical studies for any of our product candidates;
- the timing and results of clinical trials of MGTA-145, MGTA-117 and any other product candidates;
- commencement or termination of collaborations for E478 or any of our current and future programs and product candidates;

- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results or development timelines;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- disruptions to political, governmental or regulatory systems, including shutdowns of the government and its agencies;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

We are an “emerging growth company” and a “smaller reporting company,” and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, as defined in Rule 12b-2 under the Exchange Act, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an emerging growth company.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.

We have never declared nor paid cash dividends on our capital stock. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. In addition, the terms of any future debt or credit agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned approximately 55.1% of our capital stock as of December 31, 2021. This concentration of ownership control could delay, defer or prevent a change in control, entrench our management or the board of directors, or impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

Provisions in our corporate charter documents and provisions under Delaware law may prevent or frustrate attempts by our stockholders to change our management or hinder efforts to acquire a controlling interest in us.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and

- require the approval of the holders of at least 66.67% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in the best interest of our stockholders. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, certain designated courts will be the sole and exclusive forum for certain legal actions between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us or any of our current or former directors, officers, employees or stockholders arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (4) any action asserting a claim governed by the internal affairs doctrine, which we refer to herein as the "Delaware Forum Provision." The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act of 1933, as amended, or the Securities Act, and the Exchange Act. Our amended and restated bylaws further provide that the U.S. District Court for the District of Massachusetts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, which we refer to herein as the "Federal Forum Provision." We have chosen the U.S. District Court for the District of Massachusetts as the exclusive forum for such Securities Act causes of action because our principal executive offices are located in Cambridge, Massachusetts. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in any shares of our common stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and the Federal Forum Provision.

On December 19, 2018, Court of Chancery of the State of Delaware issued a decision in *Sciabacucchi v. Salzberg*, C.A. No. 2017-0931-JTL (Del. Ch.) declaring that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are ineffective and invalid under Delaware law. However, that decision was appealed to the Delaware Supreme Court and on March 18, 2020, the Delaware Supreme Court reversed the Court of Chancery and ruled that such federal forum selection provisions are "facially valid" under Delaware law. In light of the Delaware Supreme Court's ruling, we intend to enforce the Federal Forum Provision designating the District of Massachusetts as the exclusive forum for Securities Act causes of action.

We recognize that the Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts, as applicable. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. The Federal Forum Provision may also impose additional litigation

costs on stockholders who assert the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware or the U.S. District Court for the District of Massachusetts, as applicable, may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

General Risk Factors

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of changes in tax laws on an investment in our common stock.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an “emerging growth company” under the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We could be an “emerging growth company” for up to five years from the closing date of our IPO. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As has been widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, uncertainty about economic stability and increased inflation. There can be no assurance that further deterioration in credit and financial markets and confidence in economic

conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At December 31, 2021, we had $176.9 million of cash, cash equivalents and marketable securities. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since December 31, 2021, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Securities class action and derivative lawsuits and other legal proceedings are often brought against companies, which could result in substantial costs and divert management's attention, and our insurance policies may be inadequate and potentially expose us to unrecoverable risks.

Securities class action and derivative lawsuits and other legal proceedings are often brought against companies following a decline in the market price of their securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. As a result, we may be more susceptible to these types of lawsuits and legal proceedings than other companies with more stable security prices. In connection with any litigation or other legal proceedings, we could incur substantial costs, and such costs and any related settlements or judgments may not be covered by insurance. We could also suffer an adverse impact on our reputation and a diversion of management's attention and resources, which could have a material adverse effect on our business.

We have limited director and officer insurance and commercial insurance policies. Any significant insurance claims would have a material adverse effect on our business, financial condition and results of operations. Insurance availability, coverage terms and pricing continue to vary with market conditions and insurance coverage is increasingly expensive. We have observed rapidly changing conditions in the insurance markets relating to nearly all areas of traditional corporate insurance and such conditions have resulted in higher premium costs, higher policy deductibles and lower coverage limits. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify; however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage, and insurers may not respond as we intend to cover insurable events that may occur. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential class action and derivative lawsuits and other legal proceedings or claims often brought against companies following a decline in the market price of their securities, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CDMOs, our CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Our internal computer systems, or those used by our CDMOs, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CDMOs, future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. If such a system failure or security breach were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we may rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, including potential lawsuits from patients, collaborators, employees and/or stockholders, and the further development and commercialization of our product candidates could be delayed.

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 U.S. 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 U.S., 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.

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute, the False Claims Act, laws and regulations related to the reporting of payments to physicians and teaching hospitals, and HIPAA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. 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. For additional information, see “Item 1. Business – Governmental Regulation” in this Annual

Report on Form 10-K. The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies often scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. In connection with our IPO, we adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will 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, guidance 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 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, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also anticipate that we will incur costs associated with relatively recently adopted corporate governance requirements, including requirements of the SEC, and the Nasdaq Global Market. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We conduct a process each year to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We have broad discretion over the use of our cash and investments and may not use them effectively.

Our management has broad discretion to use our cash and investments to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending the use of our cash and investments to fund our operations, we may invest these resources in a manner that does not produce income or that loses value.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock may be influenced, in part, by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or one or more of the analysts who cover us issues an adverse opinion about our company, our stock price would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our headquarters are located at 100 Technology Square, Cambridge, Massachusetts, where we occupy approximately 69,000 square feet of research and development, laboratory and office space. This lease expires in February 2028. We subleased approximately 27,000 square feet of office space at our headquarters to two third parties. One sublease expired in the fourth quarter of 2021 and the other sublease expires in the second quarter of 2023. We believe that our office and laboratory space is sufficient to meet our needs for the foreseeable future and that suitable additional space will be available as and when needed.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not currently aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol "MGTA" on the Nasdaq Global Market and has been publicly traded since June 21, 2018. Prior to this time, there was no public market for our common stock.

Holders of Record

As of January 31, 2022, there were no holders of record of shares of our common stock. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

Dividends

We have never declared or paid cash dividends on our common stock, and we do not expect to pay any cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects, then applicable contractual restrictions and any other factors deemed relevant by our board of directors.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Initial Public Offering

Not applicable.

Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. RESERVED

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

Magenta Therapeutics, Inc. is a clinical-stage biotechnology company developing novel medicines designed to bring the curative power of stem cell transplants to more patients with blood cancers, genetic diseases and autoimmune diseases.

Magenta's drug development pipeline includes multiple clinical and preclinical product candidates designed to improve stem cell transplants. We are developing product candidates that are designed to deplete targeted cells in the bone marrow to make space for the bone marrow to receive newly transplanted stem cells, a process known as conditioning. Our targeted conditioning programs are intended to enhance the efficacy of and/or reduce the dosing levels, intensity or, in some cases, even the need for chemotoxic agents. Our first targeted conditioning program, MGTA-117, has entered clinical development in a Phase 1/2 trial, and our second program, a CD45-antibody drug conjugate, or CD45-ADC, is advancing in preclinical development. In addition to our conditioning programs, we are also developing a product candidate, MGTA-145, to improve the process by which stem cells are stimulated out of the bone marrow and into the bloodstream so they are available for collection for future reinfusion, known as mobilization, which is required for all transplants and gene therapy applications. MGTA-145 is a Phase 2 clinical stage program intended to enable rapid, reliable, predictable and safe mobilization and collection of high numbers of functional stem cells for transplant.

In addition to our product candidates, Magenta's research efforts are evaluating several early-stage targets that include a program for targeted lymphodepletion prior to therapies such as chimeric antigen receptor T-cells or CAR-T. We also have a cell therapy program, E478, which is a small molecule aryl hydrocarbon receptor, or AHR, antagonist designed to increase the numbers of gene-modified HSCs for stem cell-based gene therapy and genome editing. In December 2021, we notified Novartis International Pharmaceutical Ltd., or Novartis, of our termination of the Novartis license related to our cell therapy program, MGTA-456, which becomes effective 90 days from the date of notification.

Magenta intends to become a fully integrated discovery, development, and commercial company in the field of stem cell transplant. We are developing our product candidates to be used individually or, in some cases, in combination with each other or together with other therapies. As a result, our portfolio could be tailored to the patient's disease, such that a patient may receive more than one Magenta therapy as part of his or her individual stem cell transplant.

We are experiencing operational and other challenges as a result of the novel coronavirus, or COVID-19, global pandemic, which could delay or halt the development of our product candidates. See "Item 1A. Risk Factors" for further discussion of the current and expected impact on our business and product candidates.

Since our inception in 2015, we have focused substantially all of our efforts and financial resources on organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates, and undertaking preclinical studies and clinical trials, including MGTA-117 and MGTA-145. We do not have any products approved for sale and have not generated any revenue from product sales.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Net losses were $71.1 million and $74.9 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $325.6 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect our expenses and capital requirements will increase in connection with our ongoing activities, particularly as we:

- initiate, enroll and conduct a Phase 1/2 clinical trial for MGTA-117 and Phase 2 clinical trials for MGTA-145
- initiate and conduct preclinical studies and clinical trials of our other product candidates;
- develop any other future product candidates we may choose to pursue;
- seek marketing approval for any of our product candidates that successfully complete clinical development, if any;
- maintain compliance with applicable regulatory requirements;
- develop and scale up our capabilities to support our ongoing preclinical activities and clinical trials for our product candidates and commercialization of any of our product candidates for which we obtain marketing approval, if any;
- maintain, expand, protect and enforce our intellectual property portfolio;
- develop and expand our sales, marketing and distribution capabilities for our product candidates for which we obtain marketing approval, if any; and
- expand our operational, financial and management systems and increase personnel, including to support our clinical development and commercialization efforts and our operations as a public company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution. Further, we expect to incur additional costs associated with operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing and distribution or licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of December 31, 2021, we had cash, cash equivalents and marketable securities of $176.9 million. Based on our operating plan, we believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2023. See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources.”

Impact of the Ongoing COVID-19 Pandemic

In March 2020, COVID-19 was declared a pandemic by the World Health Organization. as a result, more than 40 states and certain U.S. territories, including the Commonwealth of Massachusetts where our operations are located, instituted quarantines, restrictions on travel, "stay at home" rules, restrictions on types of businesses that may continue to operate and restrictions on the types of construction projects that may continue. As a result, the COVID-19 pandemic has caused significant disruptions to the U.S., regional and global economies and has contributed to significant volatility and negative pressure in financial markets.

We have been carefully monitoring the COVID-19 pandemic and its potential impact on our business and have taken important steps to help ensure the safety of our employees and their families and to reduce the spread of COVID-19 in the Cambridge community. We have established a work-from-home policy for all employees, as well as safety measures for those using our offices and laboratory facilities that are designed to comply with applicable federal, state and local guidelines instituted in response to the COVID-19 pandemic. We will continue to assess those measures as COVID-19-related guidelines evolve. We have also maintained efficient communication with our partners and clinical sites as the COVID-19 pandemic has progressed. We have taken these precautionary steps while maintaining business continuity so that we can continue to progress our programs.

The future impact of the COVID-19 pandemic on our industry, the healthcare system and our current and future operations and financial condition will, however, depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact, including the adoption of available COVID-19 vaccines, as well as the effect of any relaxation of current restrictions within the Cambridge community or regions in which our partners and clinical sites are located, and the direct and indirect economic effects of the pandemic and containment measures, among others. See "Item 1A. Risk Factors" for a discussion of the potential adverse impact of COVID-19 on our business, results of operations and financial condition.

Components of Our Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- employee-related expenses, including salaries and related costs, and stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with contract research organizations, or CROs;
- the cost of consultants and third-party contract development and manufacturing organizations, or CDMOs, that manufacture drug products for use in our preclinical studies and clinical trials;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and supplies; and
- payments made under third-party licensing agreements.

We expense research and development costs to operations as incurred. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to consultants, central laboratories, contractors, CDMOs and CROs

in connection with our preclinical and clinical development activities. We do not allocate employee costs, costs associated with our platform technology or facility expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified.

The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties, including the following:

- the continuing impact of the COVID-19 pandemic on our industry, the healthcare system, and our current and future operations;
- successful completion of preclinical studies and clinical trials;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- raising additional funds necessary to complete clinical development of and commercialize our product candidates;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- developing and implementing marketing and reimbursement strategies;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- protecting and enforcing our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the products following approval.

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 that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as our product candidate development programs progress. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, and stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs and insurance costs, as well as professional fees for legal, patent, consulting, accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased costs associated with continuing to operate as a growing public company.

Interest and Other Income, Net

Interest and other income, net, consists of interest income and miscellaneous income and expense unrelated to our core operations.

Income Taxes

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or for our earned research and orphan drug tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2021, we had net operating loss carryforwards for federal income tax purposes of $247.2 million, of which $17.5 million begin to expire in 2035 and $229.7 million can be carried forward indefinitely. As of December 31, 2021, we had net operating loss carryforwards for state income tax purposes of $247.4 million which begin to expire in 2035. As of December 31, 2021, we also had available research and orphan drug tax credit carryforwards for federal and state income tax purposes of $10.3 million and $2.7 million, respectively, which begin to expire in 2035 and 2030, respectively.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the U.S., or GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with the preclinical development activities;
- CROs in connection with preclinical and clinical trials;

- CDMOs in connection with the production of preclinical and clinical trial materials; and
- investigative sites in connection with clinical trials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We measure all stock options and other stock-based awards granted to employees, directors and non-employees based on the fair value on the date of the grant and recognize compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Generally, we issue awards with either service-only vesting conditions and record expense using the straight-line method or service and performance vesting conditions and record expense when achievement of the performance condition becomes probable using the graded-vesting method. We have historically granted stock options with exercise prices equivalent to the fair value of our common stock as of the date of the grant. The fair value of our common stock is based on quoted market prices. We estimate the fair value of each stock option award using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. We do not estimate and apply a forfeiture rate as we have elected to account for forfeitures as they occur.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020:

	Year Ended December 31,		
	2021	2020	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 46,766	$ 50,615	$(3,849)
General and administrative	27,926	28,087	(161)
Total operating expenses	74,692	78,702	(4,010)
Loss from operations	(74,692)	(78,702)	4,010
Interest and other income, net	3,556	3,766	(210)
Net loss	$(71,136)	$(74,936)	$ 3,800

Research and Development Expenses

	Year Ended December 31, 2021	2020	Change
		(in thousands)	
Direct research and development expenses by program:			
Conditioning	$ 9,677	$16,127	$(6,450)
Mobilization	5,203	4,066	1,137
Cell therapy	684	4,398	(3,714)
Unallocated expenses:			
Personnel related (including stock-based compensation)	18,418	14,848	3,570
Consultant (including stock-based compensation)	1,488	1,196	292
Facility related and other	11,296	9,980	1,316
Total research and development expenses	$46,766	$50,615	$(3,849)

Expenses related to our conditioning program decreased primarily due to a decrease in manufacturing costs as we completed our process development activities to support the submission of our investigational new drug application and future clinical trials, partially offset by an increase in clinical trial costs related to our Phase 1/2 dose escalation trial which was initiated in December 2021. The increase in expenses related to our mobilization program was primarily due to an increase in process development activities to support future manufacturing. Expenses related to our cell therapy program decreased primarily due to the discontinuance of enrollment in our MGTA-456 Phase 2 trial in inherited metabolic diseases in June 2020.

The increase in personnel related costs was due primarily to an increase in headcount in our research and development function and an increase in stock-based compensation. Personnel related costs for the years ended December 31, 2021 and 2020 included stock-based compensation expense of $3.7 million and $3.1 million, respectively. The increase in facility related and other was primarily due to higher operating costs related to our Cambridge, Massachusetts facility.

General and Administrative Expenses

	Year Ended December 31, 2021	2020	Change
		(in thousands)	
Personnel related (including stock-based compensation)	$13,902	$14,219	$ (317)
Professional and consultant	6,555	7,290	(735)
Facility related and other	7,469	6,578	891
Total general and administrative expenses	$27,926	$28,087	$ (161)

The decrease in personnel related costs was due primarily to a decrease in headcount in our general and administrative function. The decrease in professional and consultant costs was primarily due to lower patent and recruitment costs. The increase in facility related and other was primarily due to higher operating costs related to our Cambridge, Massachusetts facility and higher director and officers' insurance costs.

Interest and Other Income, Net

Interest income and other income, net for the year ended December 31, 2021 consisted primarily of sublease income of $3.5 million and interest income $0.1 million. Interest income and other income, net for the year ended December 31, 2020 consisted primarily of sublease income of $2.9 million and interest income of $1.0 million. The increase in sublease income of $0.6 million was due to higher sublessor operating expenses. The decrease in interest income was due to lower interest rates and lower invested balances.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. In June 2018, we completed the initial public offering, or IPO, of our common stock resulting in net proceeds of $89.9 million after deducting underwriting discounts and commissions and other offering expenses. In May 2019, we completed a follow-on public offering resulting in net proceeds of $60.3 million after deducting underwriting discounts and commissions and other offering expenses. In June 2020, we issued and sold 8,625,000 shares of our common stock, including the underwriters' exercise in full of their option to purchase additional shares of common stock, in a follow-on public offering at a public offering price of $8.00 per share, resulting in net proceeds of $64.6 million after deducting underwriting discounts and commission and other offering expenses. In May 2021, we issued and sold 9,599,998 shares of our common stock in a private placement at a purchase price of $9.00 per share, resulting in net proceeds of $86.1 million, after deducting offering expenses.

On August 8, 2019, we filed a shelf registration statement on Form S-3, or Shelf, with the Securities and Exchange Commission, or SEC, which covers the offering, issuance and sale by us of up to an aggregate of $350.0 million of our common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. We simultaneously entered into a sales agreement with Cowen and Company, LLC, as sales agent, to provide for the issuance and sale by the Company of up to $100.0 million of our common stock from time to time in "at-the-market" offerings under the Shelf, which we refer to as the ATM Program. The Shelf was declared effective by the SEC on August 19, 2019. As of December 31, 2021, no sales have been made pursuant to the ATM Program.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Cash used in operating activities	$(59,531)	$(64,023)
Cash provided by (used in) investing activities	43,428	(10,635)
Cash provided by financing activities	89,601	67,739
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 73,498	$ (6,919)

Operating Activities

During the year ended December 31, 2021, operating activities used $59.5 million of cash, primarily resulting from our net loss of $71.1 million and net cash used by changes in our operating assets and liabilities of $1.5 million, partially offset by non-cash charges of $13.1 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2021 consisted of an increase of $1.1 million in prepaid expenses and other current assets and a decrease of $0.6 million in accounts payable and accrued expenses and other current liabilities.

During the year ended December 31, 2020, operating activities used $64.0 million of cash, primarily resulting from our net loss of $74.9 million and net cash used by changes in our operating assets and liabilities of $1.2 million, partially offset by non-cash charges of $12.1 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2020 consisted of a decrease of $2.7 million in accounts

payable and accrued expenses and other current liabilities, partially offset by a decrease of $1.4 million in prepaid expenses and other current assets.

Changes in accounts payable, accrued expenses and other current liabilities and prepaid expenses in both periods were generally due to the timing of vendor invoicing and payments.

Investing Activities

During the year ended December 31, 2021, net cash provided by investing activities was $43.4 million, primarily attributable to net maturities of marketable securities of $44.7 million.

