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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, 2022

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by 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, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $56.3 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, 2023, there were 60,639,909 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 2023 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, 2022, 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., or 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," "target," "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 plans and expectations regarding our strategic alternative review process and the timing and success of such process regarding a potential transaction;
- timing of and costs or charges associated with our restructurings, and the savings benefits we expect to receive from those restructurings;
- success in retaining, or changes required in, our officers, key employees or directors;
- our public securities' potential liquidity and trading;
- the initiation, timing and success of clinical trials for our product candidates;
- 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 our product candidates in conformity with the FDA'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 our product candidates;
- 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 our product candidates;
- the level of expenses related to any of our product candidates or clinical development programs;
- the benefits of the use of our product candidates, if approved;
- our ability to successfully commercialize our product candidates, if approved;
- the rate and degree of market acceptance of our product candidates;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to obtain orphan drug designation for any of our product candidates;
- 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 may pursue and treatment modalities that we may develop;
- our ability to successfully find collaborators for 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 our plans and expectations regarding our strategic alternative review process and the timing and success of such process regarding a potential transaction, our ability to resume, conduct or successfully complete certain clinical trials, 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, or 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 may not be successful in identifying and implementing any strategic transaction, and any strategic transactions that we may consummate in the future could have negative consequences. If a strategic transaction is not consummated, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.
- We are a biotechnology company with a limited operating history, have incurred significant losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future. We have no products approved for commercial sale and have not generated any revenue from product sales.
- Should we resume development of our product candidates, 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. 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 have not yet demonstrated an ability to successfully complete certain 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 of our product candidates. We have never generated revenue from product sales and may never be profitable.
- Should we resume development of our product candidates, if we are unable to advance our product candidates through development, obtain regulatory approval and commercialize them, or if we experience significant delays in doing so, our business will be materially harmed.
- The successful development of biopharmaceuticals and cell-based therapies is highly uncertain. Clinical trials or those of our collaborators involving our product candidates 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.
- 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.
- Should we resume development of our product candidates, if we are not able to identify a safe and effective dose for any of our product candidates, we may need to delay, abandon or limit our development of any potential product candidates.
- Clinical development involves a lengthy and expensive process, with an uncertain outcome. Should we resume development of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates. If we encounter delays or difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Should we resume development 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 our product candidates.
- We have no experience as a company in obtaining regulatory approval for a drug or biologic. 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.
- Should we resume development of our product candidates, 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 U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or 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.
- 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 have been and may in the future be subject to many manufacturing risks, any of which could substantially increase our costs, delay clinical programs and limit supply of our product candidates.
- We have in the past relied on and, should we resume development of our product candidates, may continue to rely on third parties to conduct our preclinical and clinical trials and we may rely on them to perform other tasks for us as well. 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.
- 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.
- 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. 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.
- 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 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.
- Should we resume development of our product candidates, our commercial success depends on our ability to obtain, maintain and protect our intellectual property and proprietary technology. If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or our technologies, we may not be able to compete effectively in our markets and our business may be adversely affected.
- Should we resume development of our product candidates, we may 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.
- Should we resume development of our product candidates, 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. If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.
- Should we resume development of our product candidates, if we lose key personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop our product candidates will be impaired and our business may be harmed.
- The trading price of our common stock has been, and will likely continue to be, highly volatile. As a result of this volatility, investors may not be able to sell common stock at or above the purchase price and may lose some or all of their investment.

This section contains forward-looking statements. You should refer to the explanation of the qualifications and limitations on forward-looking statements in this Annual Report on Form 10-K.

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 biotechnology company focused on improving stem cell transplantation.

In February 2023, after a review of Magenta's programs, resources and capabilities, including anticipated costs and timelines, we announced the decision to halt further development of our programs. Specifically, we discontinued the MGTA-117 Phase 1/2 clinical trial in patients with relapsed/refractory acute myeloid leukemia, or R/R AML, and myelodysplastic syndromes, or MDS. We discontinued the MGTA-145 Phase 2 stem cell mobilization clinical trial in patients with sickle cell disease, or SCD. Lastly, we stopped incurring certain costs relating to MGTA-45, including manufacturing and costs relating to certain other activities that were intended to support an investigative new drug application, or IND, for MGTA-45 (previously named CD45-ADC). As a result of these decisions, we conducted a corporate restructuring that resulted in a reduction in our workforce by 84%.

Coinciding with the decisions related to the programs and across the portfolio, we announced that we intended to conduct a comprehensive review of strategic alternatives for the company and its assets. As part of our strategic review process, we are exploring potential strategic alternatives that include, without limitation, an acquisition, merger, business combination or other transaction. We are also exploring strategic transactions regarding our product candidates and related assets, including, without limitation, licensing transactions and asset sales. There can be no assurance that the strategic review process or any transaction relating to a specific asset, will result in Magenta pursuing such a transaction(s), or that any transaction(s), if pursued, will be completed on terms favorable to Magenta and its stockholders in the existing Magenta entity or any possible entity that results from a combination of entities. If the strategic review process is unsuccessful, our board of directors may decide to pursue a dissolution and liquidation of Magenta.

Our product candidates have been designed to improve the patient experience when preparing for stem cell transplant or gene therapy. Our MGTA-117 product candidate was designed as an antibody drug conjugate, or ADC, designed to deplete CD117-expressing stem cells in the bone marrow in order to make room for subsequently transplanted stem cells or *ex vivo* gene therapy products. The process of making room in the bone marrow is known as conditioning, and the current standard of care for conditioning utilizes chemotoxic agents. Our second targeted conditioning product candidate, MGTA-45, is an ADC designed to selectively target and deplete both stem cells and immune cells, and it is intended to replace the use of chemotherapy-based conditioning prior to stem cell transplant in patients with blood cancers and autoimmune diseases. Lastly, our MGTA-145 product candidate, in combination with plerixafor, is designed to improve the stem cell mobilization process by which stem cells are mobilized out of the bone marrow and into the bloodstream to facilitate their collection for subsequent transplant back into the body for the purpose of resetting the immune system.

In January 2023, we voluntarily paused dosing in our MGTA-117 Phase 1/2 clinical trial for MGTA-117 in patients with R/R AML and MDS after the last participant dosed in Cohort 3 in the clinical trial experienced a Grade 5 serious adverse event, or SAE (respiratory failure and cardiac arrest resulting in death) deemed to be possibly related to MGTA-117. This safety event was reported to the FDA as the study's third safety event which is of a type referred to as a "Suspected, Unexpected, Serious Adverse Reaction," or SUSAR. The FDA subsequently placed the study on partial clinical hold in February 2023.

In April 2022, we announced a plan to more narrowly focus our capital allocation on the MGTA-117 targeted conditioning program, the MGTA-45 IND-enabling activities and the MGTA-145 stem cell mobilization efforts in sickle cell disease while also de-prioritizing other portfolio investments. We made certain reductions in our planned spending related to research platform-related investments in new disease targets, paused certain MGTA-145 investments, including the program's planned MGTA-145 dosing and administration optimization clinical trial in healthy subjects and reduced planned general and administrative expenses. In connection with these reductions to our planned spending, we also reduced our workforce by 14%.

Our Strategy

Our strategy is to continue exploring strategic alternatives that include, without limitation, an acquisition, merger, business combination or other transaction. We are also exploring strategic transactions regarding our product candidates and related assets, including, without limitation, licensing transactions and asset sales.

Our Product Candidates to Date

Stem Cell Transplant Overview

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. 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.

Conditioning Opportunity

Before a patient can receive a stem cell transplant, patients must be prepared, or conditioned, for transplant. Conditioning is intended to be a final attempt to deplete disease-causing cells circulating in the blood stream or found in the bone marrow. It is also intended to deplete a sufficient number of cells, such as HSCs, in the bone marrow to make room for newly transplanted stem cells that will rebuild the healthy blood and immune system or, in the case of gene therapy, newly transplanted gene edited cells intended to address a genetic disease. 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 increase the risk of developing cancer. 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.

Currently only approximately 6% of eligible patients with multiple sclerosis and scleroderma receive a stem cell transplant, in part due to the significant risks of conditioning. Magenta's targeted conditioning programs have also been designed to expand the number of autoimmune patients who can benefit from immune reset with effective and safe targeted conditioning.

Magenta's Targeted Conditioning Product Candidates

Magenta's targeted conditioning product candidates have been designed to address the unmet need in conditioning for stem cell transplantation or ex vivo gene therapy with a goal of being less toxic than the current radiation and chemotherapy-based treatments.

The Magenta programs have been developed with a focus on targeted conditioning where only specific cell types are removed and it is more tailored to the patient's disease and transplant requirements.

MGTA-117 and MGTA-45 utilize antibody drug conjugates, or ADCs, where a monoclonal antibody which is specific for a cell surface protein is coupled with a payload that enables cell depletion. The antibody and the payload are conjugated to each other via a molecule known as a linker. The approach is intended to allow the ADC to bind to the receptor on the cell targeted for depletion and release the payload inside the target cell to cause the target cell's depletion.

In our development of ADCs for use in conditioning, Magenta sought 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 deplete 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.

MGTA-117

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. MGTA-117 has been designed to deplete CD117-expressing target cells in the blood and/or bone marrow prior to a patient undergoing stem cell transplant or receiving an *ex vivo* gene therapy product. One of the primary goals of MGTA-117 was to lessen the need for high-dose or high-intensity chemotherapeutic agents prior to such transplant or gene therapy. In the case of HSC based gene therapy applications, a goal of MGTA-117 was to potentially eliminate the need for chemotherapeutic agents altogether.

Clinical Development of MGTA-117

In the first quarter of 2022, we initiated the Phase 1/2 clinical trial for MGTA-117 in patients with relapsed/refractory AML and MDS, and the trial was designed as a multi-center, open-label, single-ascending-dose clinical trial. Dose escalation in the clinical trial was designed as a modified Fibonacci sequence. The primary outcomes for the clinical trial were defined as the evaluation of the safety profile, pharmacokinetics and pharmacodynamics of MGTA-117 as a single dose.

We reported early clinical observations from Cohort 1 (dose level 0.02 mg/kg) on May 16, 2022 that indicated evidence of MGTA-117's potential to bind CD117+ cells, reduce CD117+ erythroid progenitor cells in the bone marrow, reduce leukemic blasts in the bone marrow, rapidly clear the body and maintain a favorable tolerability profile.

On December 12, 2022, we announced preliminary clinical results for MGTA-117 from 15 patients across the first three dose-escalation cohorts and showed single-agent activity with no dose-limiting toxicities, or DLTs. In the fourth quarter of 2022, we initiated formal engagements with regulatory agencies to transition MGTA-117 into the transplant-eligible AML and MDS patient population, with the intention of engaging regulators in the first half of 2023. Enrollment of the trial continued into Cohort 4 (dose level 0.13 mg/kg).

On December 20, 2022, we announced that we stopped dosing in Cohort 4, pursuant to the clinical trial protocol, due to the observance of DLTs involving pulmonary distress, in two of the three participants dosed in Cohort 4. As a result of these observations and due to the unexpected nature of the pulmonary involvement, two SUSARs were reported to the U.S. Food and Drug Administration, or FDA. In accordance with the clinical trial protocol and, following the recommendation of the trial's safety Cohort Review Committee, we resumed dosing in Cohort 3 (dose level 0.08 mg/kg). Each of the Cohort 4 participants who experienced a DLT subsequently recovered, and all three participants in Cohort 4 (3/3) with relapsed or refractory disease achieved morphologic and molecular remission in the bone marrow resulting in eligibility for transplant.

On January 25, 2023, we announced that the last participant dosed in Cohort 3 (dose level 0.08 mg/kg) in the clinical trial experienced a Grade 5 SAE (respiratory failure and cardiac arrest resulting in death) deemed to be possibly related to MGTA-117, and this was reported to the FDA as a SUSAR because the event was still deemed to be unexpected at the time. After consultation with the

trial's safety Cohort Review Committee, and with the highest regard for patient safety, we voluntarily paused all dosing in the clinical trial. The FDA subsequently placed the study on partial clinical hold in February 2023.

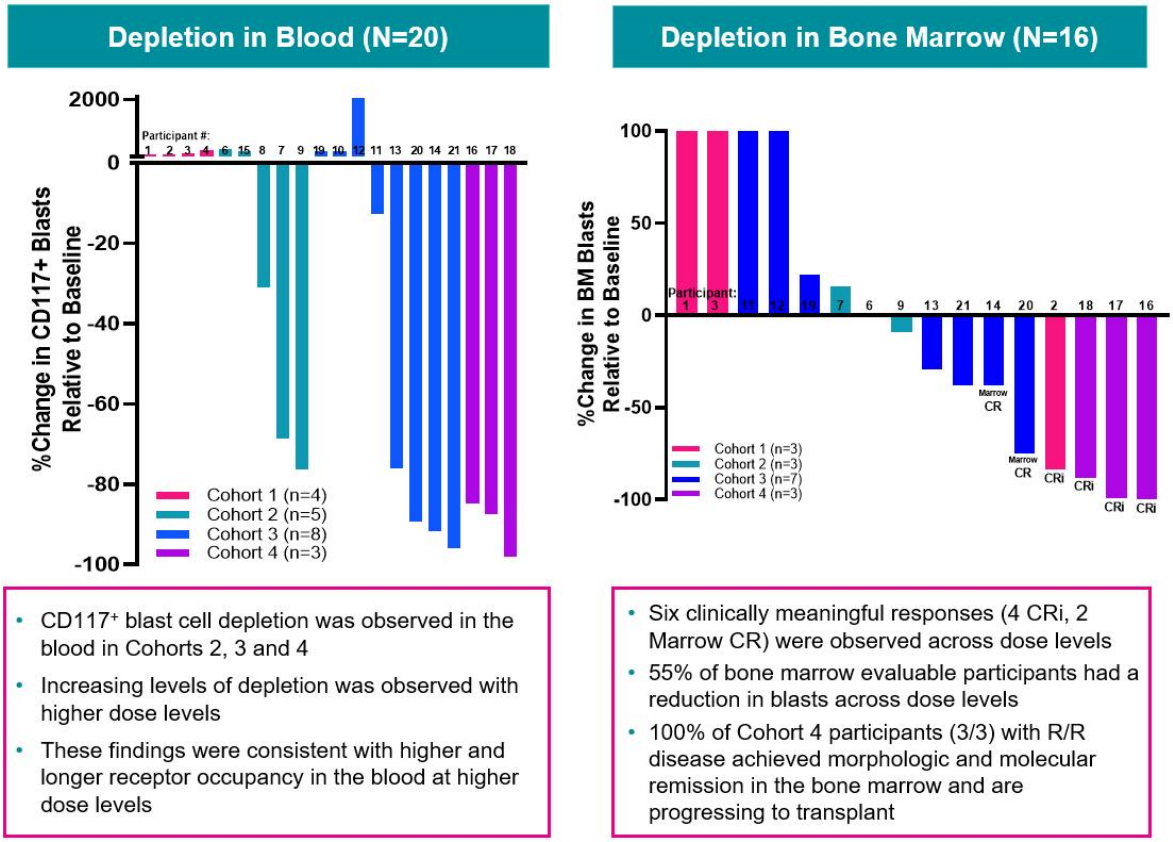
Following these events, Magenta reviewed the MGTA-117 program as well as its broader program portfolio both as stand-alone programs and collectively. In February 2023, after a thorough review of internal and external factors, we announced the decision to halt further development of Magenta's programs and to conduct a comprehensive review of strategic alternatives for the programs and the company. As a result of that decision, we discontinued the MGTA-117 Phase 1/2 clinical trial.