During the year ended December 31, 2020, net cash used by investing activities was $10.6 million, primarily attributable to net purchases of marketable securities of $10.2 million.

Financing Activities

During the year ended December 31, 2021, net cash provided by financing activities was $89.6 million, consisting of proceeds from the May 2021 private placement, net of offering costs, of $86.1 million and proceeds from the exercise of stock options of $3.4 million.

During the year ended December 31, 2020, net cash provided by financing activities was $67.7 million, consisting of proceeds from our follow-on public offering, net of underwriting discounts and commissions and offering costs, of $64.6 million and proceeds from the exercise of stock options of $3.1 million.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for our product candidates in development. In addition, we expect to incur additional costs associated with operating as a public company. As of December 31, 2021, we had cash, cash equivalents and marketable securities of $176.9 million. We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2023. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including those listed above.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, including sales under our ATM Program, debt financings, collaborations, strategic alliances, marketing and distribution arrangements, or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances, marketing and distribution arrangements, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or

grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Although we continue to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund our continuing operations, if at all.

Contractual Obligations and Commitments

Our cash flows are dependent on a number of factors in addition to our operational expenditures, including our contractual and other obligations. As a result, our liquidity and capital resources in future periods should be analyzed in conjunction with such factors.

Lease Obligations

We have a sublease for up to approximately 69,000 square feet of office and laboratory space in Cambridge, Massachusetts, which expires in February 2028. We are obligated to make remaining rent payments of $45.1 million through February 2028, of which $6.4 million are due in 2022.

Research and Development and Manufacturing Agreements

We enter into contracts in the normal course of business with CROs, CDMOs and other third parties for clinical trials, preclinical research studies and testing and manufacturing services. These contracts do not contain any minimum purchase commitments and are cancelable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation and in some cases, wind-down costs. The exact amount of such obligations is dependent on the timing of termination and the terms of the related agreement and are not known.

License and Collaboration Agreements

In March 2018, we entered into a collaboration agreement with Heidelberg Pharma Research GmbH, or HDPR, whereby the parties agreed to combine our stem cell platform with proprietary antibodies across up to four exclusive targets with HDPR's proprietary Antibody Targeted Amanitin Conjugates platform. Upon the exercise of certain license rights, we may be obligated to pay HDPR development, regulatory and commercial milestone payments of up to $83.5 million per target as well as royalties on net sales of products licensed under the agreement.

We have a license agreement with the President and Fellows of Harvard College, entered into in November 2016, for an exclusive, worldwide, royalty-bearing license for certain technologies related to conditioning and mobilization. We are obligated to pay milestone payments of up to $7.4 million for the first two licensed products upon the achievement of certain development and regulatory milestones and to pay royalties on a product-by-product and country-by-country basis on net sales of products licensed under the agreement. To date, we have paid $0.3 million related to the achievement of certain of these milestones. As of December 31, 2021, we were unable to estimate the timing or likelihood of achieving the remaining milestones or generating future product sales.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements included in this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company, as defined in Rule 12b-2 under the Exchange Act, for this reporting period and are not required to provide the information required under this item.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

MAGENTA THERAPEUTICS, INC.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Magenta Therapeutics, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Magenta Therapeutics, Inc. and subsidiary (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP
We have served as the Company's auditor since 2017.

Boston, Massachusetts
March 8, 2022

MAGENTA THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 131,650	$ 58,152
Marketable securities	45,276	90,683
Prepaid expenses and other current assets	3,767	2,692
Total current assets	180,693	151,527
Restricted cash	1,780	1,780
Property and equipment, net	7,461	8,312
Total assets	$ 189,934	$ 161,619
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,040	$ 3,760
Accrued expenses and other current liabilities	7,823	7,670
Total current liabilities	10,863	11,430
Deferred rent	6,399	6,283
Total liabilities	17,262	17,713
Commitments and contingencies (Note 8)		
Stockholders' Equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized; 58,799,157 shares issued and outstanding as of December 31, 2021 and 48,541,601 shares issued and 48,533,135 shares outstanding as of December 31, 2020	59	49
Additional paid-in capital	498,210	398,311
Accumulated other comprehensive loss	(30)	(23)
Accumulated deficit	(325,567)	(254,431)
Total stockholders' equity	172,672	143,906
Total liabilities and stockholders' equity	$ 189,934	$ 161,619

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

MAGENTA THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2021	2020
Operating expenses:		
Research and development	$ 46,766	$ 50,615
General and administrative	27,926	28,087
Total operating expenses	74,692	78,702
Loss from operations	(74,692)	(78,702)
Interest and other income, net	3,556	3,766
Net loss	$ (71,136)	$ (74,936)
Net loss per share, basic and diluted	$ (1.29)	$ (1.71)
Weighted average common shares outstanding, basic and diluted	54,948,808	43,920,121
Comprehensive loss:		
Net loss	$ (71,136)	$ (74,936)
Other comprehensive loss:		
Unrealized losses on marketable securities	(7)	(31)
Total other comprehensive loss	(7)	(31)
Total comprehensive loss	$ (71,143)	$ (74,967)

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

MAGENTA THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2019	39,260,532	$ 39	$320,641	$ 8	$ (179,495)	$ 141,193
Issuance of common stock upon public offering net of underwriting discounts, commissions and offering costs	8,625,000	9	64,554	—	—	64,563
Vesting of restricted stock	184,500	—	—	—	—	—
Issuance of common stock upon exercise of stock options	447,402	1	3,071	—	—	3,072
Issuance of common stock under Employee Stock Purchase Plan	15,701	—	104	—	—	104
Stock-based compensation expense	—	—	9,941	—	—	9,941
Unrealized losses on marketable securities	—	—	—	(31)	—	(31)
Net loss	—	—	—	—	(74,936)	(74,936)
Balances at December 31, 2020	48,533,135	49	398,311	(23)	(254,431)	143,906
Issuance of common stock upon private investment, net of offering costs	9,599,998	10	86,087	—	—	86,097
Vesting of restricted stock	218,464	—	—	—	—	—
Issuance of common stock upon exercise of stock options	421,997	—	3,363	—	—	3,363
Issuance of common stock under Employee Stock Purchase Plan	25,563	—	141	—	—	141
Stock-based compensation expense	—	—	10,308	—	—	10,308
Unrealized losses on marketable securities	—	—	—	(7)	—	(7)
Net loss	—	—	—	—	(71,136)	(71,136)
Balances at December 31, 2021	58,799,157	$ 59	$498,210	$ (30)	$ (325,567)	$ 172,672

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

MAGENTA THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year ended December 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (71,136)	$ (74,936)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	10,308	9,941
Depreciation and amortization expense	2,020	1,978
Loss on disposal of property and equipment	95	1
Net amortization of premiums on marketable securities	708	179
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,075)	1,422
Accounts payable	(720)	948
Accrued expenses and other current liabilities	153	(3,633)
Deferred rent	116	77
Net cash used in operating activities	(59,531)	(64,023)
Cash flows from investing activities:		
Purchases of property and equipment	(1,264)	(400)
Purchases of marketable securities	(45,308)	(95,735)
Maturities of marketable securities	90,000	85,500
Net cash provided by (used in) investing activities	43,428	(10,635)
Cash flows from financing activities:		
Proceeds from private investment	86,400	—
Proceeds from public offerings, net of underwriting discounts and commissions	—	64,860
Payments of offering costs	(303)	(297)
Proceeds from exercise of common stock options	3,363	3,072
Proceeds from issuance of common stock under Employee Stock Purchase Plan	141	104
Net cash provided by financing activities	89,601	67,739
Net increase (decrease) in cash, cash equivalents and restricted cash	73,498	(6,919)
Cash, cash equivalents and restricted cash at beginning of period	59,932	66,851
Cash, cash equivalents and restricted cash at end of period	$ 133,430	$ 59,932

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

MAGENTA THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business and Basis of Presentation

Magenta Therapeutics, Inc. (the "Company") is a clinical-stage biotechnology company developing novel medicines designed to bring the curative power of stem cell transplants to more patients with blood cancers, genetic diseases and autoimmune diseases. The Company was incorporated under the laws of the State of Delaware in June 2015 as HSCTCo Therapeutics, Inc. In February 2016, the Company changed its name to Magenta Therapeutics, Inc. and in June 2018 the Company completed its initial public offering.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, the continuing impact of the novel coronavirus ("COVID-19") pandemic and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The Company has incurred recurring losses since inception, including net losses of $71.1 million and $74.9 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, the Company had an accumulated deficit of $325.6 million. The Company expects to continue to generate operating losses for the foreseeable future. The Company expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance date of these consolidated financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to fund its operations.

The Company expects its expenses to increase substantially in connection with ongoing activities, particularly as the Company advances its preclinical activities and clinical trials for its product candidates in development. Accordingly, the Company will need to obtain substantial additional funding in connection with continuing operations. If the Company is unable to raise capital when needed, or on attractive terms, it could be forced to delay, reduce or eliminate its research or drug development programs or any future commercialization efforts. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated.

Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and

liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual for research and development expenses and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Concentrations of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company maintains all cash, cash equivalents and marketable securities at two accredited financial institutions in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents.

Marketable Securities

The Company's marketable securities are classified as available-for-sale and are carried at fair value with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses and declines in value judged to be other than temporary are included as a component of interest and other income, net based on the specific identification method. The Company classifies its marketable securities with maturities beyond one year as short-term, based on their highly liquid nature and because such marketable securities are available for current operations.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated Useful Life
Lab equipment	5 years
Computer equipment	3 years
Furniture and fixtures	5 years
Leasehold improvements	Shorter of life of lease or estimated useful life

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. The Company did not record any impairment losses on long-lived assets during the years ended December 31, 2021 or 2020.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company’s cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company’s accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Deferred Rent

The Company’s lease agreements include payment escalations and lease incentives, which are accrued or deferred as appropriate such that rent expense for each lease is recognized on a straight-line basis over the respective lease term. Adjustments for such items, consisting primarily of tenant improvement allowances and payment escalations, are recorded as deferred rent and amortized over the lease term.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. All of the Company’s tangible assets are held in the United States.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries, stock-based

compensation and benefits, facilities costs, depreciation, manufacturing expenses and external costs of outside vendors engaged to conduct preclinical development activities and clinical trials as well as the cost of licensing technology.

Upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Research, Development and Manufacturing Contract Costs Accruals

The Company has entered into various research, development and manufacturing contracts with research institutions and other companies both inside and outside of the United States. These agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research, development and manufacturing costs. When evaluating the adequacy of any accrual estimate, the Company analyzes a number of factors, including the Company's knowledge of the progress of the studies or trials, including the phase or completion of events; invoices received to date under the contracts; communication from the third parties of any actual costs incurred during the period that have not yet been invoiced; and the costs included in the contracts. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Stock-Based Compensation

The Company measures all stock-based awards granted to employees, directors and non-employees based on the fair value on the date of grant. Compensation expense of those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues awards with either service-only vesting conditions and records the expense using the straight-line method or service and performance vesting conditions and records the expense when achievement of the performance condition becomes probable using the graded-vesting method. The Company accounts for forfeitures as they occur.

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, the Company estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies along with the volatility of its own stock and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The Company classifies stock-based compensation expense in its statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in its consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2021 and 2020, the Company's only element of other comprehensive income (loss) was unrealized gains (losses) on marketable securities.

Net Loss per Share

Basic net income (loss) per share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock options. For periods in which the Company has reported net losses, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their affect is anti-dilutive.

The Company reported a net loss for the years ended December 31, 2021 and 2020. The following potential dilutive securities, presented based on amounts outstanding at each period end, have been excluded from the calculation of diluted net loss per share because including them would have had an anti-dilutive impact:

	As of December 31,	
	2021	2020
Stock options to purchase common stock	6,248,675	5,622,868
Unvested restricted common stock and units	479,918	373,466
Shares of common stock issuable under Employee Stock Purchase Plan	42,634	15,443
	6,771,227	6,011,777

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 requires lessees to recognize most leases on their balance sheet as a right-of-use asset and a lease liability. Leases will be

classified as either operating or finance, and classification will be based on criteria similar to current lease accounting, but without explicit bright lines. For public entities, the guidance was effective for annual reporting periods beginning after December 15, 2018 and for interim periods within those fiscal years. For nonpublic entities and emerging growth companies that choose to take advantage of the extended transition period, the guidance was effective for annual reporting periods beginning after December 15, 2019. In June 2020, the FASB issued ASU No. 2020-05, which further deferred the effective date for nonpublic entities to annual reporting periods beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted for all entities. ASU 2016-02 initially required adoption using a modified retrospective approach, under which all years presented in the financial statements would be prepared under the revised guidance. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842) Targeted Improvements*, which added an optional transition method to the existing requirements whereby an entity could adopt the provisions of ASU 2016-02 by recognizing a cumulative-effective adjustment to the opening balance of retained earnings in the period of adoption without adjustment to the financial statements for periods prior to adoption. The Company expects that the adoption of the new leasing standards will result in the recognition of material right-of-use assets and lease liabilities on the consolidated balance sheets but does not expect it to have a material impact on its results of operations or cash flows.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326)*. The new standard adjusts the accounting for assets held at amortized costs basis, including marketable securities accounted for as available for sale. The standard eliminates the probable initial recognition threshold and requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For public entities, the guidance was effective for annual reporting periods beginning after December 15, 2019 and for interim periods within those fiscal years. For nonpublic entities and emerging growth companies that choose to take advantage of the extended transition period, the guidance is effective for annual reporting periods beginning after December 15, 2020. Early adoption is permitted for all entities. In November 2019, the FASB issued ASU No. 2019-10, which deferred the effective date for nonpublic entities to annual reporting periods beginning after December 15, 2022, including interim periods within those fiscal years. The Company does not believe the guidance will have a material impact on its consolidated financial statements.

3. Marketable Securities and Fair Value Measurements

As of December 31, 2021, marketable securities by security type consisted of (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury notes (due within one year)	$ 30,213	$ —	$ (20)	$ 30,193
U.S. treasury Notes (due after one year through two years)	15,093	—	(10)	15,083
Total	$ 45,306	$ —	$ (30)	$ 45,276

As of December 31, 2020, marketable securities by security type consisted of (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury notes (due within one year)	$ 90,706	$ —	$ (23)	$ 90,683
Total	$ 90,706	$ —	$ (23)	$ 90,683

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Fair Value Measurements at December 31, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 131,542	$ —	$ —	$ 131,542
Marketable securities:				
U.S. treasury notes	—	45,276	—	45,276
Total	$ 131,542	$ 45,276	$ —	$ 176,818

	Fair Value Measurements at December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 43,182	$ —	$ —	$ 43,182
U.S. treasury notes	—	14,999	—	14,999
Marketable securities:				
U.S. treasury notes	—	90,683	—	90,683
Total	$ 43,182	$ 105,682	$ —	$ 148,864

4. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2021	2020
Laboratory and computer equipment	$ 6,397	$ 5,477
Furniture and fixtures	826	837
Leasehold improvements	6,905	6,905
	14,128	13,219
Less: Accumulated depreciation and amortization	(6,667)	(4,907)
	$ 7,461	$ 8,312

Depreciation and amortization expense was $2.0 million for each of the years ended December 31, 2021 and 2020, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2021	2020
Accrued payroll and related expenses	$3,346	$3,107
Accrued external research and development expenses	2,813	2,662
Deferred rent, current portion	555	555
Accrued professional fees	477	693
Accrued other	632	653
	$7,823	$7,670

6. Common Stock

In May 2021, the Company issued and sold 9,599,998 shares of its common stock in a private placement at a purchase price of $9.00 per share, resulting in net proceeds of $86.1 million, after deducting offering expenses. In connection with the private placement, the Company filed a resale registration statement with the Securities and Exchange Commission (the "SEC") in June 2021 to register the resale of these shares by the purchasers in the private placement.

In June 2020, the Company issued and sold 8,625,000 shares of its common stock, including the underwriters' exercise in full of their option to purchase additional shares of common stock, in a follow-on public offering at a public offering price of $8.00 per share, resulting in net proceeds of $64.6 million after deducting underwriting discounts and commissions and other offering expenses.

The Company has a shelf registration statement on Form S-3 (the "Shelf") on file with the SEC, which covers the offering, issuance and sale of up to an aggregate of $350.0 million of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. The Company simultaneously entered into a sales agreement with Cowen and Company, LLC, as sales agent, to provide for the issuance and sale by the Company of up to $100.0 million of common stock from time to time in "at-the-market" offerings under the Shelf (the "ATM Program"). The Shelf was declared effective by the SEC on August 19, 2019. As of December 31, 2021, no sales have been made pursuant to the ATM Program.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends unless declared by the board of directors.

7. Stock-Based Compensation

2018 Stock Option and Incentive Plan

The Magenta Therapeutics, Inc. 2018 Stock Option and Incentive Plan (the "2018 Plan") provides for the grant of incentive stock options, non-statutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to employees, directors and consultants. Shares of common stock underlying any awards under the 2018 Plan and the Magenta Therapeutics, Inc. 2016 Stock Option and Grant Plan (the "2016 Plan") that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) will be available for future awards under the 2018 Plan. As of December 31, 2021, 3,001,271 shares remained available for future grants under the 2018 Plan.

The 2018 Plan provides that the number of shares reserved and available for issuance under the 2018 Plan will automatically increase each January 1 by 4% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Company's compensation committee. This number is subject to adjustment in the event of a stock split, stock dividend or other change in capitalization. The number of shares reserved for issuance under the 2018 Plan was increased by 2,351,966 shares effective January 1, 2022.

2016 Stock Option and Grant Plan

The Company also has outstanding stock options and restricted stock awards under the 2016 Plan, but is no longer granting awards under this plan.

The 2018 Plan is administered by the board of directors, or at the discretion of the board of directors, by a committee of the board. The exercise prices, vesting and other restrictions are determined at the discretion of the

board of directors, or their committee if so delegated, except that the term of awards may not be greater than ten years. Vesting periods are determined at the discretion of the board of directors. Awards typically vest over three or four years. The exercise price for stock options granted may not be less than the fair value of common stock as of the date of grant. The fair value of common stock is based on quoted market prices.

2019 Employee Stock Purchase Plan

Employees may elect to participate in the Magenta Therapeutics, Inc. 2019 Employee Stock Purchase Plan (the "ESPP"). The purchase price of common stock under the ESPP is equal to 85% of the lower of the fair market value of the common stock on the offering date or the exercise date. The six-month offering periods begin in December and June of each year. During the year ended December 31, 2021, 25,563 shares of common stock were purchased under the ESPP at a weighted average purchase price of $5.53 per share. During the year ended December 31, 2020, 15,701 shares of common stock were purchased under the ESPP at a weighted average purchase price of $6.59 per share. The Company recognized less than $0.1 million of stock-based compensation during each of the years ended December 31, 2021 and 2020 related to the ESPP. As of December 31, 2021, 125,261 shares remained available for issuance under the ESPP.

The ESPP provides that the number of shares reserved and available for issuance under the ESPP will automatically increase each January 1 through January 1, 2029, by the lesser of (i) 1% of the number of shares issued and outstanding on the immediately preceding December 31, (ii) 1,000,000 shares and (iii) such number of shares as determined by the compensation committee of the Company's board of directors. The number of shares reserved for issuance under the ESPP was increased by 587,991 shares on January 1, 2022.

Common Stock Option Valuation

The assumptions that the Company used to determine the fair value of options granted were as follows, presented on a weighted average basis:

	Year Ended December 31,	
	2021	2020
Risk-free interest rate	0.9%	1.0%
Expected term (in years)	6.0	6.0
Expected volatility	80.5%	80.4%
Expected dividend yield	0%	0%

Common Stock Option Activity

The following table summarizes the Company's option activity since December 31, 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	5,622,868	$ 9.54	8.3	$ 2,136
Granted	3,095,759	$ 9.24		
Exercised	(421,997)	$ 7.97		
Forfeited	(2,047,955)	$ 10.58		
Outstanding as of December 31, 2021	6,248,675	$ 9.15	8.2	$ —
Options vested and expected to vest as of December 31, 2021	6,248,675	$ 9.15	8.2	$ —
Options exercisable as of December 31, 2021	2,693,874	$ 9.34	7.1	$ —

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of options exercised during the years ended December 31, 2021 and 2020 was $1.3 million and $1.1 million, respectively.

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2021 and 2020 was $6.32 and $6.90, respectively.

Restricted Stock Activity

Unvested shares of restricted stock may not be sold or transferred by the holder. These restrictions lapse according to the time-based vesting conditions of each award.

The table below summarizes the Company's restricted stock activity for grants issued under the 2016 Plan since December 31, 2020:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2020	8,466	$ 4.84
Vested	(8,466)	$ 4.84
Forfeited	—	
Outstanding as of December 31, 2021	—	

The total fair value of restricted stock vested during the years ended December 31, 2021 and 2020 was less than $0.1 million and $1.7 million, respectively.

Restricted Stock Units

The Company granted service-based restricted stock units to certain employees which vests over three years. Upon vesting, each restricted stock unit entitles the holder to a specified number of shares of common stock.

The table below summarizes the Company's restricted stock unit activity since December 31, 2020:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2020	205,000	$ 6.80
Granted	275,625	$ 8.07
Vested	(39,998)	$ 6.80
Forfeited	(150,709)	$ 7.22
Outstanding as of December 31, 2021	289,918	$ 7.79

The total fair value of restricted stock units vested during the year ended December 31, 2021 was $0.3 million.

Performance Restricted Stock Units

The Company grants performance-based restricted stock units to certain senior employees which vest upon the occurrence of certain operational and financial events. At the achievement of the performance-based vesting criteria, each performance-based restricted stock unit entitles the holder to a specified number of shares of common stock.

The table below summarizes the Company's performance restricted stock unit activity since December 31, 2020:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2020	160,000	$ 6.75
Granted	320,000	$ 10.45
Vested	(170,000)	$ 10.19
Forfeited	(120,000)	$ 6.75
Outstanding as of December 31, 2021	190,000	$ 9.91

The total fair value of performance restricted stock units vested during the year ended December 31, 2021 was $1.0 million.

Stock-Based Compensation

Stock-based compensation expense was classified in the consolidated statements of operations and comprehensive loss as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Research and development expenses	$ 3,836	$3,542
General and administrative expenses	6,472	6,399
	$10,308	$9,941

As of December 31, 2021, unrecognized compensation expense related to unvested share-based awards with service-based vesting conditions was $20.7 million, which is expected to be recognized over a weighted average period of 2.8 years. Additionally, the Company had unrecognized compensation cost of $1.9 million related to the unvested performance restricted stock units for which the performance conditions were not considered probable of achievement as of December 31, 2021.

8. Commitments and Contingencies

Leases

In May 2018, the Company entered into a sublease, as amended, for up to approximately 69,000 square feet of office and laboratory space in Cambridge, Massachusetts. The sublease is subject and subordinate to a prime lease between the sublandlord and the prime landlord. The term of the sublease commenced in June 2018 and expires in February 2028. The sublandlord has the right to terminate the sublease after five years. The Company is obligated to pay real estate taxes and other costs related to the premises, including costs of operations and management of the leased premises. In connection with the sublease, as amended, the sublandlord funded $5.2 million in tenant improvements to the leased facility during 2019. The Company is required to maintain a cash balance of $1.8 million to secure a letter of credit associated with the sublease. This amount was classified as noncurrent restricted cash in the consolidated balance sheets at December 31, 2021 and 2020.

As of December 31, 2021 and 2020, the Company had long-term deferred rent of $6.4 million and $6.3 million, respectively, related to lease incentives and payment escalations. As of December 31, 2021 and 2020, the short-term portion of deferred rent of $0.6 million for each period was included in accrued expenses and other current liabilities. The Company recorded rent expense of $6.2 million during each of the years ended December 31, 2021 and 2020.

As of December 31, 2021, the future minimum lease payments due under the noncancelable operating lease is as follows (in thousands):

2022	$ 6,375
2023	6,734
2024	7,100
2025	7,455
2026	7,828
Thereafter	9,617
	$ 45,109

In 2018, the Company entered into two sub-subleases of approximately 27,000 square feet of office space in Cambridge, Massachusetts. One of the sub-subleases, as amended, expired in December 2021. The remaining sub-sublease, as amended, would have expired in April 2022. In January 2022, the remaining sub-sublease was further amended to increase the square footage from 13,643 square feet to 26,114 square feet and to extend the expiration to April 2023. Total base rent payments due under the further amended sub-sublease was $3.4 million. The Company recorded other income of $3.5 million and $2.9 million during the years ended December 31, 2021 and 2020, respectively, related to its sub-subleases.

Collaboration Agreement

In March 2018, the Company entered into a collaboration agreement with Heidelberg Pharma Research GmbH (“HDPR”) whereby the parties agreed to combine the Company’s stem cell platform with proprietary antibodies across up to four exclusive targets with HDPR’s proprietary Antibody Targeted Amanitin Conjugates platform. Under the agreement, the Company may pay upfront technology access fees, research exclusivity fees and payment for research support. Additionally, upon the exercise of certain license rights, the Company may be obligated to pay HDPR development, regulatory and commercial milestone payments of up to $83.5 million per target as well as royalties on net sales of products licensed under the agreement. During the years ended December 31, 2021 and 2020, the Company recorded $0.4 million and $0.7 million, respectively, of research and development expense related to this agreement for upfront technology access fees, research exclusivity fees and research support.

Intellectual Property Licenses

The Company has a license agreement with the President and Fellows of Harvard College (“Harvard”), entered into in November 2016, for an exclusive, worldwide, royalty-bearing license for certain technologies related to conditioning and mobilization. The Company is obligated to pay Harvard maintenance fees of $0.1 million annually and to reimburse qualified expenses related to the patents. The Company is also obligated to pay milestone payments of up to $7.4 million for the first two licensed products upon the achievement of certain development and regulatory milestones and to pay royalties on a product-by-product and country-by-country basis on net sales of products licensed under the agreement. During each of the years ended December 31, 2021 and 2020, the Company recorded $0.1 million of research and development expenses related to the achievement of two of these milestones.

The Company has a license agreement with Novartis International Pharmaceutical Ltd. (“Novartis”), entered into in April 2017, to use and develop certain patent rights (the “Novartis License”). Under the Novartis License, the Company was granted an exclusive, worldwide, sublicensable license to research, develop and commercialize certain licensed products that contain Novartis compounds for the expansion of cord blood derived non-gene-edited/-modified hematopoietic stem cells. The Company is obligated to make payments of up to $177.0 million upon the achievement of specified clinical and regulatory milestones and up to $125.0 million upon the achievement of specified commercial milestones and to pay tiered royalties, on a product-by-product and

country-by-country basis, up to a maximum of 20% on net sales of products licensed under the agreement. On December 13, 2021, the Company notified Novartis of its termination of the Novartis License which becomes effective 90 days from the date of notification. Prior to the notice of termination, no milestones related to the Novartis License had been met.

The Company has agreements with third parties in the normal course of business, under which it can license certain developed technologies. If the Company exercises its rights to license the respective technologies, it may be subject to additional fees and milestone payments. During the year ended December 31, 2021, the Company did not incur any expense related to these licenses. During the year ended December 31, 2020, the Company recorded research and development expense of $0.8 million related to the license of certain developed technologies under these agreements.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and senior management that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2021 or 2020.

Legal Proceedings

The Company is not currently a party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to its legal proceedings as they are incurred.

9. 401(k) Savings Plan

The Company has a 401(k) available for participating employees who meet certain eligibility requirements. Eligible employees may defer a portion of their salary as defined by the plan. Company contributions to the plan may be made at the discretion of the board of directors of the Company. Effective August 2021, the Company began making matching contributions of up to 2% of eligible wages. During the year ended December 31, 2021, the Company recorded $0.1 million of expense related to this matching contribution.

10. Income Taxes

During the years ended December 31, 2021 and 2020, the Company recorded no income tax benefits for the net operating losses incurred or for the research and orphan drug tax credits generated in each year, due to its uncertainty of realizing a benefit from those items.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2021	2020
Federal statutory income tax rate	21.0%	21.0%
State taxes, net of federal benefit	5.8	5.8
Research and orphan drug tax credits	3.3	3.4
Other	0.5	(1.7)
Increase in deferred tax asset valuation allowance	(30.6)	(28.5)
Effective income tax rate	— %	— %

Net deferred tax assets as of December 31, 2021 and 2020 consisted of the following (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 67,236	$ 49,958
Capitalized research and development expenses	8,665	9,506
Research and orphan drug tax credit carryforwards	12,370	9,988
Stock compensation expense	5,430	2,832
Accrued expense	936	828
Other	1,891	1,867
Total deferred tax assets	96,528	74,979
Valuation allowance	(95,367)	(73,600)
Net deferred tax assets	1,161	1,379
Deferred tax liabilities:		
Depreciation and amortization	(1,161)	(1,379)
Total deferred tax liabilities	(1,161)	(1,379)
Net deferred tax assets and liabilities	$ —	$ —

As of December 31, 2021, the Company had net operating loss carryforwards for federal income tax purposes of $247.2 million, of which $17.5 million begin to expire in 2035 and $229.7 million can be carried forward indefinitely. As of December 31, 2021, the Company had net operating loss carryforwards for state income tax purposes of $247.4 million which begin to expire in 2035. As of December 31, 2021, the Company also had available research and orphan drug tax credit carryforwards for federal and state income tax purposes of $10.3 million and $2.7 million, respectively, which begin to expire in 2035 and 2030, respectively. Utilization of the net operating loss carryforwards and research and orphan drug tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code") due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. The Company has not conducted a formal study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382 and 383 of the Code, at any time since inception, utilization of the net operating loss carryforwards or research and orphan drug tax credit carryforwards may be subject to an annual limitation under Section 382 and 383 of the Code, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any

limitation may result in expiration of a portion of the net operating loss carryforwards or research and orphan drug tax credit carryforwards before utilization.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. The Company considered its history of cumulative net losses incurred since inception and its lack of commercialization of any products since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2021 and 2020. The Company reevaluates the positive and negative evidence at each reporting period.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2021 and 2020 related primarily to the increase in net operating loss carryforwards, capitalized research and development expenses and research and orphan drug tax credit carryforwards and were as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Valuation allowance as of beginning of year	$ 73,600	$ 52,248
Net increases recorded to income tax provision	21,767	21,352
Valuation allowance as of end of year	$ 95,367	$ 73,600

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2021 or 2020.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations. The Company's tax years are open under statute from 2018 to the present. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

11. Related Parties

National Marrow Donor Program (as successor in interest to Be The Match BioTherapies Collection Services, LLC (formerly known as Be The Match BioTherapies, LLC))

Effective March 2018, Amy Lynn Ronneberg, the then serving President of Be The Match BioTherapies, LLC, became a member of the Company's board of directors and subsequently was appointed Chief Executive Officer of the National Marrow Donor Program/Be The Match, or NMDP/Be The Match, organization in June 2020. The Company has collaboration agreements with the National Marrow Donor Program (as successor in interest to Be The Match BioTherapies Collection Services, LLC (formerly known as Be The Match BioTherapies, LLC)) and a research agreement with an affiliated organization, Center for International Blood and Marrow Transplant Research. In addition, in June 2020, the Company entered into a clinical collaboration agreement with NMDP/Be The Match to evaluate the potential utility of MGTA-145 for mobilizing and collecting hematopoietic stem cells from donors in a single day and then using them for allogeneic transplants in patients. Under the terms of this agreement, the Company shall fund up to fifty percent of NMDP/Be The Match clinical trial costs and provide the trial drugs which will be included in research and development expense.

For the years ended December 31, 2021 and 2020, the Company recorded expense of $0.7 million and $0.4 million, respectively, related to these agreements. As of December 31, 2021 and 2020, amounts on the consolidated balance sheets related to these agreements were $0.2 million and less than $0.1 million, respectively, which amounts were included in accounts payable and accrued expenses and other current liabilities and less than $0.1 million, which amounts were included in prepaid expenses and other current assets.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Principal Executive Officer (our Chief Executive Officer) and Principal Financial Officer (our Chief Financial and Operating Officer), has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2021, our Principal Executive Officer and Principal Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control Over Financial Reporting

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2021, our internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Amended and Restated Executive Officer Compensation Agreements

Effective March 3, 2022, we entered into amended and restated employment agreements with our Chief Executive Officer (principal executive officer), Chief Financial and Operating Officer (principal financial

officer) and other of our executive officers, which were approved by the compensation committee of our board of directors and/or our board of directors of, as applicable.

Jason Gardner, D.Phil.

Dr. Gardner's amended and restated employment agreement provides for the payment of an annual base salary and annual incentive compensation, which are subject to review and redetermination by our board of directors. Dr. Gardner's current base salary for fiscal year 2022 is $565,000 and he is eligible to earn an annual incentive with a target amount equal to 55% of his base salary. Dr. Gardner is also eligible to participate in the employee benefit plans available to our employees, subject to the terms of those plans.

Pursuant to his amended and restated employment agreement, in the event Dr. Gardner is terminated by us without "cause" (as defined in the agreement) or he resigns for "good reason" (as defined in the agreement), subject to the delivery of a fully effective general release of claims against us and all related persons and entities, a reaffirmation of all of Dr. Gardner's Continuing Obligations (as defined in the agreement) and, in our sole discretion, a one year post-employment noncompetition covenant, Dr. Gardner will be entitled to receive (i) a cash severance equal to one (1) times his base salary, plus a pro-rata portion of his target annual incentive compensation, payable over the 12-month period following the termination of his employment, and (ii) up to 12 monthly cash payments equal to the monthly contribution for health insurance for Dr. Gardner.

In the event Dr. Gardner is terminated by us without cause or he resigns for good reason, each during the three months before through 12 months following a change in control (as defined in the agreement), subject to the delivery of a fully effective general release of claims against us and all related persons and entities, a reaffirmation of all of Dr. Gardner's continuing obligations (as defined in the agreement) and, in our sole discretion, a one year post-employment noncompetition covenant, Dr. Gardner will not be entitled to receive the severance benefits described above, but will instead be entitled to the following: (i) a lump sum cash severance equal to 1.5 times his base salary, plus 150% of his target annual incentive compensation, (ii) for all outstanding time-based stock options and other time-based stock-based awards held by Dr. Gardner, full accelerated vesting of such awards, and (iii) up to 18 monthly cash payments equal to the monthly contribution for health insurance for Dr. Gardner.

The payments and benefits provided under Dr. Gardner's amended and restated employment agreement in connection with a change in control may not be eligible for federal income tax deduction for us pursuant to Section 280G of the Internal Revenue Code. These payments and benefits may also be subject to an excise tax under Section 4999 of the Internal Revenue Code. If the payments or benefits payable to Dr. Gardner in connection with a change in control would be subject to the excise tax imposed under Section 4999 of the Internal Revenue Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to him. Furthermore, if the payments and benefits provided under Dr. Gardner's amended and restated employment agreement in connection with a change in control would otherwise violate any applicable nondiscrimination rules or cause the reimbursement of claims to be taxable under the Patient Protection and Affordable Care Act of 2010, together with the Health Care and Education Reconciliation Act of 2010 or Section 105(h) of the Internal Revenue Code, then the health insurance payments shall be treated as taxable payments (subject to customary and required taxes and employment-related deductions) and be subject to imputed income tax treatment to the extent necessary to eliminate any discriminatory treatment or taxation. If we determine that we cannot provide the health insurance payments for Dr. Gardner without potentially violating applicable law, we shall instead provide Dr. Gardner with a taxable lump-sum payment in an amount equal to the sum of the monthly (or then remaining) health insurance contributions described above.

Pursuant to his amended and restated employment agreement, Dr. Gardner is subject to standard confidentiality and nondisclosure, assignment of intellectual property work product and post-termination noncompetition and non-solicitation of employees, consultants and customers covenants.

Stephen F. Mahoney

Mr. Mahoney's amended and restated employment agreement provides for the payment of an annual base salary and annual incentive compensation, which are subject to review and redetermination by the compensation committee of our board of directors. Mr. Mahoney's base salary for fiscal year 2022 is $448,000, and he is eligible to earn an annual incentive with a target amount equal to 40% of his base salary. Mr. Mahoney is also eligible to participate in the employee benefit plans available to our employees, subject to the terms of those plans.

Pursuant to his amended and restated employment agreement, in the event Mr. Mahoney is terminated by us without "cause" (as defined in the agreement) or he resigns for "good reason" (as defined in the agreement), subject to the delivery of a fully effective general release of claims against us and all related persons and entities, a reaffirmation of all of Mr. Mahoney's continuing obligations (as defined in the agreement) and, in our sole discretion, a one year post-employment noncompetition covenant, Mr. Mahoney will be entitled to receive (i) a cash severance equal to 0.75 times his base salary plus a pro-rata portion of his target annual incentive compensation, payable over the 12-month period following the termination of his employment and (ii) up to nine monthly cash payments equal to the monthly contribution for health insurance for Mr. Mahoney.

In the event Mr. Mahoney is terminated by us without cause or he resigns for good reason, each during the three months before through 12 months following a change in control (as defined in the agreement), subject to the delivery of a fully effective release of claims, Mr. Mahoney will not be entitled to receive the severance benefits described above, but will instead be entitled to the following: (i) a lump sum cash severance equal to one times his base salary, plus 100% of his target annual incentive compensation, (ii) for all outstanding time-based stock options and other time-based stock-based awards held by Mr. Mahoney, full accelerated vesting of such awards, and (iii) up to 12 monthly cash payments equal to the monthly contribution for health insurance for Mr. Mahoney.

The payments and benefits provided under Mr. Mahoney's amended and restated employment agreement in connection with a change in control may not be eligible for federal income tax deduction for us pursuant to Section 280G of the Internal Revenue Code. These payments and benefits may also be subject to an excise tax under Section 4999 of the Internal Revenue Code. If the payments or benefits payable to Mr. Mahoney in connection with a change in control would be subject to the excise tax imposed under Section 4999 of the Internal Revenue Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to him. Furthermore, if the payments and benefits provided under Mr. Mahoney's amended and restated employment agreement in connection with a change in control would otherwise violate any applicable nondiscrimination rules or cause the reimbursement of claims to be taxable under the Patient Protection and Affordable Care Act of 2010, together with the Health Care and Education Reconciliation Act of 2010 or Section 105(h) of the Internal Revenue Code, then the health insurance payments shall be treated as taxable payments (subject to customary and required taxes and employment-related deductions) and be subject to imputed income tax treatment to the extent necessary to eliminate any discriminatory treatment or taxation. If we determine that we cannot provide the health insurance payments for Mr. Mahoney without potentially violating applicable law, we shall instead provide Mr. Mahoney with a taxable lump-sum payment in an amount equal to the sum of the monthly (or then remaining) health insurance contributions described above.