MGTA-117 Clinical Data

Magenta conducted the Phase 1/2 clinical trial in R/R AML and MDS patients in which 22 participants who were ineligible for stem cell transplant due to their disease burden were dosed with MGTA-117, administered intravenously as a single dose. After treatment with MGTA-117, five study participants became eligible for and progressed to stem cell transplant. Six clinically meaningful responses were observed: four participants experienced complete remission with incomplete count recovery (CRi), and two participants experienced bone marrow complete remissions (Marrow CR). Three study participants experienced DLTs, two in Cohort 4 and one in Cohort 3, which were reported to the FDA as SUSARs. Magenta terminated the clinical trial in February 2023.

The clinical trial data were presented as a poster at the Transplantation and Cellular Therapy Conference, or TCT, on February 15-18, 2023. The poster is as follows below and was entitled **"MGTA-117, an Anti-CD117-Amanitin Antibody-Drug Conjugate, in Participants With Relapsed/Refractory Adult Acute Myeloid Leukemia (AML) and Myelodysplasia With Excess Blasts (MDS-EB): Safety, Pharmacokinetics, and Pharmacodynamics Initial Findings from a Phase 1/2 Study".**

Depletion Data

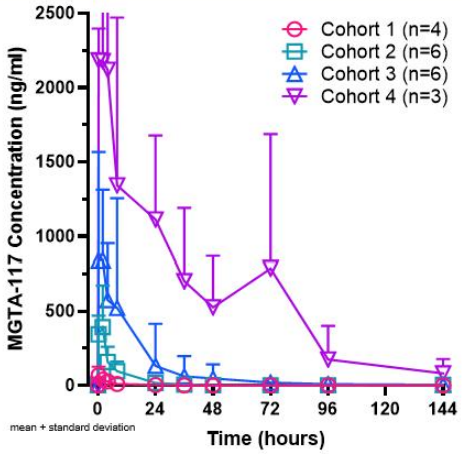


- CD117+ blast cell depletion was observed in the blood in Cohorts 2, 3 and 4
- Increasing levels of depletion was observed with higher dose levels
- These findings were consistent with higher and longer receptor occupancy in the blood at higher dose levels

- Six clinically meaningful responses (4 CRi, 2 Marrow CR) were observed across dose levels
- 55% of bone marrow evaluable participants had a reduction in blasts across dose levels
- 100% of Cohort 4 participants (3/3) with R/R disease achieved morphologic and molecular remission in the bone marrow and are progressing to transplant

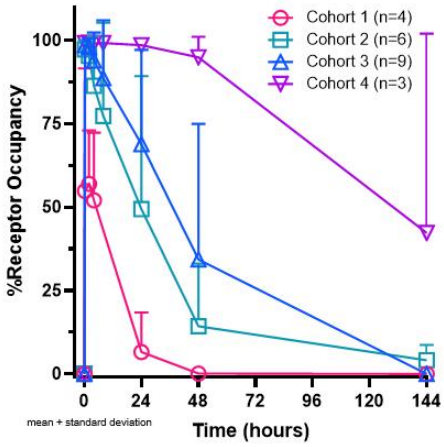
Pharmacokinetics and Receptor Occupancy, or RO, Data

Pharmacokinetics (N=19)



- Maximum concentrations of MGTA-117 reached in all participants within 2-4 hours of dosing
- As expected, there was rapid clearance in all Cohorts and non-linear clearance was observed in Cohort 4
- Confirmed *in vivo* stability of ADC: no free payload detectable at any timepoint after dosing (n=19)

Receptor Occupancy (N=21)



- Binding of $CD117^{+}$ cells was observed in all participants within 15 minutes after dosing
- Greater levels and longer duration of RO was observed in higher dose cohorts
- >90% RO for 48 hours was observed in Cohort 4

Safety and Tolerability Data

Summary of Safety and Tolerability by Cohort

Category	Cohort 1 (N=4) n (%)	Cohort 2 (N=6) n (%)	Cohort 3 (N=9) n (%)	Cohort 4 (N=3) n (%)
Participants with Treatment-Emergent Adverse Events (TEAEs)				
TEAEs classified as dose-limiting toxicities	0	0	1 (11)	2 (67)
Serious AEs	1 (25)	4 (67)	3 (33)	2 (67)
Grade 3 or higher TEAEs	3 (75)	4 (67)	5 (38)	2 (67)
TEAEs resulting in death: AML disease progression, N=2; sepsis, N=1; respiratory failure, cardiac arrest, N=1	1 (25)	3 (33)	1 (11)	0 (0)
TEAEs in >20% of Participants Regardless of Causality				
Nausea (32%), Constipation (27%), Hypokalemia (27%)				
Participants with MGTA-117 Related TEAEs				
Grade 1 (liver enzyme elevations)	1 (25)	2 (33)	0	0
Grade 2 (fever, pleural effusion, haemoptysis)	0	1 (17)[1]	1 (11)	1 (33)
Grade 3 (leukopenia, worsening anemia)	0	0	2 (22)[2]	0
Grade 4 (leukopenia, pneumonitis)	0	0	1 (11)[3]	2 (67)[4,5]
Grade 5 (respiratory failure and cardiac arrest)	0	0	1 (11)[6]	0
Total	1 (25)	3 (50)	5 (56)	3 (100)

[1] One participant (Cohort 2) had a Grade 2 liver enzyme elevation not reflected in table
[2] Participant had severe neutropenia with Grade 2 leukopenia at baseline
[3] Participant had severe neutropenia with Grade 3 leukopenia at baseline
[4] Two participants had Grade 4 pneumonitis
[5] One participant with Grade 4 pneumonitis had Grade 4 liver enzyme elevation
[6] One participant with Grade 5 respiratory failure and cardiac arrest resulting in death
TEAEs observations are from independent participants
TEAEs: Treatment- Emergent Adverse Events; AEs: Adverse Events

Collaborations Regarding MGTA-117

We had 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. We terminated this agreement in February 2023.
- **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. We terminated this agreement in February 2023.

MGTA-45

Our second ADC-based conditioning program, MGTA-45 (formerly known as CD45-ADC) is an anti-human CD45 antibody conjugated to a DNA-interacting payload, which is highly expressed on HSCs, leukemia cells and immune cells. It is designed to deplete CD45-expressing target cells in the blood and/or bone marrow prior to a patient undergoing either an allogeneic stem cell transplant, likely to treat leukemia, or an autologous transplant for severe autoimmune disease. The ability of MGTA-45 to deplete both HSC's and immune cells is a critical aspect of the immune reset needed for the treatment of severe autoimmune disease. Similarly, in the allogeneic blood cancer transplant setting, the depletion of host immune cells is critical to address immune-mediated

rejection of the incoming foreign stem cells. Additionally, MGTA-45 has the potential to target blood cancer cells expressing CD45 which may provide additional therapeutic benefit for cancer patients.

Development of MGTA-45

In the third quarter of 2022, we successfully completed a dose-ranging toxicology preclinical study. Good Manufacturing Practice, or GMP, manufacturing and other IND,-enabling activities were ongoing for the MGTA-45 program as of December 2022. In January 2023, the FDA provided feedback in a Type B response on our proposed Good Laboratory Practice, or GLP, toxicological study design and our first-in-human design, including our proposed starting dose and further dose escalations.

After our February 2023 announcement to conduct a comprehensive review of strategic alternatives for our programs and the company, we made the decision to stop incurring certain costs relating to MGTA-45 as part of our efforts to explore a program-specific transaction, including a potential licensing transaction or a sale of the asset, given the program's early and promising profile.

MGTA-45 Preclinical Data

Magenta's preclinical studies demonstrated that targeting CD45-expressing hematopoietic cells with MGTA-45 potently depleted HSCs, CD45-expressing leukemia cells and immune cells in vitro. In healthy non-human primates, a single dose of MGTA-45 depleted HSCs in the bone marrow, depleted immune cells in the bone marrow and blood and enabled autologous HSC transplant in a clinically relevant nonhuman primate gene-therapy model. MGTA-45 also significantly extended survival in a patient-derived xenograft model of AML R/R compared to standard of care. These MGTA-45 preclinical data were presented as a poster at TCT on February 15-18, 2023.

Stem Cell Mobilization Opportunity

Stem cell mobilization is a process by which stem cells are stimulated out of the bone marrow and into the bloodstream so that they are available for collection for future reinfusion. The collected cells are then preserved, frozen, and stored until the time of transplant. We developed MGTA-145 as a new approach to stem cell mobilization. There are three methods of mobilizing and 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 mobilization and collection in the peripheral blood from either donors or patients.

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 apheresis 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.

MGTA-145

MGTA-145 has been designed to be 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. MGTA-145 received Orphan Drug Designation from the FDA for mobilization of HSCs to the peripheral blood for collection and subsequent transplant.

In February 2023, after a thorough review of internal and external factors, we announced the decision to halt further development of Magenta's programs and to conduct a comprehensive review of strategic alternatives for the programs and the company. As a result of that decision, we discontinued the Phase 2 clinical trial in SCD.

Clinical Development of MGTA-145

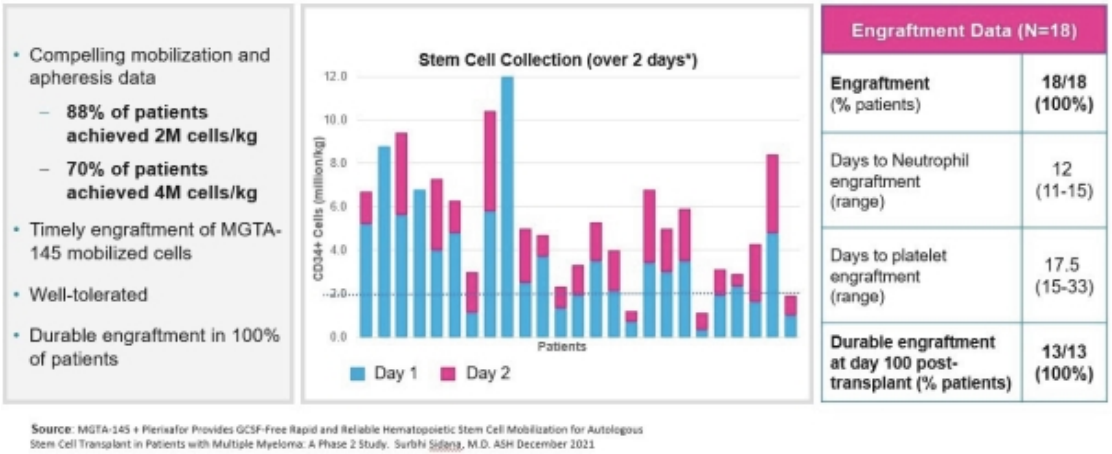
MGTA-145 Phase 1 Clinical Data – Healthy Subjects

Our Phase 1 clinical trial of MGTA-145 plus plerixafor in healthy subjects 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

Magenta supported a Phase 2 investigator-initiated clinical trial at Stanford University evaluating the utility of MGTA-145, combination with plerixafor, in mobilizing and collecting stem cells from 25 multiple myeloma patients. The clinical trial 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). As we reported previously, all patients transplanted with cells mobilized by MGTA-145 plus plerixafor 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.

Upon conclusion of the trial, we decided that a 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. But ultimately, we did not initiate that planned study due to the unfavorable state of the capital markets for biotechnology companies and our decision in April 2022 to more narrowly focus our capital allocation on MGTA-117 and the MGTA-145 Phase 2 stem cell mobilization clinical trial in patients with SCD.



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

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 would co-fund the clinical trial. Each party planned to characterize the collected cells, and we planned to gene-modify the cells and transplant them into established pre-clinical models to evaluate engraftment. Data from this clinical trial were intended to 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. No meaningful data sets were collected in the clinical trial due to a lack of enrollment. In February 2023, we discontinued the clinical trial. We subsequently terminated the collaboration agreement with bluebird.

Magenta's Research Programs

Our research efforts most recently focused 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 were 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 and/or Natural Killer cell therapy 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.

In February 2023, after a review of Magenta's business, programs, resources and capabilities, we announced the decision to halt further development of Magenta's programs and to conduct a comprehensive review of strategic alternatives. As a result of that decision, we ceased development of our research programs.

Manufacturing

We do not own or operate, and have no plans to establish, any manufacturing facilities. We have historically relied upon, and continue to rely upon, third-party contract development and manufacturing organizations, or CDMOs, for raw materials, drug substance and drug product for preclinical research and ongoing clinical trials, as needed. In February 2023, after a review of Magenta's business, programs, resources and capabilities, we announced the decision to conduct a comprehensive review of strategic alternatives. As a result of that decision, we are in the process of terminating certain manufacturing-related relationships.

Competition

The biotechnology industry is extremely competitive in the race to develop new products and treatment modalities. We may face competition 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. 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 product candidates. 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.

As part of our strategic review process, we began exploring potential strategic alternatives that include, without limitation, an acquisition, merger, business combination or other transaction. We are also exploring strategic transactions regarding our product candidates and related assets, including, without limitation, licensing transactions and asset sales.

Given the economic downturn in the capital markets, and in the biotechnology sector in particular, we may face substantial competition for attractive counterparties for any of the proposed strategic transactions we are reviewing. For example, there may be many other biotech and pharmaceutical companies that halt development of their programs and instead choose to pursue strategic transactions like the ones we are currently exploring. These companies may possess greater financial and managerial resources than we do, and they may have more attractive product candidates, intellectual property or other assets. As a result, these other companies may prove to be more attractive than Magenta to counterparties pursuing strategic transactions. There can be no assurance that our strategic review process will result in Magenta pursuing a transaction, or that any transaction, if pursued, will be completed on terms favorable to Magenta and its stockholders.

Licenses and Collaborations

For a description of our licenses and collaboration agreements, see Note 9 to our consolidated financial statements included in this Annual Report on Form 10-K.

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, 2022, 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, eleven 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, 2022, 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, five families of pending U.S. provisional patent applications, and a pending Patent Cooperation Treaty, or PCT, patent 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, 2022, we owned two issued U.S. patents, six pending U.S. patent applications, more than 14 pending foreign patent applications, and one pending PCT patent application, and we co-owned one pending U.S. patent application and six pending foreign 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 aryl hydrocarbon receptor antagonists, including E478, methods of using these compounds, and methods of treatment using expanded HSCs. As of December 31, 2022, 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 the President and Fellows of Harvard College, or 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, 2022, 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, 2022, 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 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 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 GLP requirements;
- submission to the FDA of 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, unless a waiver is applicable; 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. Should we resume the development of our product candidates, we cannot be certain that any approvals for our 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. The FDA may also impose clinical holds at any time before or during clinical trials due to safety concerns or noncompliance and may be imposed on all products within a certain class of products.

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. Additionally, the FDA may rescind a fast track designation if it believes that the designation is no longer supported by data emerging in the clinical trial process.

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 with due diligence, and, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date accelerated approval is granted. Additionally, under FDORA, the FDA has increased authority for expedited procedures to 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. The FDA may rescind the designation if the product candidate does not continue to meet the criteria for breakthrough therapy designation.

As part of the 21st Century Cures Act, Congress amended the FDCA to facilitate an efficient development program for, and expedite review of, regenerative medicine advanced therapies, or 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. The FDA may rescind RMAT designation if the product is no longer meeting the criteria for such designation.

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. The government may also assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for the purposes of the federal False Claims Act or federal civil monetary penalties. 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, including the Final Omnibus Rule published in January 2013, 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), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Federal government price reporting laws require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs. Additionally, 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. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and 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 and became effective on January 1, 2023. The amendments to the CCPA introduced by the CPRA impose additional obligations on covered businesses and enhances the protections provided for by the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The changes introduced by the CPRA also create a new state agency that will be vested with authority to implement and enforce the CCPA. 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. This new measure which became effective January 1, 2023 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 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, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program;

- 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 70% point-of-sale-discount 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 Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation.
- The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- 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.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility 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.
- 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.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. The Inflation Reduction Act of 2022, or IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The effects of the IRA on our business and the healthcare industry in general is not yet known.