Pursuant to his amended and restated employment agreement, Mr. Mahoney is subject to standard confidentiality and nondisclosure, assignment of intellectual property work product and post-termination noncompetition and non-solicitation of employees, consultants and customers covenants.

Director Resignation and Board Class Reapportionment

On March 3, 2022, solely in order to provide for an equal apportionment of directors among the three classes of the Company's classified board of directors, Thomas O. Daniel, M.D. tendered his resignation from the

board of directors as a class III director whose term of office expires at the Company's annual meeting of stockholders to be held in 2024, with such resignation effective immediately, and, with the recommendation of the nominating and corporate governance committee of the Company's board of directors, was appointed to the board of directors immediately thereafter as a class I director whose term of office expires at the Company's annual meeting of stockholders to be held in 2022. Dr. Daniel was also re-appointed to the position of chair of the compensation committee and member of the research and development committee of the board of directors. After giving effect to Dr. Daniel's resignation and immediate re-election to the Company's board of directors, there are now three directors in each of class I, class II and class III.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders 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 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Financial Statements

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page 133 of this Annual Report on Form 10-K, incorporated into this Item by reference.

2. Financial Statement Schedules

Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

3. Exhibits

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The exhibits listed in the Exhibit Index are incorporated by reference herein.

ITEM 16. FORM 10-K SUMMARY

None.

Exhibit Index

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38541) filed with the Securities and Exchange Commission on June 25, 2018).
3.2	Amended and Restated By-laws of the Registrant (Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-38541) filed with the Securities and Exchange Commission on June 25, 2018).
4.1	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333-225178) filed with the Securities and Exchange Commission on June 8, 2018).
4.2	Second Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders dated April 2, 2018 (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-225178) filed with the Securities and Exchange Commission on May 24, 2018).
4.3	Description of Securities of the Registrant (Incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K (File No. 001-38541) filed with the Securities and Exchange Commission on March 3, 2020).
10.1#	2016 Stock Option and Grant Plan, as amended, and forms of award agreements thereunder (Incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-225178) filed with the Securities and Exchange Commission on May 24, 2018).
10.2#	2018 Stock Option and Incentive Plan and forms of award agreements thereunder (Incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1/A (File No. 333-225178) filed with the Securities and Exchange Commission on June 8, 2018).
10.3#	Senior Executive Cash Incentive Bonus Plan (Incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-225178) filed with the Securities and Exchange Commission on May 24, 2018).
10.4#	Form of Director and Officer Indemnification Agreement (Incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-225178) filed with the Securities and Exchange Commission on May 24, 2018).
10.5#	2019 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38541) filed with the Securities and Exchange Commission on June 11, 2019).
10.6†	License Agreement by and between the Registrant and President and Fellows of Harvard College, dated as of November 2, 2016 (Incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-225178) filed with the Securities and Exchange Commission on May 24, 2018).
10.7†	Master Development and Manufacturing Agreement by and between the Registrant and Bachem Americas, Inc., dated as of February 13, 2018 (Incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1/A (File No. 333-225178) filed with the Securities and Exchange Commission on June 18, 2018).

Exhibit Number	Description
10.8†	Exclusive Research, Development Option and License Agreement by and between the Registrant and Heidelberg Pharma Research GmbH, dated as of March 1, 2018 (Incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-225178) filed with the Securities and Exchange Commission on May 24, 2018).
10.8.1	Letter Agreement, effective as of February 28, 2019, by and between the Registrant and Heidelberg Pharma Research GmbH, relating to the Exclusive Research, Development Option and License Agreement by and between the Registrant and Heidelberg Pharma Research GmbH, dated as of March 1, 2018 (Incorporated by reference to Exhibit 10.12.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-231097) filed with the Securities and Exchange Commission on April 29, 2019).
10.8.2†	Amendment, effective as of July 4, 2019, pursuant to the Exclusive Research, Development Option and License Agreement by and between the Registrant and Heidelberg Pharma Research GmbH, dated as of March 1, 2018 (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38541) filed with the Securities and Exchange Commission on November 13, 2019).
10.9	Sublease by and between the Registrant and Novartis Institutes for BioMedical Research, Inc., dated as of May 4, 2018 (Incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-225178) filed with the Securities and Exchange Commission on May 24, 2018).
10.9.1	First Amendment to Sublease Agreement, dated as of December 13, 2018, by and between the Registrant and Novartis Institutes for BioMedical Research, Inc. (Incorporated by reference to Exhibit 10.14.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-231097) filed with the Securities and Exchange Commission on April 29, 2019).
10.9.2	Second Amendment to Sublease Agreement, dated as of August 19, 2020, by and between the Registrant and Novartis Institutes for BioMedical Research, Inc. (Incorporated by reference to Exhibit 10.14.2 to the Registrant's Annual Report on Form 10-K (File No. 001-38541) filed with the Securities and Exchange Commission on March 3, 2021).
10.10	Securities Purchase Agreement, among the Registrant and certain of its stockholders dated May 12, 2021 (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38541) filed with the Securities and Exchange Commission on May 12, 2021).
10.11*^	Master Services Agreement, dated as of May 22, 2019, by and between the Registrant and Heidelberg Pharma Research GmbH.
10.12*#	Amended and Restated Employment Agreement by and between the Registrant and Jason Gardner, effective March 3, 2022.
10.13*#	Amended and Restated Employment Agreement by and between the Registrant and Stephen Mahoney, effective March 3, 2022.
21.1*	List of Subsidiaries of the Registrant.
23.1*	Consent of KPMG LLP, independent registered public accounting firm.
24.1*	Power of Attorney (included on signature page to this Annual Report on Form 10-K).
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certifications of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Exhibit Number	Description
101SCH*	Inline XBRL Taxonomy Extension Schema Document.
101CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
101DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101).

* Filed herewith.
** Furnished herewith.
# Represents management compensation plan, contract or arrangement.
† Application has been made to the Securities and Exchange Commission for confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.
^ Portions of this exhibit have been omitted in accordance with the rules of the Securities and Exchange Commission.

SIGNATURES

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

MAGENTA THERAPEUTICS, INC.

Date: March 8, 2022

By: /s/ Stephen Mahoney
Stephen Mahoney
Chief Financial and Operating Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Jason Gardner and Stephen Mahoney, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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

Signature	Title	Date
/s/ Jason Gardner, D.Phil. Jason Gardner, D.Phil.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 8, 2022
/s/ Stephen Mahoney Stephen Mahoney	Chief Financial and Operating Officer (Principal Financial and Accounting Officer)	March 8, 2022
/s/ Jeffrey Albers Jeffrey Albers	Director	March 8, 2022
/s/ Bruce Booth, D.Phil. Bruce Booth, D.Phil.	Director	March 8, 2022
/s/ Alexis A. Borisy Alexis A. Borisy	Director	March 8, 2022
/s/ Thomas O. Daniel, M.D. Thomas O. Daniel, M.D.	Director	March 8, 2022
/s/ Alison F. Lawton Alison F. Lawton	Director	March 8, 2022
/s/ Anne M. McGeorge Anne M. McGeorge	Director	March 8, 2022
/s/ Amy L. Ronneberg Amy L. Ronneberg	Director	March 8, 2022
/s/ David T. Scadden, M.D. David T. Scadden, M.D.	Director	March 8, 2022

Exhibit 10.11

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [**], HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT MAGENTA THERAPEUTICS, INC. TREATS AS PRIVATE OR CONFIDENTIAL.

Master Services Agreement

BETWEEN

Heidelberg Pharma Research GmbH,

with its registered offices at Schriesheimer Str. 101, 68526 Ladenburg, Germany

(hereafter "HDPR")

AND

Magenta Therapeutics, Inc.

with its registered offices at 100 Technology Square, 5th Floor, Cambridge, MA 02139, USA

(hereafter "Customer")

(each also referred to as a "Party" or collectively as the "Parties")

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Recitals

This Agreement is made this 22nd day of May, 2019.

WHEREAS:

A. Customer and HDPR have concluded an Exclusive Research, Development Option and License Agreement dated March 1st 2018 (the "**ERDOLA**"), setting forth the terms and conditions for a target-exclusive license for Customer to HDPR's technology of amatoxin-based antibody drug conjugates, as well as the framework for the negotiation of a separate agreement between Customer and HDPR on the supply of Amanitin Toxin Constructs (the term is used in this Agreement as defined in the ERDOLA);

B. HDPR is the owner of certain technology and patent rights regarding the Amanitin Toxin Constructs and is subcontracting process development, manufacturing and supply services of active pharmaceutical ingredients and intermediates related to the Amanitin Toxin Constructs to [**]; and

C. Customer will during the term of this Agreement from time to time request HDPR to perform certain services related to the manufacturing of Amanitin Toxin Constructs, and HDPR is willing to provide such services through its existing relationship with [**]; and

D. This Agreement shall exclusively govern the relationship of the Parties with regard to the provision of the Services (as defined below) by HDPR to the Customer, and no general terms and conditions of a Party shall be binding to the other Party.

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

1 Definitions

For the purpose of this Agreement:

a) **"Affiliate"** means any Person directly or indirectly, controlling, controlled by, or under common control with another Person. For purposes of this definition, "controlling" (including, "controlled by" and "under common control") shall mean: (a) ownership of more than fifty percent (50%) of the equity capital or other ownership interest in or of an entity; (b) the power to control or otherwise direct the affairs of an entity; (c) in the case of non-stock organizations, the power to control the distribution of profits of an entity; or (d) such other relationship as, in fact, results in actual control over the management, business, and affairs of an entity;

b) **"Agreement"** means this Master Services Agreement, together with all its appendices and documents incorporated by reference therein and part hereof, as amended or modified from time to time in accordance with the terms hereof;

c) **"Applicable Law"** means any law, statute, rule, regulation, order, judgement or ordinance of any governmental or Regulatory Authority or agency that may be in effect from time to time during the Term and applicable to a particular activity or country hereunder;

d) **"Business Day"** means any day that is not a Saturday, a Sunday on which banking institutions in Frankfurt A.M., Germany, Zurich, Switzerland and New York, New York are open for business.

e) [**]

f) **"Confidential Information"** means any and all non-public and proprietary information, whether technical or non-technical, oral or written, that is disclosed by one Party or its Affiliates to the other Party or its Affiliates in connection with this Agreement. Notwithstanding the foregoing, "Confidential Information" shall not include any information or any portion thereof which:

(i) was known to the recipient or any of its Affiliates, as evidenced by its written records, before receipt thereof under this Agreement;

(ii) is disclosed to the recipient or any of its Affiliates, without restriction, after the Effective Date by a Third Party who has the right to make such disclosure;

(iii) is or becomes part of the public domain through no breach of this Agreement by the recipient or any of its Affiliates; or

(iv) is independently developed by or for the recipient or any of its Affiliates, as evidenced by its written records, by individuals or entities who have not had access to the disclosing Party's Confidential Information that was disclosed under this Agreement.

The Confidential Information may include data, know-how, formulae, processes, designs, sketches, photographs, plans, drawings, specifications, samples, reports, studies, data, findings, inventions, ideas, production facilities, machines, production capacities, prices, market share, research and development projects, and other market data. The terms of this Agreement will constitute Confidential Information of both Parties. For clarity, specific aspects or details of Confidential Information will not be deemed to be within the public domain or in the possession of the recipient merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the recipient. Further, any combination of Confidential Information will not be considered in the public domain or in the possession of the recipient merely because individual elements of such Confidential Information are in the public domain or in the possession of the recipient, unless the combination and its principles are in the public domain or in the possession of the recipient.

g) **"Effective Date"** means the date first written above;

h) **"Facility"** means [**] premises where the Goods are made ready for shipment.

i) **"Good Manufacturing Practices"** or **"GMP"** means all Applicable Laws relating to manufacturing practices for products (including ingredients, testing, storage, handling, intermediates, bulk and finished products) promulgated by the FDA and any other Regulatory Authority (including, without limitation, the EMA or member state level and Swissmedic) having jurisdiction over the manufacturing practices for products, including standards in the form of Applicable Laws, guidelines, advisory opinions and compliance policy guides and current interpretations of the applicable authority or agency thereof (as applicable to pharmaceutical and biological products and ingredients), as the same may be updated, supplemented or amended from time to time.

j) **“Goods”** means the product(s), chemical(s), intermediate(s), substance(s) or compound(s) created through the performance of the Services by HDPR;

k) **“Intellectual Property Right”** means any and all intellectual property rights throughout the world, however denominated, including if registered or not (including patents, copyrights, trade secrets, trade marks, general know-how, processes, etc.);

l) **“Non-Compliance”** or **“Non-Compliant Good”** has the meaning as defined in Section 8.3;

m) **“Party”** means either HDPR or Customer, as the case may be, and “Parties” shall mean HDPR and the Customer;

n) **“Project Leader”** means the responsible person of either Customer or HDPR for planning, managing, directing and overseeing specific activities regarding the Agreement;

o) “**Project Management Fee**” means the consideration payable to HDPR by Customer for the provision of project management for Services as set forth in the applicable Work Order;

p) **“Proposal”** means a description of the Services to be provided by HDPR to Customer, including, without limitation, a description of any Goods to be created through the performance of the Services, and the Service Fees, timelines or cycle times for such Services and Goods;

q) **“Quality Agreement”** means the agreement concluded by the Parties, which shall govern the responsibilities related to quality systems, quality requirements, quality control, testing, Reports, audits, complaints, inspections and release for the Goods; as incorporated herein by reference and part hereof;

r) **“Report”** means the description of the performed Services by HDPR in written form and in the agreed depth of detail as further specified in the Agreement;

s) **“Section”** means a section of this Agreement;

t) **“Services”** means those development, synthesis, analytical purification, (pre-) formulation, packaging, storage, stability, release testing, quality control services or other related services to be provided by HDPR to Customer (including the targeted quantity of Goods to be delivered), as further defined in the applicable Work Order;

u) **“Service Fee”** means the consideration payable to HDPR by Customer for the provision of every particular Service set forth in the applicable Work Order and as set out in Section 5;

v) **“Third Party”** means any Person other than (i) a Party, (ii) an Affiliate of a Party or (iii) [**].

w) **“Work Order”** means a description of the individual Services to be performed by HDPR, including, without limitation, a description of any Goods to be created through the performance of the Services, and the Service Fees, timelines or cycle times for such Services and Goods; as incorporated herein by reference and part hereof.

2 Principles of performance of the Agreement; General obligations

2.1 Upon receipt of Customer’s request to perform certain services, HDPR will, as a rule not more than [**] of such request (the “Proposal Preparation Timeframe”), prepare a Proposal for such services. HDPR will employ commercially reasonable efforts to comply with the Proposal Preparation Timeframe. If the Proposal Preparation Timeframe cannot be met HDPR will promptly inform Customer about the reasons and the envisaged new timeline. If Customer agrees to the terms of such Proposal, it shall send to HDPR the signed Proposal as agreed by the Parties within the timeline set forth in the Proposal, for countersignature by HDPR, which countersignature shall take place without delay upon receipt of the signed Proposal by HDPR and shall not be unreasonably withheld. Upon signature by both Parties the Proposal shall become a Work Order that will be binding for both Parties. For the avoidance of any doubt, HDPR shall not be obliged to perform any Services if Customer has not, in its sole discretion, sent a signed Proposal to HDPR.

2.2 Both Parties shall always cooperate, communicate and act diligently and in good faith in order to ensure the proper performance of the Agreement. HDPR undertakes to make every commercially reasonable effort to implement requested amendments to each Work Order. Such amendments of any Work Order, including any adjustment of the Service Fee and estimated term, if applicable, shall be in writing and become binding upon the Parties execution of the amended Work Order. HDPR shall promptly notify Customer of any unanticipated adverse effect or any adverse event that becomes known to it occurring during the performance of the Agreement.

2.3 Customer has the obligation to render all necessary support reasonably requested by HDPR to enable a proper performance of the Agreement, such as, but not limited to, taking and notifying decisions, accepting or declining requests, giving or refusing consents, etc.

2.4 The day-to-day management of the Agreement shall be the responsibility of Customer's Project Leader and HDPR's Project Leader. The Customer's Project Leader shall be the ultimate authority with respect to all Agreement related issues and decisions on behalf of the Customer and hence shall be assumed to have all necessary authority and power to take any and all actions on behalf of Customer with respect to such day-to-day issues and decisions. In addition, the Parties shall appoint a joint program team composed of qualified representatives from HDPR and Customer, with the option to include representatives from [**] from time to time whenever both Parties agree that this would be necessary or useful (the "Program Team"). The Program Team shall be responsible for carrying out the Work Order(s). The Program Team shall meet at least every other week by teleconference and shall meet quarterly in person, unless the Parties mutually agree otherwise. HDPR shall be responsible for coordinating meetings and meeting minutes and circulating meeting minutes to the Program Team as soon as reasonably practicable for comments and approval. For the avoidance of doubt, the Program Team shall not have the authority to amend or modify this Agreement, the Quality Agreement, or any Work Order. Any additional responsibilities of the Program Team will be specified in the applicable Work Order.

2.5 In case of any discrepancies between the provisions of the body of this Agreement with any of its appendices or documents incorporated by reference herein, the body of this Agreement shall take precedence over all and any such appendices or documents; *provided, however*, that such appendices or documents shall expressly modify, amend or supersede a specific Section of the body of this Agreement if such appendices or documents expressly reference to the Section being modified, amended or superseded. Notwithstanding the foregoing, if an amendment or a modification of this Agreement is expressly agreed in a specific Work Order only, such amendment or modification shall only apply for such specific Work Order. The Quality Agreement (if any) shall take precedence in all matters regarding the standard of quality of the Services.

3 HDPR's specific obligations

3.1 As the Parties consider the Services as of an experiential and development nature, subject to Sections 3.2 to 3.5 below, HDPR cannot and does not guarantee the achievement of any specific or particular result or outcome nor guarantee completing thereof to or within a defined deadline. For avoidance of doubt, the foregoing sentence shall not relieve HDPR of its obligation to provide the Services or Goods in accordance with this Agreement, the Quality Agreement, or the applicable Work Order.

3.2 HDPR shall cause [**] to perform the Services (a) in accordance with this Agreement, the Quality Agreement and each Work Order, including within the agreed time targets, (b) in a manner that meets professional and industry standards reasonably to be expected from a first-class provider of similar services in similar circumstances and (c) in compliance with all Applicable Laws at the place of performance thereof.

3.3 HDPR shall ensure that [**] reserves time slots and qualified personnel as necessary to perform the Services, as agreed in each Work Order.

3.4 HDPR shall ensure that the personnel that [**] on behalf of HDPR causes to be applied in the performance of the Agreement shall be appropriately qualified and experienced for the tasks that they are to perform.

3.5 HDPR shall ensure that any machinery and equipment that [**] on behalf of HDPR provides or causes to be applied in the performance of the Agreement shall be of an appropriate quality and, as required by normal practice, shall be certified and approved by the relevant body or organisation.

3.6 HDPR shall cause [**] to have and maintain, at its own cost, any and all licenses, permits and other authorisations, which are required for its performance of this Agreement and the Services provided hereunder.

3.7 HDPR shall not be liable for any raw material supply issues beyond its or [**] direct control. The impact of any quality or delivery issues shall be discussed in good faith between Customer and HDPR and the Work Order revised accordingly. HDPR will employ commercially reasonable efforts, and shall cause [**] to employ commercially reasonable efforts to find an adequate replacement, taking into account the timelines envisaged in the Work Order.

3.8 HDPR shall cause [**] to perform the Services at its facilities as set forth in Annex 3.8. If [**] intends to perform any part of the Services at any other facility, HDPR shall seek Customer's prior written approval before doing so, such approval not to be unreasonably withheld, delayed or conditioned, and Annex 3.8 shall be amended accordingly if Customer provides its approval as aforesaid.

3.9 Notwithstanding the delegation of activities to [**] hereunder, HDPR shall remain primarily responsible for its obligations (and the obligations of [**]) under this Agreement.

4 Subcontracting

HDPR may allow [**] to subcontract the Services to subcontractors agreed between [**] and HDPR. If [**] intends to subcontract any part of the Services, HDPR shall (a) notify Customer in writing, including the identity of the proposed subcontractor and the Services to be subcontracted and (b) cause [**] to appropriately qualify the potential subcontractor according to [**] vendor qualification procedure and conclude a quality agreement with such subcontractor enforcing the terms of this Agreement and the Quality Agreement, with respect to (a)-(b), before subcontracting such activity. In addition, any documentation on supplier qualification and the quality agreement shall be available for Customer review in the course of Customer's audits pursuant to Section 7.1. Customer understands and acknowledges that parts of the documentation may be redacted to comply with [**] confidentiality obligations. However, if Customer should require the disclosure of redacted information in order to comply with its obligations towards applicable authorities it may request disclosure of such information, and HDPR shall cause [**] to discuss in good faith disclosure of such information with the corresponding subcontractor. In any event, HDPR shall be responsible for oversight of the subcontracted Services and all obligations under this Agreement and the Quality Agreement shall remain vested in HDPR.

5 Service Fee; payment

5.1 In consideration of HDPR providing the Services to Customer, Customer shall pay HDPR Service Fees specified in the applicable Work Order. The Service Fee will be agreed in each Work Order for Services.

5.2 Customer shall pay HDPR according to the payment schedule in the applicable Work Order.

5.3 All Goods are shipped FCA (Incoterms 2010) [**] loading docks at the Facility.

5.4 The amount, weight and quantity of Goods will be measured or weighed at the Facility.

5.5 The Service Fee does not include any state or local taxes, duties, governmental or similar charges, VAT, customs duties or any additional costs (such as but not limited to insurance costs, etc.). Any such costs, if any, will be additionally charged to Customer.

5.6 Costs for disposal of any Goods or unused raw materials are not included in the Service Fee. Such costs will therefore additionally be charged to Customer at cost, unless such Goods or unused raw material are required to be disposed on account of HDPR's gross negligence, fraud, intentional misconduct or breach of this Agreement, in which case, HDPR shall pay for the cost of such disposal.

5.7 Third Party costs for analytical services, specific chromatography columns, reagents or reference standards will be described in the applicable Work Order.

5.8 HDPR will cause [**] to store and insure the Goods to be delivered to Customer free of charge for a period of [**] following the date of release. Any storage and insurance exceeding this period of time will additionally be invoiced to Customer at reasonable cost. In case of postponement of the delivery date and/or the project at Customer's request, storage and insurance of Goods and raw materials will additionally be charged to Customer at reasonable cost.

5.9 Prices for raw materials will be described in the applicable Work Order.

5.10 Invoices for Service Fees and other amounts payable to HDPR are payable by Customer within [**] of the date an invoice is received by Customer. If Customer disputes all or any portion of an invoice, then the Parties will attempt to resolve such dispute in good faith for [**] following Customer's notice to HDPR that it disputes an invoice or portion thereof. In furtherance of the foregoing dispute resolution process, HDPR will maintain written records of the fees and expenses charged to Customer with respect to the Services. HDPR shall retain such records for [**] after the completion or termination of the Services to which they pertain and shall make such records available to Customer during normal business hours upon reasonable advanced notice. In the event the Parties are unable to resolve a payment dispute in such [**] period, then either Party may initiate dispute resolution in accordance with Section 21. Customer will have no obligation to pay any amounts disputed in good faith until such dispute is finally resolved and no appeal can be taken, except that HDPR may request payment of a portion of the invoice to fulfill its payment obligations towards [**], such amount to be repaid to Customer in case that no amounts are owed by Customer as a result of the dispute resolution. If amounts are finally determined to be owed to HDPR, Customer will pay such amounts to HDPR within [**] of such determination (including interest due). In the event that any payment due under this Agreement is not made when due, the payment shall accrue interest calculated on a daily basis from the due date until full payment at the rate of EURIBOR plus [**] per year.

6 Quality

6.1 The appropriate level of quality for the specific Services (GMP, non GMP, etc.) will be defined in the Work Order.

6.2 If not defined in the Work Order, the responsibilities related to quality systems, quality requirements, quality control, testing and manufacturing records, audits, complaints, inspections and release of Goods shall be governed by the Quality Agreement.

7 Customer's inspection rights

7.1 Customer's audit inspection and audit rights are set forth in the Quality Agreement.

8 Transfer of ownership and risk; Delivery; Acceptance

8.1 Delivery of Goods shall be deemed completed, and risk of loss or damage with respect thereto, shall pass to Customer upon delivery to the carrier. Title to Goods shall pass to Customer upon complete payment of the corresponding invoice.

8.2 Subject to Sections 3.2 to 3.5 above, delivery times of HDPR shall not be regarded as binding, and delays of anticipated delivery shall not entitle Customer to claim damages resulting from any such delay. However, HDPR will employ commercially reasonable efforts, and will cause [**] to employ commercially reasonable efforts to comply with the timelines agreed in the Work Orders. In case that a timeline cannot be met HDPR will notify Customer promptly upon receipt of knowledge on such deviation.

8.3 Within [**] of any Goods, Customer shall examine any such Goods and Services. Notice of all claims arising out of non-compliance with the agreed level of quality (e.g. GMP), specifications, compliance with this Agreement, the Quality Agreement, Applicable Law or the applicable Work Order, or deliverables or any shortages or defects of delivered Goods or Services (any of the before a "Non-Compliance" or "Non-Compliant Good"), shall be given in writing to HDPR within [**] (the "Notice of Rejection"). With respect to any Non-Compliance, which would not be apparent from a reasonable visual inspection on delivery and, in case of any hidden or latent Non-Compliance, Notice of Rejection shall be given not later than [**] from the time Customer discovers or should have discovered the relevant Non-Compliance, however in no event later than (i) within [**], or (ii) the expiry of the shelf life of the affected Goods; whatever is shorter. The failure of Customer or its designees to notify HDPR of any Non-Compliance of a Good in the manner set forth herein above shall constitute confirmation of the acceptance thereof.

8.4 If HDPR disputes the Notice of Rejection within [**], then the Parties shall investigate Customer's assertion of Non-Compliance and discuss in good faith a resolution of any such disagreement regarding the Goods or Services. The Parties shall act promptly and shall cooperate fully and in good faith in such investigations. If the Parties do not reach an agreement, then HDPR and Customer shall (each acting reasonably and in good faith) mutually elect an independent Third Party laboratory or expert (acting as an expert and not an arbitrator) to determine if the Goods or Services are Non-Compliant Goods and make a determination regarding the cause of the Non-Compliance. Such results shall be binding upon both Parties. The cost of the testing and evaluation by the expert shall be borne entirely by the Party against whom such laboratory's or expert's findings are made. In the event of Non-Compliance, Customer shall have the remedies set forth in Article 12.

9 Warranties of HDPR

HDPR hereby represents, warrants and covenants to Customer as of the Effective Date as follows:

a) HDPR has been duly organized and is validly subsisting and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;

b) HDPR has the right to enter into this Agreement and this Agreement is a legal and valid obligation binding upon HDPR and enforceable in accordance with its terms (including the right to enforce the actions or obligations taken by [**] on behalf of HDPR under this Agreement or any Work Order);

c) the execution, delivery and performance of this Agreement by HDPR has been duly authorized by all necessary corporate action;

d) HDPR has not made and will not make any commitments to Third Parties inconsistent with or in derogation of HDPR's obligations under this Agreement and HDPR is not subject to any obligations that would prevent it from entering into or carrying out its obligations under this Agreement;

e) all delivered Goods shall, at the time of delivery, (i) conform to the specifications agreed between HDPR and Customer in the Work Order and (ii) comply with this Agreement, the Quality Agreement and Applicable Law;

f) the Services shall be provided (a) in accordance with this Agreement, the Quality Agreement and each Work Order, including within the agreed time targets, (b) in a manner that meets professional and industry standards reasonably to be expected from a first-class provider of similar services in similar circumstances and (c) in compliance with all Applicable Laws at the place of performance thereof.

g) it has not and shall not, and shall cause [**] (or any other Third Party acting on HDPR's behalf) to not, at any time from and after the Effective Date, retain or use the services of (i) any Person of whom HDPR, respectively [**], has knowledge that such Person is debarred under 21 U.S.C. § 335a or (ii) any Person of whom HDPR, respectively [**] (or such other Third Party), has knowledge that such Person has been convicted of a crime as defined under the FDCA, in each case, in any capacity associated with or related to the Services to be provided under this Agreement. HDPR agrees to immediately disclose in writing to Customer if it receives knowledge that any of its or [**] employees or agents is debarred, or if any action or investigation is pending or, to the best of HDPR's knowledge, is threatened in relation to the debarment of HDPR or any person performing Services or providing services in any capacity in connection with this Agreement;

h) to HDPR's knowledge as of the Effective Date, the performance of Services and the Goods provided under this Agreement shall not infringe the intellectual property rights of any Third Party;

i) all records and reports required to be maintained by HDPR or [**] under Applicable Law, including GMP, where applicable, shall be accurate and complete in all material respects;

j) it shall not terminate its agreement with [**] relating to the process development, manufacturing and supply services of Amanitin Toxin Constructs without cause and shall notify Customer promptly if such agreement is terminated; and

k) each of HDPR's and [**] employees, consultants, agents or any contractors performing Services under a Work Order are bound by written obligations or Applicable Law to assign all of their rights, title and interests in, to and under any intellectual property resulting from their performance of Services to HDPR or [**], as applicable.

10 Customer's use of Goods and representations

Customer hereby represents, warrants and covenants to HDPR as of the Effective Date as follows:

a) Customer has been duly organized and is validly subsisting and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;

b) Customer has the right to enter into this Agreement and this Agreement is a legal and valid obligation binding upon Customer and enforceable in accordance with its terms;

c) the execution, delivery and performance of this Agreement by Customer has been duly authorized by all necessary corporate action;

d) Customer has not made and will not make any commitments to Third Parties inconsistent with or in derogation of Customer's obligations under this Agreement and Customer is not subject to any obligations that would prevent it from entering into or carrying out its obligations under this Agreement; and

e) Customer will use any Goods manufactured under this Agreement in strict compliance with all Applicable Laws.

11 No Other Warranty

THE REPRESENTATIONS AND WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT ARE THE SOLE REPRESENTATIONS AND WARRANTIES MADE BY EITHER PARTY TO THE OTHER AND, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE PARTIES HEREBY DISCLAIM ANY AND ALL OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

12 Liability

12.1 If Customer issues a Notice of Rejection (other than for shortages, which are governed by Section 12.2), and (a) if HDPR does not contest (or does not contest within [**]) or (b) if the independent Third Party laboratory or expert confirms such Non-Compliance pursuant to Section 8.4, with respect to each, then HDPR's sole and exclusive liability and Customer's exclusive remedy with respect to Non-Compliant Goods shall either be replacement of such Non-Compliant Goods without charge or the refund of the Service Fees paid with respect to the Non-Complaint Goods, at Customer's sole discretion. Any further claims of whatever nature (e.g. , damages, compensation, etc.) are herewith expressly excluded, except with respect to Claims brought under Article 13. HDPR shall have a right to remedy, through reprocessing, any Non-Compliance within a reasonable period of time, failing which Customer shall be entitled to the remedies set forth herein. HDPR shall not do any reprocess work without Customer's prior written approval, which shall not be withheld or delayed unreasonably.

12.2 UNLESS (A) IN CASE OF A PARTY'S GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUD, (B) BREACH OF A PARTY'S REPRESENTATIONS, WARRANTIES AND COVENANTS HEREUNDER, (C) A PARTY'S INDEMNIFICATION OBLIGATION UNDER SECTION 13, (D) A PARTY'S BREACH OF SECTION 16, OR (E) IN ANY CASE OF PERSONAL INJURY OR DEATHRESULTING FROM A PARTY'S GROSS NEGLIGENCE, INTENTIONAL MISCONDUCT OR FRAUD, WITH RESPECT TO EACH, EACH PARTY'S OVERALL LIABILITY UNDER THIS AGREEMENT SHALL NOT EXCEED [**]) UNDER THIS AGREEMENT.

12.3 UNLESS RELATING TO (A) A PARTY'S GROSS NEGLIGENCE, INTENTIONAL MISCONDUCT OR FRAUD, (B) A PARTY'S BREACH OF ITS REPRESENTATIONS, WARRANTIES OR COVENANTS, (C) A PARTY'S INDEMNIFICATION OBLIGATION UNDER SECTION 13, (D) A PARTY'S BREACH OF SECTION 16, OR (D) ANY CASE OF PERSONAL INJURY OR DEATH CAUSED BY A PARTY'S GROSS NEGLIGENCE, INTENTIONAL MISCONDUCT OR FRAUD, WITH RESPECT TO EACH, NEITHER PARTY SHALL BE LIABLE FOR ANY CONSEQUENTIAL LOSSES AND DAMAGES, PUNITIVE DAMAGES, ANTICIPATED OR LOST PROFITS, BUSINESS INTERRUPTION, INCIDENTAL DAMAGES, LOSS OF TIME, OR OTHER SIMILAR LOSSES IN CONNECTION WITH THIS AGREEMENT.

13 **Indemnification**

13.1 Each Party shall indemnify the other Party and its representatives, consultants and Affiliates from and against any and all losses and claims (including reasonable legal fees and other costs of defending any action) arising or resulting from Third Party Claims (as defined below) made against the other Party with respect to any death or personal injury arising as a result of the gross negligence, fraud or intentional misconduct of such Party in connection, directly or indirectly, with this Agreement.

13.2 Customer shall indemnify and hold HDPR and its Affiliates (and its and their officers, agents, employees, successors, subcontractors and assigns) (collectively, the "HDPR Indemnitees") harmless from and against any and all losses and claims (including reasonable legal fees and other costs of defending any action – each and all together referred to as the "Claims") that an HDPR Indemnitee incurs as a result of any action brought by a Third Party (other than [**]) against an HDPR Indemnitee in connection with (a) Customer's breach of this Agreement, (b) the gross negligence, fraud or intentional misconduct of a Customer Indemnitee or (c) the use, commercialisation, sale or transfer of the Goods by Customer. The indemnification obligations under this Section 13.2 shall not apply to the extent that any such Third Party Claim is the result of (i) the gross negligence, fraud or intentional misconduct by an HDPR Indemnitee, (ii) the breach of this Agreement by an HDPR Indemnitees (iii) any Claim for which HDPR is obligated to indemnify Customer pursuant to Section 13.3 or (iv) in any case of personal injury or death caused by the negligent conduct, fraud or intentional misconduct of an HDPR Indemnitee.

13.3 HDPR shall indemnify and hold Customer and its Affiliates (and its and their officers, agents, employees, successors, subcontractors and assigns) (collectively, the "Customer Indemnitees") harmless from and against any and all losses and Claims that a Customer Indemnitee incurs as a result of any action brought by a Third Party against a Customer Indemnitee in connection with (a) HDPR's breach of this Agreement, (b) the gross negligence, fraud or intentional misconduct of an HDPR Indemnitee or (c) claims that the Goods or Services infringe the intellectual property rights of a Third Party in violation of Section 9 h) above. The indemnification obligations under this Section 13.3 shall not apply to the extent that any such Third Party Claim is the result of (i) the gross negligence, fraud or intentional misconduct by a Customer Indemnitee, (ii) the breach of this Agreement by a Customer Indemnitees (iii) any Claim for which Customer is obligated to indemnify HDPR pursuant to Section 13.2 or (iv) in any case of personal injury or death caused by the negligent conduct, fraud or intentional misconduct of an Customer Indemnitee.

13.4 The indemnifying Party shall defend, contest or otherwise protect against any Claims at its own cost and expense; *provided that* the Party seeking indemnification regarding any such Claims gives written notice to the indemnifying Party promptly upon receiving notice of said Claims (but failure to give prompt written notice shall only relieve the indemnifying Party of its obligations under Section 13.4 if, and in such event, only to the extent that, the indemnifying Party can demonstrate actual prejudice on account of such failure). The indemnified Party may, but will not be obligated to, participate at its own expense in the defense of any Claim by counsel of its own choosing, but the indemnifying Party shall be entitled to control the defense, unless the indemnified Party has relieved

the indemnifying Party from liability with respect to the particular matter. The indemnifying Party shall have the right, after consultation with the indemnified Party, to resolve and settle any such claims or suits; ***provided that***, in no event may the indemnifying Party compromise or settle any such claim in a manner which admits fault or negligence on the part of the indemnified Party or includes injunctive relief or includes the payment of money or other property by the indemnified Party without the prior written consent of the indemnified Party. The indemnifying Party shall not be responsible for any settlement or other disposition or agreement reached in respect of any such action, claim or other matter unless the indemnifying Party shall have given its prior written consent in respect of such settlement, disposition or other agreement. The indemnified Party shall cooperate and provide such assistance as the indemnifying Party may reasonably request in connection with the defence of the matter subject to indemnification.

14 Insurance

Each Party shall have and maintain the insurance coverage that is required by Applicable Law. Each Party may self-insure its liabilities under this Agreement and shall otherwise maintain such insurance as it, in its sole discretion, deems appropriate and necessary.

15 Intellectual Property

The Parties agree that (a) as between Customer and HDPR, each Party owns its respective Confidential Information and (b) HDPR owns all rights in intellectual property related to Amanitin Toxin Constructs (subject to the licenses granted to Customer with respect thereto as set forth in the ERDOLA) and, subject to any rights of [**] thereto, all rights in intellectual property related to the performance of Services. HDPR shall diligently pay all government fees required to maintain any of its patents used for the performance of Services under this Agreement. HDPR shall not knowingly use in the performance of Services any intellectual property right of a Third Party to the extent such use would adversely impact or restrict Customer's rights to freely exploit the Goods, except with the prior written consent of Customer. For the avoidance of doubt, nothing in this Agreement shall be construed to grant Customer ownership of know-how, processes, techniques and innovations owned or controlled by HDPR or by [**], nor the right to use deliverables provided hereunder to manufacture Amanitin Toxin Constructs without the previous completion of a GMP Full Manufacturing Technology Transfer as defined in the ERDOLA.