President Biden has also issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. 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 they will continue to seek new legislative measures to control drug costs.

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.

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 any 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. In addition, the first biologic submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product is eligible for a period of exclusivity against other biologics submitted under the abbreviated approval pathway during which time the FDA may not determine that another

product is interchangeable with the same reference product for any condition of use. The FDA may approve multiple "first" interchangeable products so long as they are all approved on the same first day of marketing. This exclusivity period, which may be shared amongst multiple first interchangeable products, lasts for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologic's patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

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 previous 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 Statute 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 United Kingdom, or 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, or EC, through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA and is valid throughout the European Union and in the additional Member States of the European Economic Area, or EEA (Iceland, Norway and Liechtenstein). 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 EC making 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 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 continue to be recognized in Northern Ireland for the time being). All medicinal products with an existing centralized MA were automatically converted to Great Britain MAs on January 1, 2021. For a period of three 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 EC 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. On January 24, 2023, the MHRA announced that a new international recognition framework will be put in place from January 1, 2024, which will have regard to decisions on the approval of MAs made by the European Medicines Agency and certain other regulators. 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 MA in the European Union. During the additional two-year period of market exclusivity, a generic or biosimilar MAA 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 MA 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 MA based on an MAA with a complete and 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 may grant orphan designation in respect 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 such 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 EC 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. A marketing authorization may be granted to a similar medicinal product to an authorized orphan product during the market exclusivity period in very select cases, such as if (i) it is established that the similar medicinal product is safer, more effective or otherwise clinically superior to the authorized orphan product; (ii) the marketing authorization holder for the authorized orphan product consents to the similar medicinal product authorization; 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.

Since January 1, 2021, a separate process for orphan designation has applied in Great Britain. There is no pre-marketing authorization orphan designation (as there is in the European Union) and the application for orphan designation is 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 EEA.

Brexit and the Regulatory Framework in the U.K.

The U.K. formally left the European Union on January 31, 2020, and 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 provide for 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 aligns in many ways with European Union regulations, however it is possible that these regimes will diverge more significantly 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. However, notwithstanding that there is no wholesale recognition of European Union pharmaceutical legislation under the TCA, under the new framework mentioned above which will be put in place by the MHRA from January 1, 2024, the MHRA has stated that it will take into account decisions on the approval of MAs from the EMA (and certain other regulators) when considering an application for a Great Britain MA. On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework." This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the U.K. In particular, the MHRA will be responsible for approving all medicinal products destined for the U.K. market (Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single U.K.-wide marketing authorization will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the U.K.. Once the Windsor Framework is approved by the EU-UK Joint Committee, the U.K. Government and the European Union will enact legislative measures to enact it into law.

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 EEA, 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. The U.K. has announced plans to reform its data protection legal framework in its Data Reform Bill, but those have been put on hold. 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.

The GDPR and the U.K. GDPR prohibit the transfer of personal data from the EEA or the U.K. to third countries that are not considered to provide adequate protections are provided for personal data, including the U.S. With regard to transfers of personal data from the EEA, transfers to third countries that have not been approved as "adequate" are prohibited unless an appropriate safeguard specified by the GDPR is implemented, such as the Standard Contractual Clauses, or SCCs, approved by the EC or binding corporate rules, or a derogation applies. In the past, companies in the U.S. were able to rely upon the Privacy Shield framework to legitimize data transfers from the EEA to the U.S. In July 2020, the Court of Justice of the European Union, or CJEU, in Case C-311/18 (Data Protection Commissioner v Facebook Ireland and Maximillian Schrems, or Schrems II) invalidated the EU-U.S. Privacy Shield on the grounds that it failed to offer adequate protections to EEA personal data transferred to the U.S. The CJEU, in the same decision, deemed that the Standard Contractual Clauses, or SCCs, published by the EC are valid. However, the CJEU ruled that transfers made pursuant to the SCCs need to be assessed on a case-by-case basis to ensure the law in the recipient country provides "essentially equivalent" protections to safeguard the transferred personal data as the EEA, and required businesses to adopt supplementary measures if such standard is not met.

On June 4, 2021, the EC issued new SCCs that account for the CJEU's decision and other developments, which need to be put in place for new contracts involving the transfer of personal data from the EEA to a third country since September 27, 2021, and incorporated into existing contracts since December 27, 2022. The New SCCs do not apply to the U.K., but the U.K. Information Commissioner's Office has published its own transfer mechanism, the International Data Transfer Agreement, or U.K. IDTA, which entered into force on 21 March 2022, and enables data transfers originating from the U.K. It requires a similar assessment of the data protection provided in the importer's country. The U.K. IDTA needs to be concluded in new contracts involving the transfer of personal data from the U.K. since 22 September 2022. Organizations have until 21 March 2024 to update existing agreements. On March 25, 2022, the EC and the U.S. announced to have reached a political agreement on a new "Trans-Atlantic Data Privacy Framework", which will replace the invalidated Privacy Shield and on December 13, 2022, the EC published a draft adequacy decision on the Trans-Atlantic Data Privacy Framework. We will be required to implement these new safeguards when conducting restricted cross-border data transfers and doing so will require significant effort and cost. These and other future developments regarding the flow of data across borders could increase the cost and complexity of delivering our services in some markets and may lead to governmental enforcement actions, litigation, fines, and penalties or adverse publicity, which could adversely affect our business and financial position.

Although the U.K. is regarded as a third country under the GDPR, on June 28, 2021, the EC 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 EEA to be adequate for the purposes of data protection. This ensures that data flows between the U.K. and the EEA remain unaffected.

As these privacy, data protection and data security laws continue to evolve, we may be required to make changes to our business, including by taking on more onerous obligations in our contracts, limiting our storage, transfer and processing of data and, in some cases, limiting our activities in certain locations. Changes in these laws may also increase our potential exposure through significantly higher potential penalties for non-compliance. In addition, due to the uncertainty and potentially conflicting interpretations of these laws, it is possible that such laws and regulations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other rules or our practices. Any failure or perceived failure by us to comply with applicable laws or satisfactorily protect personal data could result in governmental enforcement actions, litigation, or negative publicity, any of which could inhibit our ability to grow our business.

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. Government authorities and other 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. 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.

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 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.

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. Net prices for drugs 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 drugs from countries where they may be sold at lower prices than in the U.S. Third-party payors are also 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 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, 2022, we had 67 full-time employees, and 47 of our employees were engaged in research and development activities. As of March 20, 2023, we had 11 full-time employees.

Our human capital resource objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our employees. 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, and 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 coronavirus, or 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 $1.235 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 the Strategic Alternative Process and Potential Strategic Transaction

We may not be successful in identifying and implementing any strategic transaction, and any strategic transactions that we may consummate in the future could have negative consequences.

We are continuing to evaluate all potential strategic options for the company, including a merger, reverse merger, sale, wind-down, liquidation and dissolution or other strategic transaction. We are also exploring strategic transactions regarding our product candidates and related assets, including, without limitation, licensing transactions and asset sales. There can be no assurance, however, that we will be able to successfully consummate any particular strategic transaction or that any transaction, if pursued, will be completed on attractive terms, within the anticipated timing, or at all. The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business.

In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available for use in our business or the execution of our strategic plan. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us, obtaining stockholder approval and the availability of financing to third parties in a potential transaction with us on reasonable terms. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

If we are not successful in setting forth a new strategic path for Magenta, or if our plans are not executed in a timely fashion, this may cause reputational harm with our stockholders and the value of our securities may be adversely impacted. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of Magenta could cause our stock price to fluctuate significantly.

We may not realize any additional value in a strategic transaction.

Potential counterparties in a strategic transaction involving our company may place minimal or no value on our assets and our public listing. Further, should we resume development of our product candidates, the development and any potential commercialization of our product candidates will require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving our company may choose not to spend additional resources and continue development of our product candidates and may attribute little or no value, in such a transaction, to those product candidates.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our business.

The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;

- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our company or any acquired business; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

If a strategic transaction is not consummated, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that a strategic transaction will be completed. If a strategic transaction is not completed, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

Our ability to consummate a strategic transaction depends on our ability to retain our employees required to consummate such transaction.

Our ability to consummate a strategic transaction depends upon our ability to retain our employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. In April of 2022, and then again in February 2023, we undertook an organizational restructuring that significantly reduced our workforce in order to conserve our capital resources. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations.

Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In April 2022, and then again in February 2023, we undertook an organizational restructuring that significantly reduced our workforce, including the departure of our chief executive officer. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, our restructuring plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing our business strategy, including retention of our remaining employees. Employee litigation related to the headcount reduction could be costly and prevent management from fully concentrating on the business.

Any future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we

may not be able to comply with legal and regulatory requirements, and loss of employees and reduced productivity among remaining employees.

The impact and results of our ongoing strategic process are uncertain and may not be successful.

Our board of directors remains dedicated to diligently deliberating upon, and making informed decisions that the directors believe are in the best interests of the company and its stockholders. There can be no assurance, however, that the company's current strategic direction, or the board's evaluation of strategic alternatives, will result in any initiatives, agreements, transactions or plans that will further enhance stockholder value.

In addition, given the substantial restructuring of our operations over the past several years, it may be difficult to evaluate our current business and future prospects on the basis of historical operating performance.

We may become involved in litigation that could divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

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 biotechnology company focused on improving stem cell transplantation, and we 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 expenses related to our ongoing operations. To date, we have invested substantially all of our efforts and financial resources in the research and development of our product candidates. In December 2022, we announced that we had stopped dosing in Cohort 4 (dose level 0.13 mg/kg) of the Phase 1/2 clinical trial for MGTA-117 in patients with relapsed/refractory acute myeloid leukemia, or R/R AML, and myelodysplastic syndromes, or MDS, pursuant to the clinical trial protocol, due to the observance of dose-limiting toxicities, or DLTs, in two of the participants dosed in Cohort 4. As a result of these observations, two SUSARs were reported to the U.S. Food and Drug Administration, or FDA. In January 2023, we announced that the last participant dosed in Cohort 3 (dose level 0.08 mg/kg) in the Phase 1/2 clinical trial experienced a Grade 5 serious adverse event, or SAE, (respiratory failure and cardiac arrest resulting in death) deemed to be possibly related to MGTA-117, and this was reported to the FDA as a SUSAR. After consultation with the trial's safety Cohort Review Committee, and with the highest regard for patient safety, we voluntarily paused dosing in the clinical trial. The FDA subsequently placed the trial on partial clinical hold in February 2023. In February of 2023, after a review of our business, programs, resources and capabilities, we announced the decision to halt further development of our programs and to conduct a comprehensive review of strategic alternatives. As a result of that decision, we discontinued the MGTA-117 Phase 1/2 clinical trial in patients with R/R AML and MDS. We discontinued the MGTA-145 Phase 2 stem cell mobilization clinical trial in patients with sickle cell disease, or SCD. Lastly, we stopped incurring certain costs relating to MGTA-45, including manufacturing and costs relating to certain other activities that were intended to support an investigative new drug application, or IND, for MGTA-45 (previously named CD45-ADC).

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, 2022 and 2021, we reported net losses of $76.5 million and $71.1 million, respectively. As of December 31, 2022, we had an accumulated deficit of $402.0 million. If we resume development of our product candidates, 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.

We expect to continue to incur costs and expenditures in connection with the process of evaluating our strategic alternatives. Should we resume development of our product candidates, we will incur substantial research and developments costs and other expenditures to develop such 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.

Should we resume development of our product candidates, we will require additional capital to fund our operations. 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. Should we resume development of our product candidates, we would 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, 2022, we had approximately $112.0 million in cash, cash equivalents and marketable securities. Should we resume development of our product candidates, 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 expenses and future funding requirements, both near and long-term, will depend on many factors, including but not limited to:

- the timing and outcome of our exploration of potential strategic alternatives;
- 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 license, acquisition, collaboration or other strategic transaction agreements;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the 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 material 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;
- 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; and
- the cost of, and ability to maintain on reasonable commercial and economic terms, sufficient office and laboratory space to support our operations.

We cannot be certain that additional funding will be available on acceptable terms, or at all, and such funding may become even more difficult to obtain due to rising interest rates and the current downturn in the U.S. capital markets and the biotechnology sector in general. Competition for additional capital among biotechnology companies may be particularly intense during this present economic downturn. We may be unable to raise capital through public offerings of our common stock and may need to turn to alternative financing arrangements. Such arrangements, if we pursue them, could involve issuances of one or more types of securities, including common stock, preferred stock, convertible debt, warrants to acquire common stock or other securities. These securities could be issued at or below the then prevailing market price for our common stock. In addition, if we issue debt securities, the holders of the debt would have a claim to our assets that would be superior to the rights of stockholders until the principal, accrued and unpaid interest and any premium or make-whole has been paid. Interest on any newly-issued debt securities and/or newly-incurred borrowings would increase our operating costs and reduce our net income, and these impacts may be material. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common stock could be materially and

adversely affected. 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, and we may also be forced to reduce or terminate our operations. 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, the ownership interest of our stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

As part of our strategic review process, we began exploring potential strategic alternatives that include, without limitation, an acquisition, merger, business combination or other transaction. We are also exploring strategic transactions regarding our product candidates and related assets, including, without limitation, licensing transactions and asset sales. In such transactions, we may relinquish valuable rights to, sell or otherwise dispose of our technologies, product candidates or other assets at unfavorable prices or on terms unfavorable to us. In particular, given the current downturn in the U.S. capital markets and the biotechnology sector in general, we may enter into such transactions on terms and at prices less favorable to us than would otherwise occur. We also could be required to seek collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable. We may also be required to relinquish or license on unfavorable terms our rights to technologies or product candidates. As a result, we may fail to realize the full potential of our product candidates.

Any of the foregoing events could have a material adverse effect upon our business and future prospects.

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 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 conducted clinical trials for certain of our product candidates, we have not yet demonstrated an ability to successfully complete certain 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, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. For example, management may fail to undertake sufficient risk mitigation strategies for elements of our business subject to heightened risk, and as a result our business may be harmed.

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

Should we resume development of our product candidates, 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 would depend heavily on our and 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 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

Should we resume development of our product candidates, if we are unable to advance our product candidates through development, obtain regulatory approval and commercialize them, or if we experience significant delays in doing so, our business will be materially harmed.

As noted above, in December 2022 we announced that two study participants in Cohort 4 in the Phase 1/2 clinical trial for MGTA-117 in patients with AML and MDS had experienced DLTs. In January 2023, we announced that the last participant dosed in Cohort 3 in the clinical trial experienced a Grade 5 SAE (respiratory failure and cardiac arrest resulting in death) deemed to be possibly related to MGTA-117 and that we voluntarily paused dosing in the clinical trial. The FDA subsequently placed the trial on partial clinical hold in February 2023. In February of 2023, after a review of our business, programs, resources and capabilities, we announced the decision to halt further development of our programs and to conduct a comprehensive review of strategic alternatives. As a result of that decision, we discontinued the MGTA-117 Phase 1/2 clinical trial in patients with R/R AML and MDS. We discontinued the MGTA-145 Phase 2 stem cell mobilization clinical trial in patients with SCD. Lastly, we stopped incurring certain costs relating to MGTA-45, including manufacturing and costs relating to certain other activities that were intended to support an investigative new drug application, or IND, for MGTA-45.

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, regulatory approval and 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.

Should we resume development of our product candidates, each of our 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, or cGLP;
- 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 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, including certain chemotherapies;
- 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, new drug application, or NDA, 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 does 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 we 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.

Clinical trials may reveal significant adverse events not seen in preclinical or 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, 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.