16 Confidentiality

16.1 It is contemplated that in the course of the performance of this Agreement each Party may, from time to time, disclose Confidential Information to the other and that HDPR and [**] may also disclose the confidential information of [**] to Customer in the course of the performance of this Agreement, which shall be regarded as the Confidential Information of HDPR. Each Party agrees:

a) to keep and use in strict confidence all Confidential Information of the other Party that each Party acquires, sees or is informed of as a direct or indirect consequence of this Agreement and to not, without the prior written consent of the other Party, disclose any such Confidential Information or recollections thereof to any Person other than its financial or legal advisors, employees and contractors who are under an obligation of confidentiality on terms substantially similar to those set out in this Agreement, who have been informed of the confidential nature of the Confidential Information and who reasonably require such information in the performance of their duties;

b) not to use, copy, duplicate, reproduce, translate or adapt, either directly or indirectly, any of the Confidential Information of the other Party or any recollections thereof for any purpose other than the performance of each Party's obligations under this Agreement, without the other Party's prior written approval; and

c) to take all reasonable steps (but never less than the degree of care such Party uses to protect its own confidential information) to prevent material in its possession that contains or refers to Confidential Information of the other Party from being discovered, used or copied by Third Parties and that it shall use reasonable steps (but never less than the degree of care such Party uses to protect its own confidential information) to protect and safeguard all Confidential Information of the other Party in its possession from all loss, theft or destruction.

Upon the termination of this Agreement, each Party shall promptly return or destroy, at the disclosing Party's election, all Confidential Information of the disclosing Party; *provided that* the receiving Party may retain one copy of all such Confidential Information in its legal records for the purposes of ensuring compliance with this Agreement and the receiving Party may keep such copies that may have been generated by automatic back-up systems. Notwithstanding anything in this Agreement to the contrary, any return or destruction of Confidential Information by the receiving Party is subject to Applicable Law.

16.2 A Party receiving Confidential Information may, with the written consent of the disclosing Party, disclose the disclosing Party's Confidential Information also to Persons other than its financial and legal advisors, employees and contractors.

16.3 The Parties agree that no press release, public announcement or publication regarding this Agreement or the relationship of the Parties (except to the extent that it may be legally required), shall be made unless mutually agreed to in writing prior to the release or dissemination of any such press release, public announcement or publication.

16.4 No provision of this Agreement shall be construed so as to preclude any disclosure of Confidential Information that is required, in the reasonable opinion of the receiving Party's legal advisors, to be disclosed by the receiving Party pursuant to Applicable Law or legal process, subpoena, warrant or court order. To the extent required by Applicable Law or legal process, subpoena, warrant or court order, the receiving Party may disclose Confidential Information only to the extent required to comply with said Applicable Law or legal process, subpoena, warrant or court order; *provided that* the receiving Party shall, if legally permitted and reasonably practicable, provide reasonable prior notice to the disclosing Party so as to allow the disclosing Party to take steps to oppose or limit the required disclosure, at the disclosing Party's sole cost and expense.

16.5 Unless otherwise agreed by the Parties in writing, the obligations of the Parties relating to Confidential Information set out in this Article 16 shall survive the termination or expiration of this Agreement for a period of [**] thereafter; *provided that* such obligations will survive with respect to any Confidential Information that constitutes a trade secret for so long as such Confidential Information remains a trade secret.

17 Force majeure

17.1 Neither Party shall be held liable for any failure in performance of any part of this Agreement or any breach of contract resulting from force majeure events, including but not limited to fire, flood, explosion, war, strike, embargo, shortages, acts of God, terrorism, riots or similar causes. If a Party is affected by an event of force majeure, it will forthwith notify the other Party of the nature and extent of such force majeure event and the Parties will enter into bona fide discussions with a view to alleviating its effects and to agreeing such alternative arrangements as may be fair, reasonable and practicable. The Party affected by a force majeure event is under obligation to give full particulars thereof and to use its best efforts to minimize the effect of occurrence and to take the necessary remedial measures.

17.2 If as a result of force majeure events, performance of the Agreement, in whole or material part, is suspended for more than [**] or [**], either Party shall have the right to terminate the Agreement or any affected Work Order by giving written notice to that effect to the other Party.

18 General provisions

18.1 No course of dealing or failure of either Party to strictly enforce any term, right or condition of this Agreement shall be construed as a waiver of that term, right or condition.

18.2 Should one of the provisions of this Agreement or of any additional stipulations agreed upon be or become invalid, the validity of the remaining conditions and stipulations shall not be affected thereby. Parties shall use their best endeavours to replace the invalid provisions with a valid provision with respect to the same subject matter.

18.3 This Agreement constitutes the entire agreement and understandings (oral and written) between the Parties relating to the subject matter hereof and supersede all previous oral and written communications between the Parties with respect hereof.

18.4 No modification, alteration or amendment to this Agreement, including without limitation this Section 18.4, shall be of any force or effect unless done in writing with the express reference to the Sections of the Agreement being modified, altered or amended and signed by duly authorized representative of both Parties.

18.5 This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their successors and permitted assigns. The provisions set forth in the ERDOLA with regard to Assignment (as defined therein) shall also apply to this Agreement (except with respect to a Non-GMP Partial Manufacturing Technology Transfer, a Non-GMP Full Manufacturing Technology Transfer or a GMP Full Manufacturing Technology Transfer (each as defined in the ERDOLA)).

18.6 The Parties hereto are independent contractors and nothing contained in this Agreement shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties.

18.7 The table of contents and headings are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless the context otherwise clearly requires or otherwise specified, whenever used in this Agreement: (a) the word “including” and words of similar import shall mean “including, without limitation”; (b) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement; (c) whenever the word “or” is used in this Agreement, it shall not be deemed to be exclusive; (d) all references to the word “will” are interchangeable with the word “shall” and shall be understood to be imperative or mandatory in nature; and (e) all words used in this Agreement shall be construed to be of such gender or number, as the circumstances require.

18.8 This Agreement may be executed in multiple counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument. Any PDF or facsimile copy of this Agreement, or of any counterpart, shall be deemed the equivalent of an original.

19 Notices

19.1 Any official notice required under this Agreement shall be in writing and shall specifically refer to this Agreement. Notices shall be sent via one of the following means and will be effective: (a) on the date of delivery, if delivered and handed over in person; (b) if sent by email (with delivery confirmed) (i) on the date of receipt, ***provided***, ***however***, *that* the email was received by recipient on a Business Day at his domicile between 00.00 and 17.00 his time zone; (ii) the next Business Day following receipt, if the email was received by recipient outside a Business Day at his domicile or between 17.00 and 24.00 his time zone; or (c) seventy two (72) hours after postage, if sent by private express courier or by first class certified mail, return receipt requested. Any notice sent via email shall be followed as soon as reasonably possible by a copy of such notice by private express courier or by first class mail.

19.2 Notices shall be sent to the other Party at the addresses set forth below. Either Party may change its addresses or addressees for purposes of this Article 19 by sending written notice to the other Party.

If to HDPR, to:	Heidelberg Pharma Research GmbH Attn: Business Development Schriesheimer Strasse 101 68526 Ladenburg Germany [**] [**]
and:	Attn: Legal Department [**] [**]
If to Customer, to:	Magenta Therapeutics, Inc. 100 Technology Square, 5th Floor Cambridge, MA 02139 USA [**] [**]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed delivered on the date received.

19.3 The provisions of this Article 19 shall not be applicable for the day-to-day communication between the Parties.

20 Term and termination

20.1 This Agreement shall be effective as of and commence on the Effective Date and continue in full force and effect for an indefinite term unless terminated pursuant to Sections 20.2, 20.3 or 20.4.

20.2 (a) Customer may terminate this Agreement or any Work Order at any time and for any reason upon at least sixty (60) calendar days written notice. (b) Either Party may terminate this Agreement if the corresponding agreement between HDPR and [**] is terminated.

20.3 Either Party may terminate this Agreement upon written notice to the other Party with immediate effect if the other Party makes a general assignment for the benefit of creditors or if a petition in bankruptcy or under any insolvency law is filed by or against the other Party and such petition is not dismissed within [**] after it has been filed.

20.4 Either Party may terminate this Agreement (in its entirety, for a material breach that relates to this Agreement in its entirety) or a Work Order (only with respect to a Work Order, if a material breach solely relates to such Work Order) upon written notice to the other Party with immediate effect if the other Party has committed a material breach of this Agreement, a Work Order, or the Quality Agreement, and:

(i) the breach is not cured within [**] after written notice of such breach has been provided to the breaching Party; or

(ii) if the breach is of a type that cannot be cured within [**], but the breaching Party has promptly commenced and is diligently pursuing remediation of such breach following the breaching Party receiving written notice of such breach, then only if such breach has not been cured within [**] after written notice of such breach has been provided to the breaching Party.

20.5 In case of termination of a Service by Customer, Customer shall pay to HDPR the fees set forth in the corresponding Work Order.

20.6 Notwithstanding the foregoing, in case of a termination by Customer pursuant to Sections 17.2, 20.3 or 20.4, or by either Party pursuant to Section 20.2(b), then Section 20.5 shall not apply.

20.7 Upon termination of this Agreement, all rights and obligations of the Parties under this Agreement shall terminate and be of no further force or effect. No termination of this Agreement will relieve the parties of any obligation accruing prior to such termination. In addition, the following Sections shall survive termination of this Agreement: 2.5; 5; 6; 8 to 19 (included); 20.5; 20.6, 20.7 and 21.

21 Applicable law and jurisdiction

21.1 This Agreement shall be construed, interpreted, governed and enforced exclusively in accordance with the substantive **Swiss law** except as for its conflict of law rules, which would refer to another applicable law. The application of the Convention of the United Nations of April 11, 1980 on Contract for the International Sale of Goods is hereby expressly excluded.

21.2 The Parties shall try to resolve any disputes arising out of or in connection with this Agreement amicably through good faith negotiations. In the event that such attempts should fail within [**] from the first negotiation, the dispute shall be exclusively and finally resolved by the **Civil-Court of Basel-Stadt, Switzerland** ("*Zivilgericht Basel-Stadt*"). This shall not limit the right to appeal in Switzerland.

[*Remainder Intentionally Blank.*]

In WITNESS OF THE FOREGOING, the Parties have caused their authorized representatives to execute this Agreement as of the Effective Date.

Heidelberg Pharma Research GmbH:		Magenta Therapeutics, Inc.:	
By:	*/s/ Dr. Jan Schmidt-Brand*	By:	*/s/ Jason Gardner*
Name:	Dr. Jan Schmidt-Brand Chief Executive Officer	Name:	Jason Gardner
Date:	23. MAI 2019	Date:	6/3/19
By:	*ppa. /s/ Prof. Dr. Andreas Pahl*	By:	/s/ Christina Isacson
Name:	Prof. Dr. Andreas Pahl Chief Scientific Officer	Name:	Christina Isacson
Date:	23. MAI 2019	Date:	6/3/19

ANNEX 3.8

[**]

EXHIBIT 10.12

AMENDED AND RESTATED
EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement ("Agreement") is made by and between Magenta Therapeutics, Inc., a Delaware corporation (the "Company"), and Jason Gardner, D.Phil. (the "Executive") and is effective as March 3, 2022.

WHEREAS, the Executive is currently serving as the Company's Chief Executive Officer and President, and possesses certain experience and expertise that qualify the Executive to provide the direction and leadership required by the Company and its affiliates;

WHEREAS, the Company and the Executive are party to an Employment Agreement dated as of June 25, 2018 (the "Original Agreement"); and

WHEREAS, the Company and the Executive wish to amend and restate the Original Agreement in accordance with the terms and conditions set forth in this Agreement.

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

1. Employment.

(a) Term. The Company and the Executive desire to continue their employment relationship pursuant to this Agreement as of the Effective Date and continuing in effect until terminated by either party in accordance with this Agreement (the "Term"). The Executive's employment with the Company will continue to be "at will," meaning that the Executive's employment may be terminated by the Company or the Executive at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. During the Term, the Executive shall serve as the President and Chief Executive Officer of the Company and shall have powers and duties that may from time to time be prescribed by the Board of Directors of the Company (the "Board**"**). The Executive shall devote his full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Executive may serve on up to two other boards of directors, with the prior written approval of the Board, or engage in not-for-profit, charitable or other community activities as long as the foregoing does not, individually or in the aggregate, materially interfere with the Executive's performance of his duties to the Company as provided in this Agreement. The Executive reaffirms that he has no contractual commitments or other legal obligations that would prohibit him from fully performing his duties for the Company.

(c) Regular Place of Employment. The Executive's regular place of work will be at Magenta Therapeutics, Inc., which is currently located at 100 Technology Square, Cambridge, MA 02139, provided that the Executive may be required to travel from time to time, consistent with business needs.

2. Compensation and Related Matters.

(a) Base Salary. The Executive's annual base salary shall be $565,000, which is subject to review and redetermination by the Board. The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for senior executives.

(b) Incentive Compensation. During the Term, the Executive shall be eligible to receive cash incentive compensation as determined by and in the sole discretion of the Board or the Compensation Committee from time to time. The Executive's target annual incentive compensation shall be fifty-five percent (55%) of his Base Salary, as may be redetermined from time to time (the "Target Incentive Compensation"). To earn incentive compensation, the Executive must be employed by the Company on the day such incentive compensation is paid.

(c) Expenses. The Executive shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by him during the Term in performing services hereunder, in accordance with the policies and procedures then in effect and established by the Company for its senior executive officers.

(d) Other Benefits. During the Term, the Executive shall be entitled to continue to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, including paid sick time under applicable law, subject to the terms of such plans and to the Company's ability to amend, modify, replace or terminate such plans and programs.

(e) Vacations. During the Term, the Executive shall be entitled to take paid vacation in accordance with the Company's vacation policy, as may be in effect from time to time. The Executive shall also be entitled to all paid holidays given by the Company to its executives.

(f) Equity. The equity awards held by the Executive shall be governed by the terms and conditions of the Company's applicable equity incentive plan(s) and the applicable award agreement(s) governing the terms of such equity awards held by the Executive (collectively, the "Equity Documents"); provided, however, and notwithstanding anything to the contrary in the Equity Documents, Section 6(a)(ii) of this Agreement shall apply in the event of a termination by the Company without Cause or by the Executive for Good Reason in either event within the Change in Control Period (as such terms are defined below).

3. Termination. During the Term, the Executive's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Executive's employment hereunder shall terminate upon his death.

(b) Disability. The Company may terminate the Executive's employment if he is disabled and unable to perform the essential functions of the Executive's then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period. If any question shall arise as to whether during any period the Executive is disabled so as to be unable to perform the essential functions of the Executive's then existing position or positions with or without reasonable

accommodation, the Executive may, and at the request of the Company shall, submit to the Company a certification in reasonable detail by a physician selected by the Company to whom the Executive or the Executive's guardian has no reasonable objection as to whether the Executive is so disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. The Executive shall cooperate with any reasonable request of the physician in connection with such certification. If such question shall arise and the Executive shall fail to submit such certification, the Company's determination of such issue shall be binding on the Executive. Nothing in this Section 3(b) shall be construed to waive the Executive's rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 *et seq*. and the Americans with Disabilities Act, 42 U.S.C. §12101 *et seq.*

(c) Termination by Company for Cause. The Company may terminate the Executive's employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean: (i) the Executive's dishonest statements or acts with respect to the Company or any affiliate of the Company, or any current or prospective customers, suppliers vendors or other third parties with which such entity does business; (ii) the Executive's commission of (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) the Executive's failure to perform his assigned duties and responsibilities to the reasonable satisfaction of the Company which failure continues, in the reasonable judgment of the Company, thirty (30) or more days after written notice has been given to the Executive by the Company reasonably describing such failure; (iv) the Executive's gross negligence, willful misconduct or insubordination with respect to the Company or any affiliate of the Company; or (v) the Executive's material violation of any provision of any agreement(s) between the Executive and the Company relating to noncompetition, nonsolicitation, nondisclosure, nondisparagement and/or assignment of inventions.

(d) Termination Without Cause. The Company may terminate the Executive's employment hereunder at any time without Cause. Any termination by the Company of the Executive's employment under this Agreement which does not constitute a termination for Cause under Section 3(c) and does not result from the death or disability of the Executive under Section 3(a) or (b) shall be deemed a termination without Cause.

(e) Termination by the Executive. The Executive may terminate his employment hereunder at any time for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" shall mean that the Executive has complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) a material diminution in the Executive's responsibilities, authority or duties; (ii) a material diminution in the Executive's Base Salary except for across-the-board salary reductions based at least in part on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; (iii) a material change in the geographic location at which the Executive provides services to the Company; or (iv) the material breach of this Agreement by the Company. "Good Reason Process" shall mean that (i) the Executive reasonably determines in good faith that a "Good Reason" condition has occurred; (ii) the Executive notifies the Company in writing of the first occurrence of the Good Reason condition within 60 days of the first occurrence of such condition; (iii) the Executive cooperates in good faith with the Company's efforts, for a period not less than thirty (30) days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason

condition continues to exist; and (v) the Executive terminates his employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

If the Executive's employment with the Company is terminated for any reason, the Company shall pay or provide to the Executive (or to his authorized representative or estate) (i) any Base Salary earned through the Date of Termination, unpaid expense reimbursements (subject to, and in accordance with, Section 2(c) of this Agreement) on or before the time required by law but in no event more than thirty (30) days after the Executive's Date of Termination; (ii) accrued but unused vacation and personal days (if applicable and in accordance with Company policy and applicable law); and (iii) any vested benefits the Executive may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans (collectively, the "Accrued Benefits").

4. Notice and Date of Termination.

(a) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Executive's employment by the Company or any such termination by the Executive shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(b) Date of Termination. "Date of Termination" shall mean: (i) if the Executive's employment is terminated by his death, the date of his death; (ii) if the Executive's employment is terminated on account of disability under Section 3(b) or by the Company for Cause under Section 3(c), the date on which Notice of Termination is given; (iii) if the Executive's employment is terminated by the Company under Section 3(d), the date on which a Notice of Termination is given; (iv) if the Executive's employment is terminated by the Executive under Section 3(e) without Good Reason, 30 days after the date on which a Notice of Termination is given, and (v) if the Executive's employment is terminated by the Executive under Section 3(e) for Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that the Executive gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement.

5. Compensation Upon Termination by the Company without Cause or by the Executive for Good Reason Outside the Change in Control Period. During the Term, if the Executive's employment is terminated by the Company without Cause as provided in Section 3(d), or the Executive terminates his employment for Good Reason as provided in Section 3(e), each outside of the Change in Control Period (as defined below), then the Company shall pay the Executive his Accrued Benefit. In addition, subject to (i) the Executive signing a separation agreement and release in a form and manner satisfactory to the Company, which shall include, without limitation, a general release of claims against the Company and all related persons and entities, a reaffirmation of all of the Executive's Continuing Obligations (as defined below) and, in the Company's sole discretion, a one year post-employment noncompetition covenant, and shall

provide that if the Executive breaches any of the Continuing Obligations, all payments of the Severance Amount shall immediately cease (the "Separation Agreement and Release"), and (ii) the Separation Agreement and Release becoming irrevocable, all within 60 days after the Date of Termination (or such shorter period as set forth in the Separation Agreement and Release):

(a) the Company shall pay the Executive an amount equal to the sum of (A) one (1) times the Executive's Base Salary plus (B) a pro-rata portion of the Executive's Target Incentive Compensation, based on the number of days that have passed as of the Date of Termination in the year in which the Date of Termination occurs (the "Severance Amount"). Notwithstanding the foregoing, if the Executive breaches any of the provisions contained in Section 8 of this Agreement or the Restrictive Covenants Agreement, all payments of the Severance Amount shall immediately cease; and

(b) if the Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay the monthly employer COBRA premium for the same level of group health coverage as in effect for the Executive on the Date of Termination until the earliest of the following: (i) the twelve (12) month anniversary of the Date of Termination; (ii) the Executive's eligibility for group health coverage through other employment; or (iii) the end of the Executive's eligibility under COBRA for continuation coverage for health care. If the payment of any COBRA or health insurance premiums by Company on behalf of Executive as described herein would otherwise violate any applicable nondiscrimination rules or cause the reimbursement of claims to be taxable under the Patient Protection and Affordable Care Act of 2010, together with the Health Care and Education Reconciliation Act of 2010 (collectively, the "Healthcare Acts") or Section 105(h) of the Code, the COBRA premiums paid by the Company shall be treated as taxable payments (subject to customary and required taxes and employment-related deductions) and be subject to imputed income tax treatment to the extent necessary to eliminate any discriminatory treatment or taxation under the Healthcare Acts or Section 105(h) of the Code. If Company determines in its sole discretion that it cannot provide the COBRA benefits described herein under Company's health insurance plan without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), Company shall in lieu thereof provide to Executive a taxable lump-sum payment in an amount equal to the sum of the monthly (or then remaining) COBRA premiums that Executive would be required to pay to maintain Executive's group health insurance coverage in effect on the separation date for the remaining portion of the period for which Executive shall receive the payments described in this Section 5(b).

(c) The amounts payable under this Section 5 shall be paid out in substantially equal installments in accordance with the Company's payroll practice, with the first installment commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

6. Compensation Upon Termination by the Company without Cause or by the Executive for Good Reason within the Change in Control Period. The provisions of this Section 6 shall apply in lieu of, and expressly supersede, the provisions of Section 5 regarding severance pay and benefits upon a termination by the Company without Cause or by the Executive for Good Reason if such termination of employment occurs during the three (3) months before through twelve (12) months after the occurrence of the first event constituting a Change in Control (such period, the "Change in Control Period"). These provisions shall terminate and be of no further force or effect beginning twelve (12) months after the occurrence of a Change in Control.

(a) Change in Control. If during the Change in Control Period the Executive's employment is terminated by the Company without Cause as provided in Section 3(d) or the Executive terminates his employment for Good Reason as provided in Section 3(e), then, subject to the signing of the Separation Agreement and Release by the Executive and the Separation Agreement and Release becoming irrevocable, all within 60 days after the Date of Termination (or such shorter period as set forth in the Separation Agreement and Release):

(i) the Company shall pay the Executive a lump sum in cash in an amount equal to the sum of (A) 1.5 times the Executive's current Base Salary (or the Executive's Base Salary in effect immediately prior to the Change in Control, if higher) plus (B) one hundred and fifty percent (150%) of the Executive's Target Incentive Compensation (the "Change in Control Payment"); and

(ii) notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all time-based stock options and other time-based stock-based awards held by the Executive shall immediately accelerate and become fully vested and exercisable or nonforfeitable as of the Date of Termination; and

(iii) if the Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay the full monthly COBRA premium for the same level of group health coverage as in effect for the Executive on the Date of Termination until the earliest of the following: (i) the 18-month anniversary of the Date of Termination; (ii) the Executive's eligibility for group health coverage through other employment; or (iii) the end of the Executive's eligibility under COBRA for continuation coverage for health care. If the payment of any COBRA or health insurance premiums by Company on behalf of Executive as described herein would otherwise violate any applicable nondiscrimination rules or cause the reimbursement of claims to be taxable under the Healthcare Acts or Section 105(h) of the Code, the COBRA premiums paid by the Company shall be treated as taxable payments (subject to customary and required taxes and employment-related deductions) and be subject to imputed income tax treatment to the extent necessary to eliminate any discriminatory treatment or taxation under the Healthcare Acts or Section 105(h) of the Code. If Company determines in its sole discretion that it cannot provide the COBRA benefits described herein under Company's health insurance plan without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), Company shall in lieu thereof provide to Executive a taxable lump-sum payment in an amount equal to the sum of the monthly (or then remaining)

COBRA premiums that Executive would be required to pay to maintain Executive's group health insurance coverage in effect on the separation date for the remaining portion of the period for which Executive shall receive the payments described in this Section 6(a).

The amounts payable under this Section 6(a) shall be paid or commence to be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Executive becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Executive receiving a higher After Tax Amount (as defined below) than the Executive would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 6(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Executive as a result of the Executive's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 6(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Executive within 15

business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Executive. Any determination by the Accounting Firm shall be binding upon the Company and the Executive.

(b) Definitions. For purposes of this Section 6, "Change in Control" shall mean any of the following:

(i) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act") (other than the Company, any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of the Company representing 50 percent or more of the combined voting power of the Company's then outstanding securities having the right to vote in an election of the Board ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from the Company); or

(ii) the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; or

(iii) the consummation of (A) any consolidation or merger of the Company where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent of the voting shares of the Company issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of the Company.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by the Company which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to 50 percent or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company) and immediately thereafter beneficially owns 50 percent or more of the combined voting power of all of the then outstanding Voting Securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (i).

7. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Executive's separation from service within the meaning of Section 409A of the Code, the Company determines that the Executive is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Executive becomes entitled to under this Agreement on account of the Executive's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Executive's separation from service, or (B) the Executive's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Executive during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Executive's termination of employment, then such payments or benefits shall be payable only upon the Executive's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

8. Restrictive Covenants.

(a) Restrictive Covenants Agreement. The terms of the Employee Confidentiality and Assignment Agreement dated June 12, 2016, between the Company and the Executive, as modified by the Original Agreement and reaffirmed herein (the "Restrictive Covenants Agreement"), continues to be in full force and effect. The Executive agrees that the term "Company," as used in the Restrictive Covenants Agreement, shall mean the Company, its subsidiaries and other affiliates, and its and their successors and assigns. The Executive hereby reaffirms the terms of the Restrictive Covenants Agreement, and as modified by the Original Agreement and reaffirmed in Section 8(b) below, as material terms of this Agreement and agrees and acknowledges that such terms are incorporated by reference in this Agreement.

(b) Noncompetition and Nonsolicitation. This Section 8(b) amends, restates, and supersedes Section 8 of the Restrictive Covenants Agreement.

(i) Non-Solicitation. In order to protect the Company's proprietary information and good will, both during Executive's employment and for a period of one (1) year following the date of the cessation of Executive's employment with the Company for any reason, (the "Restricted Period"), the Executive will not either alone or in association with others:

(1) solicit, induce or attempt to induce, any employee or independent contractor of the Company to terminate his/her employment or other engagement with the Company;

(2) solicit, hire, or recruit or attempt to hire as an employee, or engage or attempt to engage as an independent contractor, any person who was employed or otherwise engaged by the Company at any time during the term of my employment with the Company; *provided* that this clause (2) shall not apply to the recruitment or hiring or other engagement of any individual whose employment or other engagement with the Company has been terminated for a period of six (6) months or longer, or was terminated at the discretion of the Company and not by such person; *provided, further*, that subsection (b) shall not apply to individuals who are employed by the Company or a subsequent employer, in California; or

(3) solicit, divert or take away, or attempt to divert or take away, the business or patronage of any of the clients, customers, or business partners of the Company that were contacted, solicited, or served by the Company during the twelve (12) month period prior to the termination or cessation of my employment with the Company; *provided, however*, the foregoing shall not apply to services rendered by me in California after the date my employment by the Company terminates.

(ii) Non-Compete.

(1) Executive will not without the prior written approval of an executive officer of the Company, engage or assist others in engaging in any business or enterprise (whether as owner, partner, officer, director, employee, consultant, investor, lender or otherwise, except as the holder of not more than 1% of the outstanding stock of a publicly-held company) that is competitive with the Company's business by engaging in the research, development, manufacture, marketing, distribution, sale or commercialization of any products that the Company is, at the time of my termination, so engaged in, or, to my knowledge, planning to engage in or otherwise actively evaluating, or any alternatives to such products. This Section 8(b)(ii)(1) shall be effective (i) during the term of my employment by the Company, and (ii) for a period of one (1) year after my employment with the Company ends for any reason, provided that the Company makes a one-time payment to me of $5,000 within fifteen (15) calendar days after the date of my termination.

(2) Executive understands and agrees that payment set forth in Section 8(b)(ii)(1) above (i) has been mutually agreed upon by Executive and the Company; (ii) is fair and reasonable; and (iii) is sufficient in exchange for my obligations set forth in this paragraph.

(3) Executive understands and agrees, at or around the time Executive's employment with the Company ends, and in the Company's sole discretion, the Company may waive the Executive's obligations in this Section 8(b)(ii)(1), in which case the Company will not be required to provide me with any of the payments set forth in Section 8(b)(ii)(1) above.

The Executive acknowledges and agrees that if he violates any of the provisions of this Section 8(b), the running of the Restricted Period will be extended by the time during which the Executive engages in such violation(s). The Executive understands that the restrictions set forth in this Section 8(b) are intended to protect the Company's interest in its confidential information and established employee, customer and supplier relationships and goodwill, and agrees that such restrictions are reasonable and appropriate for this purpose. For purposes of this Agreement, the obligations in this Section 8 and those that arise in the Restrictive Covenants Agreement and any other agreement relating to confidentiality, assignment of inventions, or other restrictive covenants shall collectively be referred to as the "Continuing Obligations."

(c) Third-Party Agreements and Rights. The Executive hereby confirms that the Executive is not bound by the terms of any agreement with any previous employer or other party which restricts in any way the Executive's use or disclosure of information or the Executive's engagement in any business. The Executive represents to the Company that the Executive's execution of this Agreement, the Executive's employment with the Company and the performance of the Executive's proposed duties for the Company will not violate any obligations the Executive may have to any such previous employer or other party. In the Executive's work for the Company, the Executive will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and the Executive will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(d) Litigation and Regulatory Cooperation. During and after the Executive's employment, the Executive shall cooperate fully with the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Executive was employed by the Company. The Executive's full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Executive's employment, the Executive also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Executive was employed by the Company. The Company shall reimburse the Executive for any reasonable out-of-pocket expenses incurred in connection with the Executive's performance of obligations pursuant to this Section 8(d).

(e) Injunction. The Executive agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Executive of the promises set forth in this Section 8, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, the Executive agrees that if the Executive breaches, or proposes to breach, any portion of this Agreement, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company.

(f) Protected Disclosures and Other Protected Actions. Nothing in this Agreement shall be interpreted or applied to prohibit the Executive from making any good faith report to any governmental agency or other governmental entity (a "Government Agency") concerning any act or omission that the Executive reasonably believes constitutes a possible violation of federal or state law or making other disclosures that are protected under the anti-retaliation or whistleblower provisions of applicable federal or state law or regulation. In addition, nothing contained in this Agreement limits the Executive's ability to communicate with any Government Agency or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including the Executive's ability to provide documents or other information, without notice to the Company. In addition, for the avoidance of doubt, pursuant to the federal Defend Trade Secrets Act of 2016, the Executive shall not be held criminally or civilly liable under any federal or state trade secret law or under this Agreement or the Restrictive Covenants Agreements for the disclosure of a trade secret that (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

9. Consent to Jurisdiction. The parties hereby consent to the jurisdiction of the Superior Court of the Commonwealth of Massachusetts and the United States District Court for the District of Massachusetts. Accordingly, with respect to any such court action, the Executive (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

10. Representations and Warranties. By signing this agreement, Executive represents that Executive has not been debarred under Subsection (a) or (b) of Section 306 of the United States Federal Food, Drug, and Cosmetic Act (21 U.S. C. 335a); and is not on any FDA clinical investigator enforcement lists (including the (i) Disqualified/Totally Restricted List, (ii) Restricted List and (iii) Adequate Assurances List).

11. Integration. This Agreement constitutes the entire agreement between the parties with respect to compensation, severance pay, benefits and accelerated vesting and supersedes in all respects all prior agreements between the parties concerning such the subject matter hereof, including without limitation the Original Agreement or any offer letter, employment agreement or severance agreement relating to the Executive's employment relationship with the Company and/or the ending of that employment relationship. Notwithstanding the foregoing, the Restrictive Covenants Agreement (as modified herein), the Equity Documents, and any other agreement relating to confidentiality, noncompetition, nonsolicitation or assignment of inventions shall not be superseded by this Agreement and the Executive acknowledges and agrees that any such agreements remain in full force and effect.

12. Withholding. All payments made by the Company to the Executive under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.

13. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

14. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Executive's employment to the extent necessary to effectuate the terms contained herein.

15. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

16. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Executive at the last address the Executive has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

17. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Executive and by a duly authorized representative of the Company.

18. Effect on Other Plans and Agreements. An election by the Executive to resign for Good Reason under the provisions of this Agreement shall not be deemed a voluntary termination of employment by the Executive for the purpose of interpreting the provisions of any of the Company's benefit plans, programs or policies. Nothing in this Agreement shall be construed to limit the rights of the Executive under the Company's benefit plans, programs or policies except as otherwise may be provided in Section 8 hereof, and except that the Executive shall have no rights to any severance benefits under any Company severance pay plan, offer letter or otherwise. In the event that the Executive is party to an agreement with the Company providing for payments or benefits under such agreement and this Agreement, the terms of this Agreement shall govern and the Executive may receive payment under this Agreement only and not both. Further, Section 5 and Section 6 of this Agreement are mutually exclusive and in no event shall the Executive be entitled to payments or benefits pursuant to Section 5 and Section 6 of this Agreement.

19. Governing Law. This is a Massachusetts contract and shall be construed under and be governed in all respects by the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of laws principles of such Commonwealth. With respect to any disputes concerning federal law, such disputes shall be determined in accordance with the law as it would be interpreted and applied by the United States Court of Appeals for the First Circuit.

20. Assignment. Neither the Executive nor the Company may make any assignment of this Agreement or any interest in it, by operation of law or otherwise, without the prior written consent of the other; provided, however, that the Company may assign its rights and obligations under this Agreement (including the Restrictive Covenants Agreement) without the Executive's consent to any affiliate or to any person or entity with whom the Company shall hereafter effect a reorganization, consolidate with, or merge into or to whom it transfers all or substantially all of its properties or assets; provided further that if the purchaser in any transaction involving the transfer of all or substantially all of the Company's assets assumes this Agreement and the Executive accepts a position with the purchaser that is equivalent or better to his position immediately preceding such transaction, then the Executive shall not be entitled to any Severance Amount pursuant to Section 5 or any Change in Control Payment pursuant to Section 6. This Agreement shall inure to the benefit of and be binding upon the Executive and the Company, and each of the Executive's and the Company's respective successors, executors, administrators, heirs and permitted assigns.

21. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

22. Gender Neutral. Wherever used herein, a pronoun in the masculine gender shall be considered as including the feminine gender unless the context clearly indicates otherwise.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the Effective Date.

MAGENTA THERAPEUTICS, INC.

By: /s/ Kristen Stants
Kristen Stants
Its: Chief People Officer

EXECUTIVE

/s/ Jason Gardner
Jason Gardner, D.Phil.

AMENDED AND RESATED
EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement ("Agreement") is made by and between Magenta Therapeutics, Inc., a Delaware corporation (the "Company"), and Stephen Mahoney (the "Executive") and is effective as of March 3, 2022 (the "Effective Date").

WHEREAS, the Executive is currently serving as the Company's Chief Financial and Operating Officer and possesses certain experience and expertise that qualify the Executive to provide the direction and leadership required by the Company and its affiliates;

WHEREAS, the Company and the Executive are party to an Employment Agreement dated as of November 9, 2020 (the "Original Agreement"); and

WHEREAS, the Company and the Executive wish to amend and restate the Original Agreement in accordance with the terms and conditions set forth in this Agreement.

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

1. Employment.

(a) Term. The Company and the Executive desire to continue their employment relationship pursuant to this Agreement as of the Effective Date and continuing in effect until terminated by either party in accordance with this Agreement (the "Term"). The Executive's employment will continue to be "at will," meaning that the Executive's employment may be terminated by the Company or the Executive any time and for any reason, subject to the terms of this Agreement.

(b) Position and Duties. During the Term, the Executive shall serve as the Chief Financial and Operating Officer of the Company and shall have powers and duties that may from time to time be prescribed by the Company's Chief Executive Officer (the "CEO") or another authorized executive. The Executive shall devote Executive's full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Executive may serve on up to two (2) for-profit boards of directors, with the prior written approval of the CEO, or engage in not-for-profit, charitable or other community activities, as long as the foregoing does not, individually or in the aggregate, materially interfere with the Executive's performance of Executive's duties to the Company as provided in this Agreement. The Executive reaffirms that Executive has no contractual commitments or other legal obligations that would prohibit Executive's from fully performing Executive's duties for the Company.

(c) Regular Place of Employment. The Executive's regular place of work will be at Magenta Therapeutics, Inc., which is currently located at 100 Technology Square, Cambridge, MA 02139, provided that the Executive may be required to travel from time to time, consistent with business needs.

2. Compensation and Related Matters.

(a) Base Salary. The Executive's annual base salary shall be $448,000, which is subject to review and redetermination by the Company's Board or the Compensation Committee thereof. The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for senior executives.

(b) Incentive Compensation. During the Term, the Executive shall be eligible to receive cash incentive compensation as determined by and in the sole discretion of the Board or the Compensation Committee from time to time. The Executive's target annual incentive compensation shall be 40% of the Executive's Base Salary, as may be redetermined from time to time (the "Target Incentive Compensation"), with any incentive compensation for the year in which employment commences to be prorated based on the Effective Date. To earn incentive compensation, the Executive must be employed by the Company on the day such incentive compensation is paid.

(c) Expenses. The Executive shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by Executive during the Term in performing services hereunder, in accordance with the policies and procedures then in effect and established by the Company for its senior executive officers.

(d) Other Benefits. During the Term, the Executive shall be entitled to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, including paid sick time under applicable law, subject to the terms of such plans and to the Company's ability to amend, modify, replace or terminate such plans and programs.

(e) Vacations. During the Term, the Executive shall be entitled to take paid vacation in accordance with the Company's vacation policy, as may be in effect from time to time. The Executive shall also be entitled to all paid holidays given by the Company to its executives.

(f) Equity Awards. The equity awards held by the Executive shall be governed by the terms and conditions of the Company's applicable equity incentive plan(s) and the applicable award agreement(s) governing the terms of such equity awards held by the Executive (collectively, the "Equity Documents"); provided, however, and notwithstanding anything to the contrary in the Equity Documents, Section 6(a)(ii) of this Agreement shall apply in the event of a termination by the Company without Cause or by the Executive for Good Reason in either event within the Change in Control Period (as such terms are defined below).

3. Termination. During the Term, the Executive's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Executive's employment hereunder shall terminate upon his death.