As noted above, in December 2022 we announced that two study participants in Cohort 4 in the Phase 1/2 clinical trial for MGTA-117 in patients with AML and MDS had experienced DLTs. In January 2023, we announced that the last participant dosed in Cohort 3 in the clinical trial experienced a Grade 5 SAE (respiratory failure and cardiac arrest resulting in death) deemed to be possibly related to MGTA-117 and that we voluntarily paused dosing in the clinical trial. Ultimately, we reported three safety events that were deemed to be Suspected, Unexpected, Serious Adverse Reactions, or SUSARs, to the FDA and the FDA placed the clinical trial on partial clinical hold in February 2023. In February of 2023, after a review of our business, programs, resources and capabilities, we announced the decision to halt further development of our programs and to conduct a comprehensive review of strategic alternatives. As a result of that decision, we discontinued the MGTA-117 Phase 1/2 clinical trial in patients with R/R AML and MDS. We discontinued the MGTA-145 Phase 2 stem cell mobilization clinical trial in patients with SCD. Lastly, we stopped incurring certain costs relating to MGTA-45, including manufacturing and costs relating to certain other activities that were intended to support an investigative new drug application, or IND, for MGTA-45.

If any other significant adverse events or side effects are observed in any of our future clinical trials, we may have difficulty recruiting patients to the clinical trial, patients may drop out of a 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 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 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, evidence of lower than expected efficacy, 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 were not directly or specifically caused or exacerbated by our product candidates. In the event we need to limit, delay or abandon the clinical development of any of our product candidates, our business will likely be materially adversely affected.

In addition, patients who are in 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. This may cause negative outcomes for those patients that could slow down the trial, prevent the trial from moving to the next phase or even suspend the trial. As a result, the FDA could put the trial on clinical hold until any potential FDA concerns are satisfied.

Should we resume development of our product candidates, if we are not able to identify a safe and effective dose for any of our product candidates, we may need to delay, abandon or limit our development of any potential product candidates.

Should we resume development of our product candidates, we may not be able to identify a safe and effective dose for our product candidates, and as a result we may need to delay, abandon or limit their development. Some of our product candidates may utilize ADCs, which utilize toxins to kill cells. 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. For example, 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, but three study participants in our Phase 1/2 clinical trial for MGTA-117 in patients with AML and MDS experienced safety events, two in Cohort 4 (dose level 0.13 mg/kg) and one in Cohort 3 (dose level 0.08 mg/kg), that were ultimately reported to the FDA as SUSARs. The patient in Cohort 3 who experienced a safety event experienced a Grade 5 SAE (respiratory failure and cardiac arrest resulting in death) deemed to be possibly related to MGTA-117, and we voluntarily paused dosing in the clinical trial in January 2023. The FDA placed the study on partial clinical hold in February 2023 and we subsequently discontinued the trial. Resuming development of MGTA-117 would require among other things that we address and resolve the FDA's partial clinical hold for MGTA-117.

The dose required for efficacy may differ for different populations, for example between adult and pediatric populations, between populations with diseases that involve bone marrow to different extents, or between uses of our product candidates as a monotherapy or as combination with other therapeutic agents. Additional trials to determine the safe and effective dose for different settings of use of any product candidates would be required.

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

Should we resume their development, our product candidates would be in the preclinical development and/or clinical trial stages, and their risk of failure is high. It is impossible to predict when or if any of our product candidates 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.

Additionally, some of our past clinical trials utilized, and any future clinical trial we conduct may 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.

Successful completion of clinical trials is a prerequisite to submitting a BLA 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. Our clinical trials may be delayed or may not be completed on schedule, if at all, and this may lead to delay in obtaining regulatory approval for our product candidates.

We may experience delays in completing preclinical studies and initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any clinical trials that we could conduct that may delay or prevent our ability to develop, receive marketing approval for 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 organizations, 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, and/or greater than we have budgeted for;
- 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 future 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 the 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 clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product 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. As noted above, the FDA placed our MGTA-117 Phase 1/2 clinical trial for MGTA-117 in patients with R/R AML and MDS on partial clinical hold in February 2023, and we subsequently discontinued the study.

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 a future 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 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 preclinical or future clinical development programs may harm our business, financial condition and prospects significantly.

As noted, we have ceased development of our product candidates. There is an additive degree of risk to any development program that is paused because the time to restart the program and the associated expense may be longer and more costly than previously anticipated. It may also not be possible to restart the program altogether.

Should we resume development of our product candidates, if we encounter delays or difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Should we resume development of our product candidates, we may experience delays or 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;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- adequate staffing at institutions running our clinical trials to efficiently conduct such trials.

In addition, our clinical trials may 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 may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which would 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 or advancement of these trials into the next phase and may adversely affect our ability to advance the development of our product candidates.

Should we resume development of our product candidates, interim, preliminary and "topline" data from clinical trials that we may 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.

Should we resume development of our product candidates, we may disclose interim data from preclinical studies and clinical trials, which are based on an interim analysis of then-available data from ongoing studies or trials. Interim data from 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 preclinical studies or clinical trials that are based on a preliminary analysis of final data. Preliminary data from 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 preclinical studies and clinical trials, which are a subset of the total data and are intended to provide the important results from the study or trial. Deeper analysis of the data beyond the topline data may provide more color and context to the results. If the additional color or context shows, in retrospect, that the topline data was incomplete or adverse, it 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 they 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 stockholders 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 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. Should we resume development of our product candidates, it is possible that the FDA may refuse to accept any or all future NDAs or BLAs for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval for any 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 our product candidates, 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.

Should we resume development of our product candidates, because we may develop them 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.

Should we resume development of our product candidates, during the regulatory review process, we would need to identify clinical trial designs, 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 our product candidates may seek 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 design or 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. The FDA, the EMA, or other regulatory authorities may lack the specific subject matter knowledge or guiding historical precedent to properly analyze the clinical data and results from our clinical trials, which may adversely affect our ability to obtain regulatory approval for our product candidates.

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, if at all.

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 any of our 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 may 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 may 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 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 product candidates using the FDA's accelerated approval pathway. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verity and describe the drug's clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of accelerated approval was granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the Agency, that all advertising and promotional materials intended for dissemination or publication be submitted to the Agency for review which can delay the commercialization of the product. There can be no assurance that the FDA would allow any of the product candidates we may develop to proceed on an 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 product candidates may not be eligible for Orphan drug status.

We may seek Orphan drug designation for MGTA-145 in other indications or our product candidates if the clinical data support such a designation. For example, the FDA granted orphan designation to MGTA-145 for the mobilization of HSCs to the peripheral blood for collection and subsequent transplant in May 2020. The U.S. and European Union may designate drugs for relatively small patient populations as orphan drugs. Orphan 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 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 (or EMA in the European Union) 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. (the applicable period in the European Union is 10 years). 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 its regulations and policies under the Orphan Drug Act. 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, 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, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume pre-pandemic inspection activities, including routine surveillance, bioresearch monitoring and pre-approval inspections. 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. In the course of the COVID-19 pandemic, a number of companies have 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 have been and may in the future be subject to many manufacturing risks, any of which could substantially increase our costs, delay clinical programs and limit supply of our product candidates.

We have historically contracted with third party manufacturers to make our product candidates to support preclinical and clinical trials. Our CDMOs may not be able to adopt, adapt or scale up the manufacturing process in a timely manner to support our future clinical trials. The process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including:

- the manufacturing processes are susceptible to product loss due to contamination by adventitious microorganisms, equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions. Even minor deviations from normal manufacturing processes could result in reduced production yields and quality as well as other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and eliminate the contamination;
- the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor and raw material shortages, financial difficulties of our CDMOs, natural disasters, power failures, local political unrest and numerous other factors;
- any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our product candidates. We may also have to record inventory write-offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts or seek more expensive manufacturing alternatives.

The manufacture of our product candidates requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of these biopharmaceutical products sometimes encounter difficulties in production, especially during scale-up from the manufacturing process used for preclinical and early clinical trials to a validated process needed for pivotal clinical studies and commercial launch. These problems include failure to meet target production costs and yields, sub-par quality control testing, including stability of the product, quality assurance system failures, operator error and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot assure you that any product quality issues relating to the manufacture of our product candidates will not occur in the future.

We do not have and we do not currently plan to acquire or build the facilities or internal capabilities to manufacture bulk drug substance or filled drug product for use in preclinical studies, clinical trials or commercialization. To a large extent, that makes us dependent on the goodwill of our contract manufacturing partners to quickly fix deviations that will inevitably occur during the manufacturing of our product. Any delay or interruption in the supply of clinical trial materials could delay the completion of preclinical studies or clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new pre-clinical studies or clinical trials at additional expense or terminate preclinical studies or clinical trials altogether.

We have no manufacturing facility. As a result, we have been dependent on third-party manufacturers, as well as on third parties for our supply chain. If we experience problems with any third parties, or the actual demand for our future product candidates, if any, exceed our forecasts, the manufacture of adequate supplies of our future product candidates or products could be delayed.

We do not own or operate facilities for the manufacture of our future product candidates, if any. We currently have no plans to build our own manufacturing facilities for clinical or commercial operations. We have in the past relied on third party manufacturers for the chemical manufacture of active pharmaceutical ingredient and for the production of final product formulation and packaging for clinical trials, and we expect to rely on such third party manufacturers for any future product candidate we develop. Although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers should we resume clinical development of our product candidates. We may encounter technical difficulties or delays in the transfer of manufacturing on a commercial scale to third party manufacturers. We may be unable to enter into agreements for commercial supply with third party manufacturers or may be unable to do so on acceptable terms. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or obtain regulatory approval to market them.

Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves. These risks include reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to manufacture our

product candidates or any products we may eventually commercialize in accordance with our specifications, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates and could cause us to incur higher costs and prevent us from commercializing our product candidates successfully. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of products, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties.

We have in the past relied on and, should we resume development of our product candidates, may continue to rely on third parties to conduct our preclinical and clinical trials and we may rely on them to perform other tasks for us as well. 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.

We have in the past relied on and, should we resume development of our product candidates, we may continue to rely upon medical institutions, clinical investigators, contract laboratories, our CROs and other third parties to conduct future preclinical studies and 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 we 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 any CROs we engage will be required to comply with regulations, including cGCPs and cGLPs 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 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 or cGLP, 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 clinical trials will comply with cGCPs or cGLPs. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements in the FDA's cGMP 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.

If we rely on CROs to conduct future clinical trials of our product candidates, 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.

Any significant disruption in our manufacturer or supplier relationships could harm our business. Any significant delay in the supply of a product candidate or its key materials for a clinical trial could considerably delay completion of clinical trials, product testing, potential regulatory approval of our product candidates and the commercial launch of our product candidates, if approved, which would impair our ability to generate revenues from the sale of our product candidates.

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. Further, we may determine not to commercialize a product candidate based on that analysis or based on unfavorable pricing and reimbursement terms. Any 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. Should we resume development of our product candidates, 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. Should we resume development of our product candidates, we would 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. 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.

Should we resume development of our product candidates, their success, if approved, depends on the availability of adequate coverage and reimbursement from third-party payors. 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 addition, we plan to develop certain of our product candidates to be used in conjunction with gene therapy treatments that have encountered challenges in obtaining coverage and reimbursement, and such challenges may also affect the coverage and reimbursement we may obtain for our product candidates, or may indirectly impact the commercial potential for our product candidates if the gene therapy treatment which with our product candidate would be used is not adequately covered or reimbursed. For additional information regarding laws and regulations related to reimbursement, see “Item 1. Business – Reimbursement.”

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.

The regulations that govern marketing approvals, pricing, and reimbursement for new medicines vary widely from country to country. For example, 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.

There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. 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. 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. 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.

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. 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.

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.

Should we resume development of our product candidates, we would 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.

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. 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 – Current and Future Legislation.”

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

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. We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a

similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Data collection is governed by complex and restrictive regulations governing the use, processing, and transfer of personal information, and compliance with these regulations could result in additional costs and limitations on our ability to collect and process data. Failure to comply with these regulations could subject us to significant penalties, which may adversely affect our business.

In the event we decide to conduct clinical trials or enroll subjects in 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 European Union's General Data Protection Regulation, or EU GDPR. Following the U.K.'s withdrawal from the European Union, or Brexit, the EU GDPR has been incorporated into U.K.'s laws, or U.K. GDPR and together with the EU GDPR, the GDPR. Despite Brexit, the EU and U.K. GDPR remain largely aligned. Currently, the most impactful point of divergence relates to transfer mechanisms (i.e., the ability for companies in the European Union or the U.K. to transfer personal data to third countries, including the United States), because it requires us to implement a variety of different contractual clauses approved by European Union's or U.K.'s regulators. This complexity and the additional contractual burden increases our overall risk exposure. There may be further divergence in the future, including with regard to administrative burdens. The U.K. has announced plans to reform the country's data protection legal framework in its Data Reform Bill, which will introduce significant changes from the EU GDPR. This and the subsequent separation of the data protection regimes of these territories mean we are required to comply with separate data protection laws in the European Union and the U.K., which may lead to additional compliance costs and could increase our overall risk exposure as we may no longer be able to take a unified approach across the European Union and the U.K., and we will need to amend our processes and procedures to align with the new framework. The data protection obligations of the GDPR continue to apply to U.K.-related processing of personal data in substantially unvaried form under the U.K. General Data Protection Regulation, or U.K. GDPR. However, going forward, there is an increasing risk of divergence in application, interpretation and enforcement of the data protection laws as between the U.K. and the European Union. Achieving and maintaining compliance with the EU 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 EU GDPR and U.K. 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 California Consumer Protection Act, or 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 Health Insurance Portability and Accountability Act, or 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.

The California Privacy Rights Act, or CRPA, which became effective on January 1, 2023, significantly modifies the CCPA and imposes additional obligations on companies covered by the legislation, including by expanding consumers' rights with respect to certain sensitive personal information, and establishing a state agency vested with the authority to enforce the CCPA.

In addition, 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. The CCPA, as amended by the CPRA, has prompted the enactment of similar, comprehensive privacy and data protection legislation in other states. For example, in March 2021, Virginia enacted the Consumer Data Protection Act, or CDPA, which became effective on January 1, 2023. In July 2021, Colorado passed the Colorado Privacy Act, or CPA, which will become effective on July 1, 2023. Additionally, in March 2022, Utah enacted the Utah Consumer Privacy Act, or UCPA, which will become effective on December 31, 2023. Also, in May 2022, Connecticut signed the Connecticut Data Privacy Act, or CTDPA, into law, which will become effective on July 1, 2023. Furthermore, a number of other U.S. states have proposed similar privacy and data protection legislation, and it is possible that certain of these proposals will pass. Although many of the existing state privacy laws exempt clinical trial information and health information governed by HIPAA, future privacy and data protection laws may be broader in scope. 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 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 or our third-party manufacturers 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. In the past, our operations have

involved the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also have produced hazardous waste products. We generally contracted 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 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 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. In addition, certain gene therapy companies are also developing their own conditioning programs to be used in connection with their therapies.

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. Such competitors may also 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 also include companies focused on developing technologies to improve the distinct steps of stem cell transplant.

Risks Related to Intellectual Property

We depend 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. Certain of our product candidates are dependent on the patents, know-how and proprietary technology licensed from Harvard. In addition, in March 2018, we entered into an exclusive 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. On August 1, 2022 we entered into an amendment to the exclusive research, development option and license agreement with Heidelberg Pharma mutually clarifying certain performance obligations. Any material 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 product candidates, should we resume development of our 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, material 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, increase what we believe to be our financial or other obligations under the relevant agreement, or decrease the financial or other benefits we might otherwise receive under the relevant agreement. On August 1, 2022 we entered into an amendment to the exclusive research, development option and license agreement with Heidelberg Pharma mutually clarifying certain performance obligations. If material 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 material 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.

Should we resume development of our product candidates, our commercial success depends on our ability to obtain, maintain and protect our intellectual property and proprietary technology.

Should we resume development of our product candidates, our commercial success would depend 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 and access to intellectual property owned or controlled by third parties in order to advance our research or allow commercialization of our product candidates. We may fail to obtain these licenses and/or access to such intellectual property 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 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.

In addition, a European Unified Patent Court, or UPC, is scheduled to come into force during 2023. The UPC will be a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products.

Moreover, the controlling laws and regulations of the UPC will develop over time and may adversely affect our ability to enforce or defend the validity of our European patents. We may decide to opt out our European patents and patent applications from the UPC. If certain formalities and requirements are not met, however, our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

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

Should we resume development of our product candidates, we may 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.

Should we resume development of our product candidates, we may depend on collaborations with third parties for the research, development, and commercialization of certain of the product candidates we may develop. For example, we had collaboration agreements with bluebird bio, Inc. for our 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. Each of these collaborations were terminated after our decision in February 2023 to halt further development of our programs.

In any collaboration agreements that 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 our product candidates and generate revenues from our collaborations will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements, as well as the success of the collaborators' underlying therapies. 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 following:

- 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.
- Material 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.
- Collaborators, including in the gene therapy space, may be unable to financially partner with us to develop our product candidates due to the current challenging conditions in the financial markets and their limited ability to raise capital.

- Collaborators may be unable to survive in the current challenging economic environment, and as a result they may be forced to terminate their business operations, including termination of the performance of their collaboration agreements with us.

If such 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.

Should we resume development of our product candidates, 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 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. 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 could adversely affect us financially and could harm our business reputation.

Should we resume development of our product candidates, if we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Should we resume development of our product candidates, 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.

Should we resume development of our product candidates, 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.

Should we resume development of our product candidates, 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 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 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 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 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 vaccines, and the direct and indirect economic effects of the pandemic and containment measures, among others. For example, 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 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. Should we resume development of our product candidates, the COVID-19 pandemic may have an adverse impact on various aspects of our clinical trials and preclinical studies. These risks include but are not limited to the following:

- Impacts on patient dosing and study monitoring, which may be paused or delayed due to changes in policies at various clinical sites, and interruption or delays in the operations of the FDA, among other reasons related to the COVID-19 pandemic. If the COVID-19 pandemic continues, other aspects of our future 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 clinical trials in order to preserve health resources and protect trial participants. It is unknown how long these pauses or disruptions could continue.
- We will rely on third parties, including CROs, CDMOs, and other contractors and consultants to, among other things, conduct 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 future product candidates for our clinical trials and conduct our research and development operations.
- We have established a hybrid 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 may not be able to access our laboratory for an extended period of time as a result of the COVID-19 pandemic 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.

Should we resume development of our product candidates, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2022, we had 67 full-time employees. If we resume development of our product candidates, as our development, manufacturing and commercialization plans and strategies develop, and as we continue to operate as a public company, we would expect to need 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 may 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. We may also overextend consultants in certain roles. 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.

Should we resume development of our product candidates, 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.

Should we resume development of our product candidates, if we lose key personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop our product candidates will be impaired and our business may be harmed.

Should we resume development of our product candidates, our ability to compete in the highly competitive biotechnology and pharmaceutical industries will depend upon our ability to attract and retain highly qualified managerial, scientific and medical personnel with particular subject matter expertise. We are highly dependent on our management team. The loss of the services of such key personnel, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business. Further, unless we are able to replace departed employees effectively, we may require current employees to fill additional roles, and this could overextend their responsibilities. As a result, we may experience increased turnover due to employees being overworked. Employees also may be unable to perform these multiple roles effectively due to time and resource constraints.

Additionally, if we are unable to retain key personnel, we may be required to cover the roles previously performed by such employees with consultants. These consultants may lack the same skills and performance of departed employees and, as a result, 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 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 may grant equity awards that vest over time or vest upon the achievement of certain pre-established milestones. The value to employees of equity awards has been, and may continue to be, significantly affected by movements in our stock price that are beyond our control, and these equity awards may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, they 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.

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 and information technology systems and infrastructure, or those of our collaborators, other contractors or consultants, may fail or suffer security compromises or breaches, which could result in a material disruption of our product development programs.

Our internal computer and information technology systems and infrastructure and those of our current and any future collaborators and other contractors or consultants are vulnerable to breakdown or damage or interruption or otherwise may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, system malfunction, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We could also be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems, infrastructure and networks of our company and our vendors, including personal information of our employees and study subjects, and company and vendor confidential or proprietary data, whether stored on our systems or on those of third parties. 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. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include wrongful conduct by insider employees, vendors or other third parties, hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud or cyber-attacks, including the deployment of harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, phishing attacks and social engineering and business email compromises, and other means to affect service reliability and threaten or compromise systems, infrastructure, or the security, confidentiality, integrity and availability of information. Because the techniques used by threat actors who may attempt to penetrate and sabotage our computer systems or those of our collaborators or other contractors or consultants change frequently and may not be recognized until launched against a target, we may be unable to anticipate these techniques. Accordingly, if our cybersecurity measures or those of our service providers fail, the market perception of the effectiveness of our security measures could be harmed and our reputation, credibility, customer trust, business, results of operations and financial condition could be damaged.

While we have not experienced any such material system failure, accident, cyber-attack or security compromise or 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 compromise or breach were to result in a loss of, damage to, unauthorized access or acquisition, or misuse of our data, systems, infrastructure or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability (including in connection with or resulting from litigation or governmental investigations and enforcement actions), our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed and our business could be otherwise adversely affected.

We could be required to expend significant amounts of money and other resources to repair or replace information systems, infrastructure or networks, and we may need to devote significant resources to defend against, respond to and recover from cybersecurity incidents, diverting resources from the growth and expansion of our business. In addition, we could be subject to regulatory actions, regulatory inquiry or investigation 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 compromise or 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 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 or may contract, such as 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, 2022, we had net operating loss carryforwards for federal income tax purposes of $272.9 million, of which $17.5 million begin to expire in 2035 and $255.4 million can be carried forward indefinitely. As of December 31, 2022, we had net operating loss carryforwards for state income tax purposes of $272.6 million, which begin to expire in 2035. As of December 31, 2022, we also had available research and orphan drug tax credit carryforwards for federal and state income tax purposes of $12.3 million and $3.4 million, respectively, which begin to expire in 2035 and 2030, respectively. Under current law, federal net operating losses generated in taxable years ending after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses may be limited to 80% of our taxable income annually for tax years beginning after December 31, 2020. Net operating losses generated prior to December 31, 2017, however, have a 20-year carryforward period, but are not subject to the 80% limitation.

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. There is also a risk that due to regulatory changes, such as suspensions on the use of net operating losses by federal or state taxing authorities or other unforeseen reasons, our existing net operating losses could expire or otherwise be unavailable to reduce future income tax liabilities. For these reasons, we may not be able to utilize a material portion of the net operating losses and research and orphan drug tax credit carryforwards reflected on our balance sheet, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our operating results and financial condition.

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, 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.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the requirement to maintain a minimum bid price of $1.00 per share of our common stock pursuant to Nasdaq Listing Rule 5450(a)(1), or the Minimum Bid Price Requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. Any such delisting could also adversely impact our ability to raise additional capital or enter into strategic transactions.

On January 31, 2023, we received a written notice from the staff, or the Staff, of Nasdaq's Listing Qualifications Department, notifying us that, for the 30 consecutive business day period between December 15, 2022 through January 30, 2023, our common stock had not complied with the Minimum Bid Price Requirement. Nasdaq's written notice does not result in the immediate delisting of our common stock from Nasdaq.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has 180 calendar days, or until July 31, 2023, or the Compliance Date, to regain compliance with the Minimum Bid Price Requirement. According to the written notice, if, at any time during this 180-day period, the closing bid price for our common stock is at least $1.00 per share for a minimum of ten consecutive business days, the Staff will provide written confirmation of compliance and the common stock will remain listed on The Nasdaq Global Market.

If we do not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would be required to transfer our listing to The Nasdaq Capital Market and meet the continued listing requirement for the market value of publicly held shares and all other applicable initial listing standards for The Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and would need to provide written notice to Nasdaq of our intention to cure the deficiency during the additional 180-day compliance period, such as by effecting a reverse stock split, if necessary.

As part of its review process, the Staff will make a determination of whether it believes we will be able to cure this deficiency. If the Staff determines that we will not be able to cure the deficiency, then the Staff will provide us written notice that our common stock will be subject to delisting. At that time, we may appeal the Staff's delisting determination to a Nasdaq Hearing Panel. There can no

assurance that, if we receive a delisting notice and appeal the delisting determination by the Staff to the Nasdaq Hearing Panel, such appeal would be successful.

We intend to monitor the closing bid price of our common stock and may, if appropriate, consider available options to regain compliance with the Minimum Bid Price Requirement. However, we can provide no assurance that actions taken or not taken by us will restore compliance with Nasdaq's listing requirements, stabilize the market price of our common stock, improve the liquidity of our common stock or prevent future non-compliance with Nasdaq's listing requirements.

Additionally, if our common stock is not listed on, or becomes delisted from, Nasdaq for any reason, trading our common stock could be conducted only in the over-the-counter, or OTC, market or on an electronic bulletin board established for unlisted securities such as the OTC Bulletin Board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, and the liquidity and price of our common stock may be more limited than if we were quoted or listed on Nasdaq or another national securities exchange. In such circumstances, you may be unable to sell your common stock unless a market can be established or sustained.

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, has 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, and has been, influenced by many factors, including but not limited to:

- the status of our review of strategic alternatives, including an acquisition, merger, business combination or other transaction;
- whether we are able to pursue or consummate a strategic transaction, or whether we pursue a dissolution and liquidation;
- 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 our product candidates;
- commencement or termination of collaborations for any of our 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 material 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 $1.235 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 43% of our capital stock as of December 31, 2022. 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 by-laws 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 by-laws.

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 by-laws 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.

Our by-laws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) 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, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our charter or our by-laws, or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, 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 and the Exchange Act. Our by-laws further provide that, unless we consent in writing to an alternative forum, federal district courts of the United States 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." In addition, our by-laws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

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. Additionally, the forum selection clauses in our by-laws 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.

General Risk Factors

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations, financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California

Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership.

We currently have a deposit account and a collateral account supporting a letter of credit with SVB related to our sublease with Novartis Institutes for Biomedical Research, Inc., or Novartis, and we are currently evaluating our banking relationships. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder.

In addition, if any of the parties with whom we conduct business are unable to access funds pursuant to credit agreements or certain other financial instruments or lending arrangements, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have such arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delayed or lost access to, or reductions in borrowings available under revolving existing credit facilities or other working capital sources and/or delays, inability or reductions in the ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements;
- Potential or actual breach of financial covenants in credit agreements or credit arrangements;
- Potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the

factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by companies with whom we do business, which in turn could have a material adverse effect on our current and/or projected business operations, results of operations and financial condition. For example, a company may fail to make payments when due, default under its agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a company could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. The bankruptcy or insolvency of any company with whom we do business, any breach or defeault by a company with whom we do business or the loss of any significant supplier relationship could have a material adverse impact on our business.

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. Insufficient 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” up until December 31, 2023. 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 recently, 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. We may also fail to secure additional financing altogether. 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, collaboration partners and other business partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks.

At December 31, 2022, we had $112.0 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, 2022, 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. Our financial condition and results of operations may also be impacted by other factors we may not be able to control, such as global supply chain disruptions, global trade disputes or political instability. 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 such as ours that 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. Litigation and other disputes may divert management's attention and resources away from running our business and could otherwise negatively affect our reputation. Any of the foregoing items 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 litigation often brought against companies following a decline in the market price of their securities, we will be exposed to significant liabilities that may materially and adversely affect our business and financial position.

Actions of activist stockholders could cause us to incur substantial costs, divert management's attention and resources, and have an adverse effect on our business.

Stockholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. From time to time, we may be subject to proxy solicitations or proposals by activist stockholders urging us to take certain corporate actions, or otherwise effect changes or assert influence on our board of directors and management. For example, volatility in the price of our common stock or other reasons may in the future cause us to become the target of stockholder activism. If activist stockholder activities ensue, our business could be adversely affected because responding to proxy contests and reacting to other actions by activist stockholders can be costly and time-consuming, disrupt our operations and divert the attention of management and our employees. For example, we may be required to retain the services of various professionals to advise us on activist stockholder matters, including legal, financial and communications advisors, the costs of which may negatively impact our future financial results. In addition, perceived uncertainties as to our future direction, strategy or leadership created as a consequence of activist stockholder initiatives may result in the loss of potential business opportunities, harm our ability to enter into strategic transactions, harm our ability to attract new investors, customers, employees and joint venture partners and cause our stock price to experience periods of volatility or stagnation.

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, 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 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. 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. For additional information, see “Item 1. Business – Governmental Regulation – Other Regulatory Matters.”

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, and this scrutiny 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 comply 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. While we remain an emerging growth company, however, 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. If no or few securities or industry analysts cover our business, or one or more of the analysts who cover us issues an adverse opinion about our company, our stock price may 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. Additionally, if analyst estimates for the commercial value of our product candidates differ materially from the ultimate commercial value of such candidates, the price of our common stock may decline and our ability to raise capital may be impaired.

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 a third party. The sublease expires in the second quarter of 2024. 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, 2023, there were 3 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 biotechnology company focused on improving stem cell transplantation.

In February 2023, after a review of Magenta's programs, resources and capabilities, including anticipated costs and timelines, we announced the decision to halt further development of our programs. Specifically, we discontinued the MGTA-117 Phase 1/2 clinical trial in patients with relapsed/refractory acute myeloid leukemia, or R/R AML, and myelodysplastic syndromes, or MDS. We discontinued the MGTA-145 Phase 2 stem cell mobilization clinical trial in patients with sickle cell disease, or SCD. Lastly, we stopped incurring certain costs relating to MGTA-45, including manufacturing and costs relating to certain other activities that were intended to support an investigative new drug application, or IND, for MGTA-45 (previously named CD45-ADC). As a result of these decisions, we conducted a corporate restructuring that resulted in a reduction in our workforce by 84%.

Coinciding with the decisions related to the programs and across the portfolio, we announced that we intended to conduct a comprehensive review of strategic alternatives for the company and its assets. As part of our strategic review process, we are exploring potential strategic alternatives that include, without limitation, an acquisition, merger, business combination or other transaction. We are also exploring strategic transactions regarding our product candidates and related assets, including, without limitation, licensing transactions and asset sales. There can be no assurance that the strategic review process or any transaction relating to a specific asset, will result in Magenta pursuing such a transaction(s), or that any transaction(s), if pursued, will be completed on terms favorable to Magenta and its stockholders in the existing Magenta entity or any possible entity that results from a combination of entities. If the strategic review process is unsuccessful, our board of directors may decide to pursue a dissolution and liquidation of Magenta.

Our product candidates have been designed to improve the patient experience when preparing for stem cell transplant or gene therapy. Our MGTA-117 product candidate was designed as an antibody drug conjugate, or ADC, designed to deplete CD117-expressing stem cells in the bone marrow in order to make room for subsequently transplanted stem cells or ex vivo gene therapy products. The process of making room in the bone marrow is known as conditioning, and the current standard of care for conditioning utilizes chemotoxic agents. Our second targeted conditioning product candidate, MGTA-45, is an ADC designed to selectively target and deplete both stem cells and immune cells, and it is intended to replace the use of chemotherapy-based conditioning prior to stem cell transplant in patients with blood cancers and autoimmune diseases. Lastly, our MGTA-145 product candidate, in combination with plerixafor, is designed to improve the stem cell mobilization process by which stem cells are mobilized out of the bone marrow and into the bloodstream to facilitate their collection for subsequent transplant back into the body for the purpose of resetting the immune system.