(b) Disability. The Company may terminate the Executive's employment if Executive is disabled and unable to perform the essential functions of the Executive's then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period. If any question shall arise as to whether during any period the Executive is disabled so as to be unable to perform the essential functions of the Executive's then-existing position or positions with or without reasonable accommodation, the Executive may, and at the request of the Company shall, submit to the Company a certification in reasonable detail by a physician selected by the Company to whom the Executive or the Executive's guardian has no reasonable objection as to whether the Executive is so disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. The Executive shall cooperate with any reasonable request of the physician in connection with such certification. If such question shall arise and the Executive shall fail to submit such certification, the Company's determination of such issue shall be binding on the Executive. Nothing in this Section 3(b) shall be construed to waive the Executive's rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 *et seq*. and the Americans with Disabilities Act, 42 U.S.C. §12101 *et seq.*

(c) Termination by Company for Cause. The Company may terminate the Executive's employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean: (i) the Executive's dishonest statements or acts with respect to the Company or any affiliate of the Company, or any current or prospective customers, suppliers, vendors or other third parties with which such entity does business; (ii) the Executive's commission of (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) the Executive's failure to perform Executive's assigned duties and responsibilities to the reasonable satisfaction of the Company which failure continues, in the reasonable judgment of the Company, thirty (30) or more days after written notice has been given to the Executive by the Company reasonably describing such failure; (iv) the Executive's gross negligence, willful misconduct or insubordination with respect to the Company or any affiliate of the Company; or (v) the Executive's material violation of any provision of any agreement(s) between the Executive and the Company relating to noncompetition, nonsolicitation, nondisclosure, nondisparagement and/or assignment of inventions.

(d) Termination Without Cause. The Company may terminate the Executive's employment hereunder at any time without Cause. Any termination by the Company of the Executive's employment under this Agreement which does not constitute a termination for Cause under Section 3(c) and does not result from the death or disability of the Executive under Section 3(a) or (b) shall be deemed a termination without Cause.

(e) Termination by the Executive. The Executive may terminate his employment hereunder at any time for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" shall mean that the Executive has complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) a material diminution in the Executive's responsibilities, authority or duties ; provided that, a change in title, reporting relationships and/or responsibilities of the Executive could, but

do not necessarily in and of themselves, individually or in the aggregate, constitute a material diminution for purposes of this Section 3(e), and in all instances, the determination of whether a material diminution has occurred shall be made by the Company in good faith; (ii) a material diminution in the Executive's Base Salary except for across-the-board salary reductions based at least in part on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; (iii) a material change in the geographic location of the principal office of the Company to which the Executive is assigned such that there is an increase of at least thirty (30) *additional* miles of diving distance to such new location from the Executive's principal residence as of such change; or (iv) the material breach of this Agreement by the Company. "Good Reason Process" shall mean that (i) the Executive reasonably determines in good faith that a "Good Reason" condition has occurred; (ii) the Executive notifies the Company in writing of the first occurrence of the Good Reason condition within sixty (60) days of the first occurrence of such condition; (iii) the Executive cooperates in good faith with the Company's efforts, for a period not less than thirty (30) days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) the Executive terminates his employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

If the Executive's employment with the Company is terminated for any reason, the Company shall pay or provide to the Executive (or to his authorized representative or estate) (i) any Base Salary earned through the Date of Termination, unpaid expense reimbursements (subject to, and in accordance with, Section 2(c) of this Agreement) on or before the time required by law but in no event more than 30 days after the Executive's Date of Termination; (ii) accrued but unused vacation and personal days (if applicable and in accordance with Company policy and applicable law); and (iii) any vested benefits the Executive may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans (collectively, the "Accrued Benefits").

4. Notice and Date of Termination.

(a) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Executive's employment by the Company or any such termination by the Executive shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(b) Date of Termination. "Date of Termination" shall mean: (i) if the Executive's employment is terminated by his death, the date of his death; (ii) if the Executive's employment is terminated on account of disability under Section 3(b) or by the Company for Cause under Section 3(c), the date on which Notice of Termination is given; (iii) if the Executive's employment is terminated by the Company under Section 3(d), the date on which a Notice of Termination is given; (iv) if the Executive's employment is terminated by the Executive under Section 3(e) without Good Reason, 30 days after the date on which a Notice of Termination is given, and (v) if the Executive's employment is terminated by the Executive under Section 3(e)

for Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that the Executive gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement.

5. Compensation Upon Termination by the Company without Cause or by the Executive for Good Reason Outside the Change in Control Period. During the Term, if the Executive's employment is terminated by the Company without Cause as provided in Section 3(d), or the Executive terminates his employment for Good Reason as provided in Section 3(e), each outside of the Change in Control Period (as defined below), then the Company shall pay the Executive his Accrued Benefits. In addition, subject to (i) the Executive signing a separation agreement and release in a form and manner satisfactory to the Company, which shall include, without limitation, a general release of claims against the Company and all related persons and entities, a reaffirmation of all of the Executive's Continuing Obligations (as defined below) and, in the Company's sole discretion, a one year post-employment noncompetition covenant, and shall provide that if the Executive breaches any of the Continuing Obligations, all payments of the Severance Amount shall immediately cease (the "Separation Agreement and Release"), and (ii) the Separation Agreement and Release becoming irrevocable, all within sixty (60) days after the Date of Termination (or such shorter period as set forth in the Separation Agreement and Release):

(a) the Company shall pay the Executive an amount equal to (A) 0.75 times the Executive's Base Salary plus (B) a pro-rata portion of the Executive's Target Incentive Compensation, based on the number of days that have passed as of the Date of Termination in the year in which the Date of Termination occurs (the "Severance Amount"); provided that in the event the Executive is entitled to any payments pursuant to the Restrictive Covenants Agreement, the Severance Amount received in any calendar year will be reduced by the amount the Executive is paid in the same such calendar year pursuant to the Restrictive Covenants Agreement (the "Restrictive Covenants Agreement Setoff"); and

(b) if the Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay the full monthly COBRA premium for the same level of group health coverage as in effect for the Executive on the Date of Termination until the earliest of the following: (i) the 9-month anniversary of the Date of Termination; (ii) the Executive's eligibility for group health coverage through other employment; or (iii) the end of the Executive's eligibility under COBRA for continuation coverage for health care. If the payment of any COBRA or health insurance premiums by Company on behalf of Executive as described herein would otherwise violate any applicable nondiscrimination rules or cause the reimbursement of claims to be taxable under the Patient Protection and Affordable Care Act of 2010, together with the Health Care and Education Reconciliation Act of 2010 (collectively, the "Healthcare Acts") or Section 105(h) of the Code, the COBRA premiums paid by the Company shall be treated as taxable payments (subject to customary and required taxes and employment-related deductions) and be subject to imputed income tax treatment to the extent necessary to eliminate any discriminatory treatment or taxation under the Healthcare Acts or Section 105(h) of the Code. If Company determines in its sole discretion that it cannot provide the COBRA benefits described herein under Company's health

insurance plan without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), Company shall in lieu thereof provide to Executive a taxable lump-sum payment in an amount equal to the sum of the monthly (or then remaining) COBRA premiums that Executive would be required to pay to maintain Executive's group health insurance coverage in effect on the separation date for the remaining portion of the period for which Executive shall receive the payments described in this Section 5(b).

(c) The amounts payable under this Section 5 shall be paid out in substantially equal installments in accordance with the Company's payroll practice, with the first installment commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

6. Compensation Upon Termination by the Company without Cause or by the Executive for Good Reason within the Change in Control Period. The provisions of this Section 6 shall apply in lieu of, and expressly supersede, the provisions of Section 5 regarding severance pay and benefits upon a termination by the Company without Cause or by the Executive for Good Reason if such termination of employment occurs during the three (3) months before through twelve (12) months after the occurrence of the first event constituting a Change in Control (such period, the "Change in Control Period"). These provisions shall terminate and be of no further force or effect beginning twelve (12) months after the occurrence of a Change in Control.

(a) Change in Control. If during the Change in Control Period the Executive's employment is terminated by the Company without Cause as provided in Section 3(d) or the Executive terminates his employment for Good Reason as provided in Section 3(e), then, subject to the signing of the Separation Agreement and Release by the Executive and the Separation Agreement and Release becoming irrevocable, all within 60 days after the Date of Termination (or such shorter period as set forth in the Separation Agreement and Release):

(i) the Company shall pay the Executive a lump sum in cash in an amount equal to the sum of (A) 1.00 times the Executive's current Base Salary (or the Executive's Base Salary in effect immediately prior to the Change in Control, if higher) plus (B) one hundred percent (100%) of the Executive's Target Incentive Compensation (the "Change in Control Payment"); provided that the Change in Control Payment shall be reduced by the amount of the Restrictive Covenants Agreement Setoff, if applicable, paid or to be paid in the same calendar year; and

(ii) notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all time-based stock options and other time-based stock-based awards held by the Executive shall immediately accelerate and become fully vested and exercisable or nonforfeitable as of the Date of Termination; and

(iii) if the Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay the full monthly COBRA premium for the same level of group health coverage as in effect for the Executive on the Date of Termination until the earliest of the following: (i) the 12-month anniversary of the Date of Termination; (ii) the Executive's eligibility for group health coverage through other employment; or (iii) the end of the Executive's eligibility under COBRA for continuation coverage for health care. If the payment of any COBRA or health insurance premiums by Company on behalf of Executive as described herein would otherwise violate any applicable nondiscrimination rules or cause the reimbursement of claims to be taxable under the Healthcare Acts or Section 105(h) of the Code, the COBRA premiums paid by the Company shall be treated as taxable payments (subject to customary and required taxes and employment-related deductions) and be subject to imputed income tax treatment to the extent necessary to eliminate any discriminatory treatment or taxation under the Healthcare Acts or Section 105(h) of the Code. If Company determines in its sole discretion that it cannot provide the COBRA benefits described herein under Company's health insurance plan without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), Company shall in lieu thereof provide to Executive a taxable lump-sum payment in an amount equal to the sum of the monthly (or then remaining) COBRA premiums that Executive would be required to pay to maintain Executive's group health insurance coverage in effect on the separation date for the remaining portion of the period for which Executive shall receive the payments described in this Section 6(b).

The amounts payable under this Section 6(a) shall be paid or commence to be paid within sixty (60) days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Executive becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Executive receiving a higher After Tax Amount (as defined below) than the Executive would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based

payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 6(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Executive as a result of the Executive's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 6(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Executive. Any determination by the Accounting Firm shall be binding upon the Company and the Executive.

(c) Definitions. For purposes of this Section 6, Change in Control" shall mean any of the following:

(i) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act") (other than the Company, any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of the Company representing 50 percent or more of the combined voting power of the Company's then outstanding securities having the right to vote in an election of the Board ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from the Company); or

(ii) the date a majority of the members of the Board is replaced during any 12- month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; or

(iii) the consummation of (A) any consolidation or merger of the Company where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing

in the aggregate more than 50 percent of the voting shares of the Company issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of the Company.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by the Company which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to 50 percent or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company) and immediately thereafter beneficially owns 50 percent or more of the combined voting power of all of the then outstanding Voting Securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (i).

7. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Executive's separation from service within the meaning of Section 409A of the Code, the Company determines that the Executive is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Executive becomes entitled to under this Agreement on account of the Executive's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Executive's separation from service, or (B) the Executive's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six- month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Executive during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Executive's termination of employment, then such payments or benefits shall be payable only upon the Executive's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

8. Restrictive Covenants.

(a) Restrictive Covenants Agreement. The Executive acknowledges and agrees that in consideration and as a condition of the commencement of employment by the Company, the Executive is required to enter into the Restrictive Covenants Agreement attached hereto as Exhibit A (the "Restrictive Covenants Agreement"). For purposes of this Agreement, the obligations in this Section 8 and those that arise in the Restrictive Covenants Agreement and any other agreement relating to confidentiality, assignment of inventions, or other restrictive covenants shall collectively be referred to as the "Continuing Obligations."

(b) Third-Party Agreements and Rights. The Executive hereby confirms that the Executive is not bound by the terms of any agreement with any previous employer or other party which restricts in any way the Executive's use or disclosure of information or the Executive's engagement in any business. The Executive represents to the Company that the Executive's execution of this Agreement, the Executive's employment with the Company and the performance of the Executive's proposed duties for the Company will not violate any obligations the Executive may have to any such previous employer or other party. In the Executive's work for the Company, the Executive will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and the Executive will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(c) Litigation and Regulatory Cooperation. During and after the Executive's employment, the Executive shall cooperate fully with the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf

of the Company which relate to events or occurrences that transpired while the Executive was employed by the Company. The Executive's full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Executive's employment, the Executive also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Executive was employed by the Company. The Company shall reimburse the Executive for any reasonable out-of-pocket expenses incurred in connection with the Executive's performance of obligations pursuant to this Section 8(c).

(d) Injunction. The Executive agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Executive of the promises set forth in this Section 8, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, the Executive agrees that if the Executive breaches, or proposes to breach, any portion of this Agreement, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company.

(e) Protected Disclosures and Other Protected Actions. Nothing in this Agreement shall be interpreted or applied to prohibit the Executive from making any good faith report to any governmental agency or other governmental entity (a "Government Agency") concerning any act or omission that the Executive reasonably believes constitutes a possible violation of federal or state law or making other disclosures that are protected under the anti-retaliation or whistleblower provisions of applicable federal or state law or regulation. In addition, nothing contained in this Agreement limits the Executive's ability to communicate with any Government Agency or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including the Executive's ability to provide documents or other information, without notice to the Company. In addition, for the avoidance of doubt, pursuant to the federal Defend Trade Secrets Act of 2016, the Executive shall not be held criminally or civilly liable under any federal or state trade secret law or under this Agreement or the Restrictive Covenants Agreement for the disclosure of a trade secret that (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

9. Consent to Jurisdiction. In the event of any dispute regarding the terms or interpretation of this Agreement, the parties hereby consent to the sole and exclusive jurisdiction of the Superior Court of the Commonwealth of Massachusetts and the United States District Court for the District of Massachusetts. Accordingly, with respect to any such court action, the Executive (a) submits to the personal jurisdiction and venue of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction, venue or service of process.

10. Indemnification. Executive shall be entitled to indemnification pursuant to the Officer Indemnification Agreement between the parties effective as of November 2, 2020, 2022 ("Indemnification Agreement").

11. Representations and Warranties. By signing this agreement, Executive represents that Executive has not been debarred under Subsection (a) or (b) of Section 306 of the United States Federal Food, Drug, and Cosmetic Act (21 U.S. C. 335a); and is not on any FDA clinical investigator enforcement lists (including the (i) Disqualified/Totally Restricted List, (ii) Restricted List and (iii) Adequate Assurances List).

12. Notice of Resignation. If Executive elects to resign from employment with the Company, the Executive must provide the Company with written notification of resignation at least three (3) weeks prior to the Executive's intended resignation date. The Company may elect to waive all or part of the three (3) week notice period in its sole discretion.

13. Integration. This Agreement, together with the Restrictive Covenants Agreement, the Indemnification Agreement and the Equity Documents, constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes in all respects all prior agreements between the parties relating to the Executive's employment relationship with the Company and/or the ending of that employment relationship.

14. Withholding. All payments made by the Company to the Executive under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.

15. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

16. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Executive's employment to the extent necessary to effectuate the terms contained herein.

17. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

18. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Executive at the last address the Executive has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

19. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Executive and by a duly authorized representative of the Company.

20. Effect on Other Plans and Agreements. An election by the Executive to resign for Good Reason under the provisions of this Agreement shall not be deemed a voluntary termination of employment by the Executive for the purpose of interpreting the provisions of any of the Company's benefit plans, programs or policies. Nothing in this Agreement shall be construed to limit the rights of the Executive under the Company's benefit plans, programs or policies except as otherwise may be provided herein, and except that the Executive shall have no rights to any severance benefits under any Company severance pay plan, offer letter or otherwise. Except with respect to the Restrictive Covenants Agreement, in the event that the Executive is party to an agreement with the Company providing for payments or benefits under such agreement and this Agreement, the terms of this Agreement shall govern and the Executive may receive payment under this Agreement only and not both. Further, Section 5 and Section 6 of this Agreement are mutually exclusive and in no event shall the Executive be entitled to payments or benefits pursuant to Section 5 and Section 6 of this Agreement.

21. Governing Law. This is a Massachusetts contract and shall be construed under and be governed in all respects by the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of laws principles of such Commonwealth. With respect to any disputes concerning federal law, such disputes shall be determined in accordance with the law as it would be interpreted and applied by the United States Court of Appeals for the First Circuit.

22. Assignment. Neither the Executive nor the Company may make any assignment of this Agreement or any interest in it, by operation of law or otherwise, without the prior written consent of the other; provided, however, that the Company may assign its rights and obligations under this Agreement (including the Restrictive Covenants Agreement) without the Executive's consent to any affiliate or to any person or entity with whom the Company shall hereafter effect a reorganization, consolidate with, or merge into or to whom it transfers all or substantially all of its properties or assets; provided further that if the purchaser in any transaction involving the transfer of all or substantially all of the Company's assets assumes this Agreement and the Executive accepts a position with the purchaser that is equivalent or better to his or her position immediately preceding such transaction, then the Executive shall not be entitled to any Severance Amount pursuant to Section 5 or any Change in Control Payment pursuant to Section 6. This Agreement shall inure to the benefit of and be binding upon the Executive and the Company, and each of the Executive's and the Company's respective successors, executors, administrators, heirs and permitted assigns.

23. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

IN WITNESS WHEREOF, the parties have executed this Agreement, under seal, effective on the Effective Date.

MAGENTA THERAPEUTICS, INC.

By: /s/ Jason Gardner
Its: Chief Executive Officer
Date: March 3, 2022

EXECUTIVE

/s/ Stephen Mahoney
Stephen Mahoney

Date: March 3, 2022

Exhibit 21.1

Legal Name	State of Organization
Magenta Securities Corporation	Massachusetts

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Magenta Therapeutics, Inc.:

We consent to the incorporation by reference in the registration statements (No. 333-233127 and No. 333-257381) on Form S-3 and (No. 333-225838, No. 333-230387, No. 333-233125, No. 333-236853, and No. 333-253815) on Form S-8 of Magenta Therapeutics, Inc. and subsidiary, of our report dated March 8, 2022, with respect to the consolidated balance sheets of Magenta Therapeutics, Inc. as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes, which report appears in the December 31, 2021 annual report on Form 10-K of Magenta Therapeutics, Inc.

/s/ KPMG LLP

Boston, Massachusetts
March 8, 2022

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13A-14(A) / RULE 15D-14(A) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Jason Gardner, D.Phil., certify that:

1. I have reviewed this Annual Report on Form 10-K of Magenta Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2022

/s/ Jason Gardner

Jason Gardner, D.Phil.
President, Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13A-14(A) / RULE 15D-14(A) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Stephen Mahoney, certify that:

1. I have reviewed this Annual Report on Form 10-K of Magenta Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2022

/s/ Stephen Mahoney

Stephen Mahoney
Chief Financial and Operating Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Annual Report on Form 10-K of Magenta Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his or her knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 8, 2022

/s/ Jason Gardner
Jason Gardner, D.Phil.
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Stephen Mahoney
Stephen Mahoney
Chief Financial and Operating Officer
(Principal Financial and Accounting Officer)