In January 2023, we voluntarily paused dosing in our MGTA-117 Phase 1/2 clinical trial for MGTA-117 in patients with R/R AML and MDS after the last participant dosed in Cohort 3 in the clinical trial experienced a Grade 5 serious adverse event, or SAE (respiratory failure and cardiac arrest resulting in death) deemed to be possibly related to MGTA-117. This safety event was reported to the FDA as the study's third safety event which is of a type referred to as a "Suspected, Unexpected, Serious Adverse Reaction," or SUSAR. The FDA subsequently placed the study on partial clinical hold in February 2023.

In April 2022, we announced a plan to more narrowly focus our capital allocation on the MGTA-117 targeted conditioning program, the MGTA-45 IND-enabling activities and the MGTA-145 stem cell mobilization efforts in sickle cell disease while also de-prioritizing other portfolio investments. We made certain reductions in our planned spending related to research platform-related investments in new disease targets, paused certain MGTA-145 investments, including the program's planned MGTA-145 dosing and administration optimization clinical trial in healthy subjects and reduced planned general and administrative expenses. In connection with these reductions to our planned spending, we also reduced our workforce by 14%.

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, MGTA-45 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. Net losses were $76.5 million and $71.1 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $402.0 million.

We expect to continue to incur costs and expenditures in connection with the process of evaluating our strategic alternatives. There can be no assurance, however, that we will be able to successfully consummate any particular strategic transaction. The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal, accounting and advisory fees and expenses and other related charges. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business. In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available for use in our business or the execution of our strategic plan. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

Should we resume development of our product candidates, 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. In addition, we will incur substantial research and developments costs and other expenditures to develop such product candidates particularly as we:

- enroll and conduct clinical trials for our product candidates;
- 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.

If we resume development of our product candidates, 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.

Should we resume development of our product candidates, we will need substantial additional funding to support our continuing operations. 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. Additionally, 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. Accordingly, if we fail to raise capital or enter into necessary strategic agreements, or fail to ever become profitable, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates, and we may also be forced to reduce or terminate our operations.

As of December 31, 2022, we had cash, cash equivalents and marketable securities of $112.0 million. Based on our current 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 for the next twelve months from the issuance date of this Annual Report on Form 10-K. See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

Impact of the COVID-19 Pandemic

The COVID-19 pandemic, including the emergence of various variants, has caused and could continue to cause 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 hybrid 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.

The future impact of the COVID-19 pandemic on our industry, the healthcare system and our current and future operations and financial condition will depend on future developments, which are uncertain and cannot be predicted with confidence. These developments may include, without limitation, changes in the scope, severity and duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact, including the adoption, administration and effectiveness of available vaccines, the effect of any relaxation of current restrictions within the Cambridge community or regions in which our partners are located and the direct and indirect economic effects of the pandemic and containment measures. 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.

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

- 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;
- maintaining a continued acceptable safety profile of the products following approval; and
- the continuing impact of the COVID-19 pandemic on our industry, the healthcare system, and our current and future operations.

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 have historically been 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 our research and development expenses to decrease in the near future as we halted the development of our product candidates while we explore strategic alternatives. Should we resume development of our product candidates, we expect research and development costs to increase significantly for the foreseeable future as our product candidate development programs progress.

Inflation generally affected us by increasing our cost of labor and clinical trial costs. While we do not believe that inflation had a material effect on our financial condition and results of operations during the periods presented, it may result in increased costs in the foreseeable future.

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, pre-commercialization, accounting and audit services. We expect our general and administrative expenses to decrease in the near future due to recent workforce reductions. We do expect to incur significant costs, however, related to our exploration of strategic alternatives, including legal, accounting and advisory expenses and other related charges.

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, 2022, we had net operating loss carryforwards for federal income tax purposes of $272.9 million, of which $17.5 million begin to expire in 2035 and $255.4 million can be carried forward indefinitely. As of December 31, 2022, we had net operating loss carryforwards for state income tax purposes of $272.6 million which begin to expire in 2035. As of December 31, 2022,

we also had available research and orphan drug tax credit carryforwards for federal and state income tax purposes of $12.9 million and $3.4 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 compensation expense for 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 such compensation expense 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, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

	Year Ended December 31,		
	2022	2021	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 55,141	$ 46,766	$ 8,375
General and administrative	25,761	27,926	(2,165)
Total operating expenses	80,902	74,692	6,210
Loss from operations	(80,902)	(74,692)	(6,210)
Interest and other income, net	4,440	3,556	884
Net loss	$ (76,462)	$ (71,136)	$ (5,326)

Research and Development Expenses

	Year Ended December 31,		
	2022	2021	Change
	(in thousands)		
Direct research and development expenses by program:			
Conditioning	$ 22,951	$ 9,677	$ 13,274
Mobilization	2,819	5,203	(2,384)
Cell therapy	18	684	(666)
Unallocated expenses:			
Personnel-related (including stock-based compensation)	18,878	18,418	460
Consultant (including stock-based compensation)	667	1,488	(821)
Facility related and other	9,808	11,296	(1,488)
Total research and development expenses	$ 55,141	$ 46,766	$ 8,375

Expenses related to our conditioning program increased primarily due to an increase of $10.1 million in costs related to MGTA-45 and an increase of $3.6 million in costs related to MGTA-117. The increase in costs related to MGTA-45 was primarily due to higher preclinical and manufacturing costs to support our investigational new drug, or IND, enabling studies and costs incurred in connection with a license agreement entered into in November 2022. The increase in costs related to MGTA-117 was primarily due to costs incurred upon the achievement of a development milestone under our collaboration agreement and increased costs to support our Phase 1/2 clinical trial which was initiated in December 2021. The decrease in expenses in our mobilization program was primarily due to a decrease in clinical trial costs related to our Phase 2 investigator-initiated clinical trial in multiple myeloma patients, which was completed in the fourth quarter of 2021, and our Phase 2 allogeneic donor clinical trial, which was closed in early 2022. The decrease in expenses in our mobilization program was also due to lower process development activities to support future manufacturing. Expenses related to our cell therapy program decreased as result of the discontinuance of our MGTA-456 program.

The increase in personnel-related costs was due primarily to an increase in severance resulting from our headcount reductions, partially offset by a decrease in stock-based compensation. Personnel-related costs for the years ended December 31, 2022 and 2021 included stock-based compensation expense of $1.8 million and $3.7 million, respectively. The decrease in consultant costs was due to a decrease in certain research activities as a result of our reprioritization efforts in April 2022. The decrease in facility related and other costs was primarily due to lower operating costs related to our Cambridge, Massachusetts facility.

General and Administrative Expenses

	Year Ended December 31,		
	2022	2021	Change
	(in thousands)		
Personnel-related (including stock-based compensation)	$ 13,165	$ 13,902	$ (737)
Professional and consultant	5,308	6,555	(1,247)
Facility related and other	7,288	7,469	(181)
Total general and administrative expenses	$ 25,761	$ 27,926	$ (2,165)

The decrease in personnel-related costs was due primarily to a decrease in stock-based compensation, partially offset by an increase in headcount. Personnel-related costs for the years ended December 31, 2022 and 2021 included stock-based compensation expense of $5.1 million and $6.5 million, respectively. The decrease in professional and consultant costs was primarily due to lower legal, patent and investor relations costs.

Interest and Other Income, Net

Interest income and other income, net for the year ended December 31, 2022 consisted primarily of sublease income of $3.1 million and interest income of $1.4 million. 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 of $0.1 million. The decrease in sublease income was due to the expiration of one of our two subleases in December 2021. The increase in interest income was due to higher interest rates on our invested cash.

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. Since our initial public offering in June 2018, we have funded our operations primarily with proceeds from the sale of our common stock in both private and public offerings.

We have a shelf registration statement on Form S-3, or the Shelf on file with the SEC, which covers the offering, issuance and sale of up to an aggregate of $250.0 million of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. We also entered into a sales agreement, as amended, with Cowen and Company, LLC, as sales agent to provide for the issuance and sale by us of up to $50.0 million of common stock from time to time in "at-the-market" offerings under the Shelf, or the ATM Program. The Shelf was declared effective by the SEC on August 12, 2022. During the year ended December 31, 2022, we sold 1,644,200 shares of our common stock under the ATM Program at a weighted average price per share of $1.82 resulting in net proceeds of $2.8 million after commissions and offering costs. As of December 31, 2022, $247.0 million remained available under the Shelf, including up to $47.0 million available for sale under 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,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (67,090)	$ (59,531)
Net cash provided by (used in) investing activities	(9,812)	43,428
Net cash provided by financing activities	2,878	89,601
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (74,024)	$ 73,498

Operating Activities

During the year ended December 31, 2022, operating activities used $67.1 million of cash, primarily resulting from our net loss of $76.5 million and net cash used by changes in our operating assets and liabilities of $2.7 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, 2022 consisted primarily of a decrease of $3.1 million in operating lease liabilities, partially offset by a decrease of $0.2 million in prepaid expenses and other current assets and an increase of $0.2 million in accounts payable and accrued expenses and other current liabilities.

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.

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, 2022, net cash used by investing activities was $9.8 million, primarily attributable to net purchases of marketable securities of $9.5 million.

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.

Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was $2.9 million, consisting primarily of net proceeds from the issuance of common stock under our ATM Program.

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.

Funding Requirements

We currently expect our expenses to decrease in 2023 compared to 2022 due to our decision to halt further development of our product candidates and conduct workforce reductions while we explore strategic alternatives. If we decide to resume the development of our product candidates, however, we expect our expenses to increase in order to advance preclinical activities and clinical trials for our product candidates in development. As of December 31, 2022, we had cash, cash equivalents and marketable securities of $112.0 million. Based on our current 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 for the next twelve months from the issuance date of this Annual Report on Form 10-K. 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. In addition, our resource requirements could materially change depending on the outcome of our ongoing strategic alternative review process, including to the extent we identify and enter into any potential strategic transaction. Because our resource requirements could materially change depending on the outcome of our ongoing strategic alternative review process, 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 and subject to our pursuit of a potential strategic transaction and the consummation of such potential transaction, we expect to finance our future 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 resume the development of our product candidates and 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.

Nasdaq Delisting Notice

As previously disclosed, on January 31, 2023, we received a written notice from the staff of Nasdaq's Listing Qualifications Department, notifying us that, for the 30 consecutive business day period between December 15, 2022 through January 30, 2023, the bid price for our common stock had closed below the $1.00 per share minimum bid price requirement for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5450(a)(1), or the Minimum Bid Price Requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has 180 calendar days, or until July 31, 2023 to regain compliance with the Minimum Bid Price Requirement. If we fail to satisfy the continued listing requirements of Nasdaq, such as the Minimum Bid Price Requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and may, among other things, adversely impact our ability to raise additional capital or enter into strategic transactions. See "Item 1A. Risk Factors" for additional information.

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 $39.9 million through February 2028, of which $6.9 million are due in 2023.

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.

In November 2022, we entered into a license agreement with ImmunoGen, Inc. for an exclusive, worldwide, royalty-bearing license for certain technology related to one of our conditioning programs. Upon execution of the agreement, we made a nonrefundable payment of $4.4 million in partial consideration for the license. We are also obligated to pay milestone payments of up to $125 million in the aggregate upon the achievement of certain development, regulatory and sales-based milestones and to pay single-digit royalties on a product-by-product and country-by-country basis on net sales of products licensed under the agreement. To date, we have not incurred any expense related to the achievement of these milestones.

As of December 31, 2022, we were unable to estimate the timing or likelihood of achieving the remaining milestones or generating future product sales.

Restructuring Costs

In February 2023, we announced a corporate restructuring that resulted in a reduction in workforce by 84% that was substantially completed in February 2023, resulting in severance and related costs of approximately $5.4 million, a significant portion of which will be paid in the first quarter of 2023.

Advisory Fee

In February 2023, we entered into an agreement with Wedbush Securities Inc, or Wedbush, to act as our exclusive strategic financial advisor in connection with a potential strategic transaction including but not limited to an acquisition, merger, business combination or other transaction. Upon the consummation of such transaction, we agreed to pay Wedbush a success fee of 1.0% of the transaction value with a minimum fee of $1.5 million.

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.

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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, 2022 and 2021, 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, 2022 and 2021, 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 23, 2023

MAGENTA THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 57,626	$ 131,650
Marketable securities	54,415	45,276
Prepaid expenses and other current assets	3,561	3,767
Total current assets	115,602	180,693
Restricted cash	1,780	1,780
Operating lease, right-of-use asset	23,168	—
Property and equipment, net	6,095	7,461
Total assets	$ 146,645	$ 189,934
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,454	$ 3,040
Accrued expenses and other current liabilities	8,271	7,823
Operating lease liability, current portion	3,824	—
Total current liabilities	14,549	10,863
Operating lease liability, net of current portion	26,138	—
Deferred rent	—	6,399
Total liabilities	40,687	17,262
Commitments and contingencies (Note 9)		
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; 60,639,909 and 58,799,157 shares issued and outstanding as of December 31, 2022 and 2021, respectively	61	59
Additional paid-in capital	508,107	498,210
Accumulated other comprehensive loss	(181)	(30)
Accumulated deficit	(402,029)	(325,567)
Total stockholders' equity	105,958	172,672
Total liabilities and stockholders' equity	$ 146,645	$ 189,934

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,	
	2022	2021
Operating expenses:		
Research and development	$ 55,141	$ 46,766
General and administrative	25,761	27,926
Total operating expenses	80,902	74,692
Loss from operations	(80,902)	(74,692)
Interest and other income, net	4,440	3,556
Net loss	$ (76,462)	$ (71,136)
Net loss per share, basic and diluted	$ (1.29)	$ (1.29)
Weighted average common shares outstanding, basic and diluted	59,372,357	54,948,808
Comprehensive loss:		
Net loss	$ (76,462)	$ (71,136)
Other comprehensive loss:		
Unrealized losses on marketable securities	(151)	(7)
Total other comprehensive loss	(151)	(7)
Total comprehensive loss	$ (76,613)	$ (71,143)

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 Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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
Issuance of common stock under the ATM Program, net of commissions and offering costs	1,644,200	2	2,761	—	—	2,763
Vesting of restricted stock	76,539	—	—	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	120,013	—	115	—	—	115
Stock-based compensation expense	—	—	7,021	—	—	7,021
Unrealized losses on marketable securities	—	—	—	(151)	—	(151)
Net loss	—	—	—	—	(76,462)	(76,462)
Balances at December 31, 2022	60,639,909	$ 61	$ 508,107	$ (181)	$ (402,029)	$ 105,958

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,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (76,462)	$ (71,136)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	7,021	10,308
Depreciation and amortization expense	1,925	2,020
Loss on disposal of property and equipment	—	95
Noncash lease expense	2,920	—
Net amortization of premiums on marketable securities	208	708
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	206	(1,075)
Accounts payable	(801)	(720)
Accrued expenses and other current liabilities	973	153
Operating lease liabilities	(3,080)	—
Deferred rent	—	116
Net cash used in operating activities	(67,090)	(59,531)
Cash flows from investing activities:		
Purchases of property and equipment	(314)	(1,264)
Purchases of marketable securities	(69,498)	(45,308)
Maturities of marketable securities	60,000	90,000
Net cash provided by (used in) investing activities	(9,812)	43,428
Cash flows from financing activities:		
Proceeds from private investment	—	86,400
Proceeds from issuance of common stock under the ATM Program, net of commissions	2,904	—
Payments of offering costs	(141)	(303)
Proceeds from exercise of common stock options	—	3,363
Proceeds from issuance of common stock under Employee Stock Purchase Plan	115	141
Net cash provided by financing activities	2,878	89,601
Net increase (decrease) in cash, cash equivalents and restricted cash	(74,024)	73,498
Cash, cash equivalents and restricted cash at beginning of period	133,430	59,932
Cash, cash equivalents and restricted cash at end of period	$ 59,406	$ 133,430
Supplemental disclosure of non-cash investing and financing activities:		
Purchase of property and equipment included in accounts payable and accrued expenses	$ 245	$ —

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 biotechnology company focused on improving stem cell transplantation. 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 an initial public offering of its common stock.

On February 2, 2023, after a review of the Company's business, programs, resources and capabilities, including anticipated costs and timelines, the Company announced the decision to halt further development of its programs and to conduct a comprehensive review of strategic alternatives. The Company also announced a corporate restructuring on February 7, 2023 that resulted in a reduction in its workforce by 84% that was substantially completed in February 2023 resulting in severance and related costs of approximately $5.4 million (see Note 13).

As part of the strategic review process, the Company is exploring potential strategic alternatives that include, without limitation, an acquisition, merger, business combination or other transactions. The Company is also exploring strategic alternatives related to its product candidates and related assets, including, without limitation, licensing transactions and asset sales. There can be no assurance that the strategic review process will result in the Company pursuing a transaction, or that any transaction, if pursued, will be completed on terms favorable to the Company and its stockholders. If the strategic review process is unsuccessful, the Company may decide to pursue a dissolution and liquidation of the Company.

In addition, 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 ongoing coronavirus ("COVID-19") pandemic and the ability to secure additional capital to fund operations. Product candidates 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 $76.5 million and $71.1 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, the Company had an accumulated deficit of $402.0 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 the results of the strategic review process and its ability to raise additional capital to fund its operations.

The Company expects to continue to incur costs and expenditures in connection with the process of evaluating strategic alternatives. There can be no assurance, however, that the Company will be able to successfully consummate any particular strategic transaction. The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and the Company has incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal, accounting and advisory fees and expenses and other related charges. Should the Company resume the development of its programs, it will need to obtain substantial additional funding in connection with continuing operations, particularly as the Company advances its preclinical activities and clinical trials for its product candidates in development. 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. 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 include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated. The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). 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 (see Note 13).

The Company has been dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company has historically relied 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 and right-of-use assets. 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, 2022 or 2021.

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.

Leases

Prior to January 1, 2022, the Company accounted for leases under ASC 840, *Leases* ("ASC 840"). Effective January 1, 2022, the Company accounts for leases under ASC 842, *Leases* ("ASC 842"). Therefore, as of December 31, 2021, the Company's consolidated financial statements continue to be presented in accordance with ASC 840, the accounting standard originally in effect for such period. As of and for the year ended December 31, 2022, the Company's consolidated financial statements are presented in accordance with ASC 842.

In accordance with ASC 842, the Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset's economic benefits. The Company determines if an arrangement is a lease or contains an embedded lease at inception. For arrangements that meet the definition of a lease, the Company determines the initial classification and measurement of its right-of-use asset and lease liability at the lease commencement date and thereafter if modified. The lease term includes any renewal options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term. The Company's policy is to not record leases with an original term of twelve months or less on its consolidated balance sheets and recognizes those lease payments in the income statement on a straight-line basis over the lease term. The Company's existing leases are for office and laboratory space.

In addition to rent, the leases may require the Company to pay additional costs, such as utilities, maintenance and other operating costs, which are generally referred to as non-lease components. The Company has elected to not separate lease and non-lease components. Only the fixed costs for lease components and their associated non-lease components are accounted for as a single lease component and recognized as part of a right-of-use asset and lease liability. Rent expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expense in the consolidated statements of operations and comprehensive loss.

Deferred Rent

The Company's lease agreements include payment escalations and lease incentives, which, prior to the adoption of ASC 842 on January 1, 2022, were accrued or deferred as appropriate such that rent expense for each lease was recognized on a straight-line basis over the respective lease term. Adjustments for such items, consisting primarily of tenant improvement allowances and payment escalations, were 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 compensation expense for all stock options and other stock-based awards granted to employees, directors and non-employees based on the fair value on the date of grant and recognizes such compensation expense 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 consolidated 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, 2022 and 2021, 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, 2022 and 2021. 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,	
	2022	2021
Stock options to purchase common stock	8,475,816	6,248,675
Unvested restricted common stock units	427,244	479,918
Shares of common stock issuable under Employee Stock Purchase Plan	72,611	42,634
	8,975,671	6,771,227

Recently Issued Accounting Pronouncements

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 and emerging growth companies 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.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which require lessees to recognize most leases on their balance sheet as a right-of-use asset and a lease liability. In general, lease arrangements exceeding a twelve-month term must be recognized as assets and liabilities on the balance sheet. Under ASU 2016-02, a right-of-use asset and lease obligation is recorded for all leases, whether operating or financing, while the income statement reflects lease expense for operating leases and amortization and interest expense for financing leases. The FASB also issued ASU 2018-10, *Codification Improvements to Topic 842 Leases*, and ASU 2018-11, *Targeted Improvements to Topic 842 Leases*, which allows the new lease standard to be applied as of the adoption date with a cumulative-effect adjustment to the opening balance of retained earnings rather than retroactive restatement of all periods presented. The Company adopted the new leasing standards on January 1, 2022 using a modified retrospective approach applied at the beginning of the period of adoption.

The Company elected the "package of practical expedients," which permits the Company not to reassess under the new standards for prior conclusions about lease identification, lease classification and initial direct costs. The Company did not apply the hindsight practical expedient when determining the lease term for existing leases and assessing impairment of expired or existing leases. The Company elected to utilize its incremental borrowing rate based on the remaining lease term as of the date of adoption. In connection with the adoption of ASU 2016-02, the Company recognized a right-of-use asset of $26.1 million and lease liabilities of $33.0 million on its consolidated balance sheet. The deferred rent balance of $7.0 million as of January 1, 2022 was recorded as an offset to the Company's right-of-use asset. The adoption of the standard did not have a material impact on the Company's results of operations or cash flows.

3. Marketable Securities and Fair Value Measurements

As of December 31, 2022, 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)	$ 54,596	$ 2	$ (183)	$ 54,415
Total	$ 54,596	$ 2	$ (183)	$ 54,415

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

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, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 56,663	$ —	$ —	$ 56,663
Marketable securities:				
U.S. treasury notes	—	54,415	—	54,415
Total	$ 56,663	$ 54,415	$ —	$ 111,078

	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

4. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2022	2021
Laboratory and computer equipment	$ 6,954	$ 6,397
Furniture and fixtures	826	826
Leasehold improvements	6,905	6,905
	14,685	14,128
Less: Accumulated depreciation and amortization	(8,590)	(6,667)
	$ 6,095	$ 7,461

Depreciation and amortization expense was $1.9 million and $2.0 million for the years ended December 31, 2022 and 2021, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued payroll and related expenses	$ 4,162	$ 3,346
Accrued external research and development expenses	3,091	2,813
Deferred rent, current portion	—	555
Accrued other	1,018	1,109
	$ 8,271	$ 7,823

6. Common Stock

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 $250.0 million of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. The Company also entered into a sales agreement, as amended, with Cowen and Company, LLC, as sales agent to provide for the issuance and sale by the Company of up to $50.0 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 12, 2022. During the year ended December 31, 2022, the Company sold 1,644,200 shares of its common stock under the ATM Program at a weighted average price per share of $1.82 resulting in net proceeds of $2.8 million after commissions and offering costs. As of December 31, 2022, $247.0 million remained available under the Shelf, including up to $47.0 million available for sale under the ATM Program.

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 SEC in June 2021 to register the resale of these shares by the purchasers in the private placement.

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, 2022, 3,102,231 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 2,425,596 shares effective January 1, 2023.

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 eighteen months to 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, 2022, 120,013 shares of common stock were purchased under the ESPP at a purchase price per share of $0.96. 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. The Company recognized $0.1 million and less than $0.1 million of stock-based compensation during the years ended December 31, 2022 and 2021, respectively, related to the ESPP. As of December 31, 2022, 593,239 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 did not increase on January 1, 2023.

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,	
	2022	2021
Risk-free interest rate	2.5%	0.9%
Expected term (in years)	5.9	6.0
Expected volatility	81.2%	80.5%
Expected dividend yield	0%	0%

Common Stock Option Activity

The following table summarizes the Company's option activity since December 31, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
			(in years)	(in thousands)
Outstanding as of December 31, 2021	6,248,675	$ 9.15	8.2	$ —
Granted	4,509,673	$ 2.13		
Exercised	—	$ —		
Forfeited	(2,282,532)	$ 7.31		
Outstanding as of December 31, 2022	8,475,816	$ 5.91	8.2	$ —
Options vested and expected to vest as of December 31, 2022	8,475,816	$ 5.91	8.2	$ —
Options exercisable as of December 31, 2022	3,641,107	$ 8.27	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. There were no option exercises during the year ended December 31, 2022. The aggregate intrinsic value of options exercised during the year ended December 31, 2021 was $1.3 million.

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2022 and 2021 was $1.48 and $6.32, respectively.

Restricted Stock Units

The Company granted service-based restricted stock units to certain employees which vests over eighteen months to four 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, 2021:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2021	289,918	$ 7.79
Granted	185,871	$ 1.90
Vested	(76,539)	$ 6.46
Forfeited	(142,006)	$ 6.97
Outstanding as of December 31, 2022	257,244	$ 4.38

The total fair value of restricted stock units vested during the years ended December 31, 2022 and 2021 was $0.1 million and $0.3 million, respectively.

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, 2021:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2021	190,000	$ 9.91
Granted	—	$ —
Vested	—	$ —
Forfeited	(20,000)	$ 7.51
Outstanding as of December 31, 2022	170,000	$ 10.19

There was no performance restricted stock units vested during the year ended December 31, 2022. 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,	
	2022	2021
Research and development expenses	$ 1,877	$ 3,836
General and administrative expenses	5,144	6,472
	$ 7,021	$ 10,308

As of December 31, 2022, unrecognized compensation expense related to unvested share-based awards with service-based vesting conditions was $13.6 million, which is expected to be recognized over a weighted average period of 2.2 years. Additionally, the Company had unrecognized compensation cost of $1.7 million related to the unvested performance restricted stock units for which the performance conditions were not considered probable of achievement as of December 31, 2022.

8. Leases

The Company has 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 classified this sublease as an operating lease under ASC 842. 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. To the extent these costs are variable, they were not included in the measurement of the right-of-use asset and lease liability. 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, 2022 and 2021.

As of December 31, 2021, the Company had long-term deferred rent of $6.4 million related to lease incentives and payment escalations. As of December 31, 2021, the short-term portion of deferred rent of $0.6 million was included in accrued expenses and other current liabilities. In connection with the adoption of ASC 842 on January 1, 2022, these amounts were recorded as a reduction to the operating lease, right-of-use asset.

The components of the Company's lease expense under ASC 842 were as follows (in thousands):

	Year Ended December 31, 2022
Operating lease cost	$ 6,407
Short-term lease cost	—
Variable lease cost	1,406
	$ 7,813

Supplemental disclosure of cash flow information related to the lease was as follows (in thousands):

	Year Ended December 31, 2022
Cash paid for amounts included in the measurement of operating lease liabilities	$ 6,567
Operating lease liabilities arising from obtaining right-of-use asset	$ —

The weighted average remaining lease term and discount rate were as follows:

	December 31, 2022
Weighted-average remaining lease term - operating lease (in years)	5.17
Weighted-average discount rate - operating lease	11.00%

Because the interest rate implicit in the lease was not readily determinable, the Company's estimated incremental borrowing rate was used to calculate the present value of the lease.

As of December 31, 2022, the future minimum lease payments due under the noncancelable operating lease was as follows (in thousands):

2023	$ 6,936
2024	7,313
2025	7,679
2026	8,062
2027	8,466
Thereafter	1,439
Total future minimum lease payments	39,895
Less: imputed interest	(9,933)
Total operating lease liabilities	$ 29,962

The following table represents the lease liabilities on the consolidated balance sheet (in thousands):

	December 31, 2022
Current operating lease liability	$ 3,824
Operating lease liability, net of current portion	26,138
Total operating lease liabilities	$ 29,962

As previously disclosed in the Company's Annual Report on Form 10-K and under the previous lease accounting standard, ASC 840, *Leases*, the following table summarizes the future minimum lease payments due under the operating lease as of December 31, 2021 (in thousands):

2022	$ 6,375
2023	6,734
2024	7,100
2025	7,455
2026	7,828
Thereafter	9,617
	$ 45,109

Rent expense for the year ended December 31, 2021 was $6.2 million.

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, was set to expire in April 2022 but 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 2024. As of December 31, 2022, the remaining base rent payments due to the Company under the amended sub-sublease was $3.6 million. The Company recorded other income of $3.1 million and $3.5 million during the years ended December 31, 2022 and 2021, respectively, related to these sub-subleases.

9. Commitments and Contingencies

Leases

The Company's commitments under its leases are described in Note 8.

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 each of the years ended December 31, 2022 and 2021, the Company recorded $0.4 million of research and development expense related to this agreement for upfront technology access fees, research exclusivity fees and research support. During the year ended December 31, 2022, the Company recorded $2.0 million of research and development expense related to the achievement of a development milestone. During the year ended December 31, 2021, the Company did not incur any expense related to the achievement of these milestones.

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 the year ended December 31, 2022, the Company did not incur any expense related to the achievement of these milestones. During the year ended December 31, 2021, the Company recorded $0.1 million of expense related to the achievement of one of these milestones.

In November 2022, the Company entered into a license agreement with ImmunoGen, Inc. ("ImmunoGen"), for an exclusive, worldwide, royalty-bearing license for certain technology related to one of the Company's conditioning programs. Upon execution of the agreement, the Company made a nonrefundable payment of $4.4 million in partial consideration for the license. The Company is also obligated to pay milestone payments of up to $125.0 million in the aggregate upon the achievement of certain development, regulatory and sales-based milestones and to pay single-digit royalties on a product-by-product and country-by-country basis on net sales of products licensed under the agreement. During the year ended December 31, 2022, the Company did not incur any expense related to the achievement of these milestones. Effective December 29, 2022, Michael Vasconcelles, a member of the Company's board of directors, became ImmunoGen's Executive Vice President of Research, Development, and Medical Affairs (see Note 12).

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, 2022, the Company recorded research and development expense of $0.1 million related to the license of certain developed technologies under these agreements. During the year ended December 31, 2021, the Company did not incur any expense related to these licenses.

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, 2022.

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.

10. 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 years ended December 31, 2022 and 2021, the Company recorded $0.2 million and $0.1 million, respectively, of expense related to this matching contribution.

11. Income Taxes

During the years ended December 31, 2022 and 2021, 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,	
	2022	2021
Federal statutory income tax rate	21.0 %	21.0 %
State taxes, net of federal benefit	5.9	5.8
Research and orphan drug tax credits	4.1	3.3
Other	(1.1)	0.5
Increase in deferred tax asset valuation allowance	(29.9)	(30.6)
Effective income tax rate	— %	— %

Net deferred tax assets as of December 31, 2022 and 2021 consisted of the following (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 73,843	$ 67,236
Capitalized research and development expenses	20,137	8,665
Research and orphan drug tax credit carryforwards	15,550	12,370
Operating lease liability	8,110	—
Stock compensation expense	6,683	5,430
Accrued expense	1,112	936
Other	—	1,891
Total deferred tax assets	125,435	96,528
Valuation allowance	(118,215)	(95,367)
Net deferred tax assets	7,220	1,161
Deferred tax liabilities:		
Operating lease, right-of-use asset	(6,271)	—
Depreciation and amortization	(949)	(1,161)
Total deferred tax liabilities	(7,220)	(1,161)
Net deferred tax assets and liabilities	$ —	$ —

As of December 31, 2022, the Company had net operating loss carryforwards for federal income tax purposes of $272.9 million, of which $17.5 million begin to expire in 2035 and $255.4 million can be carried forward indefinitely. As of December 31, 2022, the Company had net operating loss carryforwards for state income tax purposes of $272.6 million which begin to expire in 2035. As of December 31, 2022, the Company also had available research and orphan drug tax credit carryforwards for federal and state income tax purposes of $12.9 million and $3.4 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, 2022 and 2021. 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, 2022 and 2021 related primarily to the increase in net operating loss carryforwards, capitalized research and development expenses and research and orphan drug tax credit carryforwards. During the year ended December 31, 2022, capitalized research and development expenses increased pursuant to Section 174 of the Code. The changes in the valuation allowance for the years ended December 31, 2022 and 2021 and were as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Valuation allowance as of beginning of year	$ 95,367	$ 73,600
Net increases recorded to income tax provision	22,848	21,767
Valuation allowance as of end of year	$ 118,215	$ 95,367

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2022 or 2021.

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 2019 to the present. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

12. Related Parties

Effective December 29, 2022, Michael Vasconcelles, a member of the Company's board of directors, became ImmunoGen's Executive Vice President of Research, Development, and Medical Affairs. The Company and ImmunoGen entered into a license agreement in November 2022 (see Note 9) and a Material Transfer and Evaluation Agreement, as amended, in August 2020. For the year ended December 31, 2022, the Company recorded expense of $4.6 million related to these agreements. As of December 31, 2022, amounts on the consolidated balance sheet related to these agreements was $0.1 million which was included in accounts payable and accrued expenses.

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 transplant 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, 2022 and 2021, the Company recorded expense of $0.3 million and $0.7 million, respectively, related to these agreements. As of December 31, 2022 and 2021, amounts on the consolidated balance sheets related to these agreements were $0.1 million and $0.2 million, respectively, which amounts were included in accounts payable and accrued expenses and other current liabilities and less than $0.1 million as of December 31, 2021, which amount was included in prepaid expenses and other current assets.

13. Subsequent Events

As of December 31, 2022, the Company had approximately $5.7 million on deposit at Silicon Valley Bank ("SVB"), consisting of $3.9 million of cash and cash equivalents and $1.8 million of restricted cash. SVB was closed on March 10, 2023, by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Subsequent to the closure of SVB, the FDIC created Silicon Valley Bridge Bank, N.A. ("SVB Bridge Bank") and the Company's SVB deposits were transferred to SVB Bridge Bank. As of March 20, 2023, the Company had approximately $36.9 million, including $1.8 million of restricted cash, on deposit at SVB Bridge Bank.

On January 31, 2023, the Company received a written notice from the staff of Nasdaq's Listing Qualifications Department, notifying the Company that, for the 30 consecutive business day period between December 15, 2022 through January 30, 2023, the bid price for its common stock had closed below the $1.00 per share minimum bid price requirement for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5450(a)(1), or the Minimum Bid Price Requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has 180 calendar days, or until July 31, 2023, to regain compliance with the Minimum Bid Price Requirement. If the Company fails to satisfy the continued listing requirements of Nasdaq, such as the Minimum Bid Price Requirement, Nasdaq may take steps to delist its common stock.

On February 2, 2023, after a review of the Company's business, programs, resources and capabilities, including anticipated costs and timelines, the Company announced the decision to halt further development of its programs and to conduct a comprehensive review of strategic alternatives. The Company also announced a corporate restructuring on February 7, 2023 that resulted in a reduction in its workforce by 84% that was substantially completed in February 2023 resulting in severance and related costs of approximately $5.4 million.

As part of the strategic review process, the Company is exploring potential strategic alternatives that include, without limitation, an acquisition, merger, business combination or other transaction. The Company is also exploring strategic alternatives related to its product candidates and related assets, including, without limitation, licensing transactions and asset sales. There can be no assurance that the strategic review process will result in the Company pursuing a transaction, or that any transaction, if pursued, will be completed on terms favorable to the Company and its stockholders. If the strategic review process is unsuccessful, our board of directors may decide to pursue a dissolution and liquidation of the Company.

On February 6, 2023, the Company entered into an agreement with Wedbush Securities Inc ("Wedbush") to act as the Company's exclusive strategic financial advisor in connection with a potential strategic transaction including but not limited to an acquisition, merger, business combination or other transaction. Upon the consummation of such transaction, the Company agreed to pay Wedbush a success fee of 1.0% of the transaction value with a minimum fee of $1.5 million.

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 and Principal Financial and Accounting Officer (our President, Chief Financial and Operating Officer), has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. 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, 2022, our Principal Executive Officer and Principal Financial and Accounting 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, 2022, 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, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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 2023 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 2023 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 2023 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 2023 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 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

1. Financial Statements

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page 98 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	Second Amended and Restated By-laws 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 December 13, 2022).
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.
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	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).
10.6.1	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).
10.6.2	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).
10.7	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).
10.8#	Amended and Restated Employment Agreement by and between the Registrant and Jason Gardner, effective March 3, 2022 (Incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K (File No. 001-38541) filed with the Securities and Exchange Commission on March 8, 2022).
10.9#	Amended and Restated Employment Agreement by and between the Registrant and Stephen Mahoney, effective March 3, 2022 (Incorporated by reference to Exhibit 10.13 to the Registrant's Annual Report on Form 10-K (File No. 001-38541) filed with the Securities and Exchange Commission on March 8, 2022).
10.10*#	Amended and Restated Employment Agreement by and between the Registrant and Jeffrey Humphrey, effective May 2, 2022.

Exhibit Number	Description
10.11*#	Amended and Restated Employment Agreement by and between the Registrant and Lisa Olson, effective May 2, 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 and Principal Financial and Accounting 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 and Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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 a management compensation plan, contract or arrangement.

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.

By: /s/ Stephen Mahoney

Date: March 23, 2023

Stephen Mahoney
President, Chief Financial and Operating Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Stephen Mahoney 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/ Stephen Mahoney Stephen Mahoney	President, Chief Financial and Operating Officer (Principal Executive Officer and Principal Financial and Accounting Officer)	March 23, 2023
/s/ Jeffrey Albers Jeffrey Albers	Director	March 23, 2023
/s/ Bruce Booth, D.Phil. Bruce Booth, D.Phil.	Director	March 23, 2023
/s/ Thomas O. Daniel, M.D. Thomas O. Daniel, M.D.	Director	March 23, 2023
/s/ Alison F. Lawton Alison F. Lawton	Director	March 23, 2023
/s/ Anne M. McGeorge Anne M. McGeorge	Director	March 23, 2023
/s/ Amy L. Ronneberg Amy L. Ronneberg	Director	March 23, 2023
/s/ David T. Scadden, M.D. David T. Scadden, M.D.	Director	March 23, 2023
/s/ Michael Vasconcelles, M.D. Michael Vasconcelles, M.D.	Director	March 23, 2023

Exhibit 4.3

Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended

The common stock, par value $0.001 per share ("Common Stock"), of Magenta Therapeutics, Inc. ("Magenta," "we," or "our") is registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The following description sets forth certain general terms and provisions of our Common Stock. These descriptions are in all respects subject to and qualified in their entirety by, and should be read in conjunction with, the applicable provisions of our Amended and Restated Certificate of Incorporation (our "Charter") and our Second Amended and Restated By-laws (our "By-laws"), each of which is incorporated herein by reference and copies of which are incorporated by reference as exhibits to our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission. We encourage you to read our Charter, By-laws and the applicable provisions of the General Corporation Law of the State of Delaware (the "DGCL") for additional information.

Authorized Capital Stock

We are authorized to issue 150,000,000 shares of Common Stock and 10,000,000 shares of undesignated preferred stock, par value $0.001 per share ("Preferred Stock").

Common Stock

Dividends

Holders of our Common Stock are entitled to receive dividends ratably, if any, as may be declared by our board of directors out of legally available funds, subject to any preferential dividend rights of any Preferred Stock then outstanding.

Voting

Holders of our Common Stock are entitled to one vote for each share of our Common Stock held of record for the election of directors of Magenta and on all matters submitted to a vote of the stockholders. The holders of our Common Stock do not have any cumulative voting rights.

Distributions on Liquidation

In the event of our dissolution, liquidation or winding up, holders of our Common Stock are entitled to share ratably in our net assets legally available after the payment of all our debts and other liabilities, subject to the preferential rights of any Preferred Stock then outstanding. The rights, preferences and privileges of holders of our Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of Preferred Stock that we may designate and issue in the future.

Other Rights

Holders of our Common Stock are not entitled to preemptive, subscription, redemption or conversion rights, and no sinking fund provisions are applicable to our Common Stock.

Relationship to Preferred Stock

Under our Charter, our board of directors is authorized, without further action by the stockholders, to designate and issue up to an aggregate of 10,000,000 shares of Preferred Stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of our Common Stock. Our board of directors may authorize the issuance of Preferred Stock with voting or conversion

rights that could adversely affect the voting power or other rights of the holders of our Common Stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation.

The purpose of authorizing our board of directors to issue Preferred Stock in one or more series and determine the number of shares in the series and its rights, preferences, privileges and restrictions is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of Preferred Stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes could, under certain circumstances, have the effect of delaying, deferring or preventing a change in control of our company. See the section entitled "Anti-Takeover Effects of Delaware Law and Provisions of our Charter and our By-laws—Undesignated Preferred Stock" for more information.

Registration Rights

Pursuant to the terms of our Second Amended and Restated Investors' Rights Agreement, dated as of April 2, 2018, with certain of our stockholders (the "Investors' Rights Agreement"), certain of our stockholders are entitled to rights with respect to the registration of their shares (which we refer to herein as "registrable securities") under the Securities Act of 1933, as amended (the "Securities Act"), including demand registration rights, short-form registration rights and piggyback registration rights.

Demand Registration Rights

The holders of our registrable securities are entitled to demand registration rights. Under the terms of the Investors' Rights Agreement, we will be required, upon the written request of holders of at least 25% of our outstanding registrable securities, to file a registration statement with an anticipated offering amount of at least $3.0 million and use commercially reasonable efforts to effect the registration of these shares for public resale. We are required to effect up to two registrations pursuant to this provision of the Investors' Rights Agreement.

Short-Form Registration Rights

The holders of our registrable securities are also entitled to short form registration rights. Pursuant to the Investors' Rights Agreement, if we are eligible to file a registration statement on Form S-3, upon the written request of holders of at least 10% of our outstanding registrable securities to sell registrable securities with an anticipated aggregate offering amount of at least $1.0 million, we will be required to use our commercially reasonable efforts to effect a registration of such shares. We are required to effect up to two registrations in any twelve month period pursuant to this provision of the Investors' Rights Agreement.

Piggyback Registration Rights

The holders of our registrable securities are also entitled to piggyback registration rights. If we register any of our securities either for our own account or for the account of other security holders, the holders of our outstanding registrable securities are entitled to include their shares in the registration. Subject to certain exceptions contained in the Investors' Rights Agreement, we and the underwriters may limit the number of shares included in the underwritten offering if the underwriters determine that marketing factors require a limitation of the number of shares to be underwritten.

Indemnification

The Investors' Rights Agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expiration of Registration Rights

The registration rights granted under the Investors' Rights Agreement will terminate upon the earlier of (i) a deemed liquidation event, as defined in our Charter, (ii) at such time after our initial public offering when all registrable securities could be sold under Rule 144 of the Securities Act or a similar exemption without limitation during a three-month period without registration or (iii) the fifth anniversary of our initial public offering.

Anti-Takeover Effects of Delaware Law and Provisions of our Charter and our By-laws

Certain provisions of the DGCL and of our Charter and our By-laws could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our Common Stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our board of directors. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our Common Stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the date that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by the board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition (in one or more transactions) involving the interested stockholder of 10% or more of either the aggregate market value of all (i) the assets of the corporation or (ii) the outstanding capital stock of the corporation, involving the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or any subsidiary to the interested stockholder;

- subject to exceptions, any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation or of any subsidiary beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation or any direct or indirect majority-owned subsidiary.

In general, Section 203 defines an "interested stockholder" as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person that is an affiliate or associate of the corporation and who beneficially owned 15% or more of the outstanding voting stock of the corporation at any time within the three year period immediately prior to the date of determining whether such entity or person is an interested stockholder, and any affiliate or associate of that entity or person.

Choice of Forum

Our By-laws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) 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, (iii) 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 DGCL, our Charter or our By-Laws, or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, 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 or the Exchange Act. Our By-laws further provide that, unless we consent in writing to an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which we refer to herein as the "Federal Forum Provision." In addition, our By-laws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision.

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. Additionally, the forum selection clauses in our By-laws 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 the filing of lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. Alternatively, if the Federal Forum Provision is found inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have an adverse effect on our business, financial condition or results of operations. The Court of Chancery of the State of Delaware or the federal district courts of the United States 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.

Board Composition and Filling Vacancies

In accordance with our Charter, our board is divided into three classes serving staggered three-year terms, with one class being elected each year. Our Charter also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of the remaining directors then in office, even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our Charter provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This requirement may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our By-laws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our Charter and our By-Laws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our By-laws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our By-laws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our By-laws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to our Charter and our By-laws

As required by the DGCL, any amendment of our Charter must first be approved by a majority of our board of directors, and if required by law or our Charter, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our Charter must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class.

Our By-laws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the By-laws, and may also be amended by the affirmative vote of at least two-thirds of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our Charter provides for 10,000,000 authorized shares of Preferred Stock. The existence of authorized but unissued shares of Preferred Stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of Preferred Stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. The issuance of shares of Preferred Stock could decrease the amount of earnings and assets available for distribution to holders of shares of our Common Stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

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 Jeffrey Humphrey (the "Executive") and is effective as of May 2, 2022 (the "Effective Date").

WHEREAS, the Executive is currently serving as the Company's Chief Medical 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 with an effective date of October 1, 2021 (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 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 Chief Medical 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 report to the CEO. 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 $489,000, 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; (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 October 1, 2021 ("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: May 2, 2022

EXECUTIVE

/s/ Jeffrey Humphrey
Jeffrey Humphrey

Date: May 2, 2022

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 Lisa Olson (the "Executive") and is effective as of May 2, 2022 (the "Effective Date").

WHEREAS, the Executive is currently serving as the Company's Chief Scientific 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 with an effective date of September 14, 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 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 Chief Scientific 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 $428,000, 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 her 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 her 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 her 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 her 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 her death, the date of her 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 her 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 her 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 her 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 September 14, 2020 ("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: May 2, 2022

EXECUTIVE

/s/ Lisa Olson
Lisa Olson

Date: May 2, 2022

Exhibit 21.1

SUBSIDIARIES

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 (Nos. 333-257381 and 333-266511) on Form S-3 and (Nos. 333-225838, 333-230387, 333-233125, 333-236853, 333-253815 and 333-263358) on Form S-8 of our report dated March 23, 2023, with respect to the consolidated financial statements of Magenta Therapeutics, Inc.

/s/ KPMG LLP

Boston, Massachusetts
March 23, 2023

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL AND ACCOUNTING 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. I am 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. I have disclosed, based on my 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 23, 2023

/s/ Stephen Mahoney

Stephen Mahoney
President, Chief Financial and Operating Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL AND ACCOUNTING 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, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer 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 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 23, 2023

/s/ Stephen Mahoney

Stephen Mahoney
President, Chief Financial and Operating Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)