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, 2020

OR

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

For the transition period from to

Commission File Number 001-36112

MACROGENICS, INC.

(Exact name of registrant)

Delaware	06-1591613
(State of organization)	*(I.R.S. Employer Identification Number)*

9704 Medical Center Drive, Rockville, Maryland 20850
(Address of principal executive offices and zip code)

(301) 251-5172
(Registrant's telephone number)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.01 per share	MGNX	Nasdaq Global Select 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 15(d) of the Exchange 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes ☑ No ☐

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

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

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

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

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

The aggregate market value of the registrant's common stock, par value $0.01 per share, held by non-affiliates of the registrant on June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $1.5 billion based on the closing price of the registrant's common stock on the Nasdaq Global Select Market on that date. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

The number of shares of the registrant's common stock outstanding on February 22, 2021 was 56,258,468.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of MacroGenics, Inc.'s definitive proxy statement for the 2021 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report.

MACROGENICS, INC.
ANNUAL REPORT ON FORM 10-K
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FORWARD-LOOKING STATEMENTS

This report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements include statements that may relate to our plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditures, financing needs and other information that is not historical information. Many of these statements appear, in particular, under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report on Form 10-K. Forward-looking statements can often be identified by the use of terminology such as "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions, or by discussions of strategy.

All forward-looking statements, including, without limitation, our examination of historical operating trends, are based upon our current expectations and various assumptions. We believe there is a reasonable basis for our expectations and beliefs, but they are inherently uncertain. We may not realize our expectations, and our beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements. The following uncertainties and factors, among others (including those set forth under "Risk Factors"), could affect future performance and cause actual results to differ materially from those matters expressed in or implied by forward-looking statements:

- the severity and duration of the impact of the COVID-19 global pandemic on our business, operations, clinical programs, manufacturing, financial results and other aspects of our business;
- our plans to develop and commercialize our product candidates;
- the outcomes of our ongoing and planned clinical trials and the timing of those outcomes, including when clinical trials will be initiated or completed, and when data will be reported or regulatory filings will be made;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to raise additional capital through the capital markets or through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales;
- our ability to enter into new collaborations or to identify additional products or product candidates with significant commercial potential that are consistent with our commercial objectives;
- the potential benefits and future operation of our existing collaborations;
- our ability to recover the investment in our manufacturing capabilities;
- the rate and degree of market acceptance and clinical utility of our products;
- our commercialization, marketing and manufacturing capabilities and strategy;
- significant competition in our industry;
- costs of litigation and the failure to successfully defend lawsuits and other claims against us;
- economic, political and other risks associated with our international operations;
- our ability to receive research funding and achieve anticipated milestones under our collaborations;
- our ability to protect and enforce patents and other intellectual property;
- costs of compliance and our failure to comply with new and existing governmental regulations including, but not limited to, tax regulations;
- loss or retirement of key members of management;
- failure to successfully execute our growth strategy, including any delays in our planned future growth; and
- our failure to maintain effective internal controls.

Consequently, forward-looking statements speak only as of the date that they are made and should be regarded solely as our current plans, estimates and beliefs. You should not place undue reliance on forward-looking statements. We cannot guarantee future results, events, levels of activity, performance or achievements. Except as required by law, we do not undertake and specifically decline any obligation to update, republish or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events.

PART I

ITEM 1. BUSINESS

Except as otherwise indicated herein or as the context otherwise requires, references in this annual report on Form 10-K to "MacroGenics," the "company," "we," "us" and "our" refer to MacroGenics, Inc. and its consolidated subsidiaries. "MacroGenics®, the MacroGenics logo, DART®, TRIDENT®, MARGENZA™ and the phrases Breakthrough Biologics, Life-Changing Medicines® and Developing Breakthrough Biologics, Life-Changing Medicines® are our trademarks. The other trademarks, trade names and service marks appearing in this report are the property of their respective owners.

Overview

We are a biopharmaceutical company focused on developing and commercializing innovative antibody-based therapeutics designed to modulate the human immune response for the treatment of cancer. In December 2020, the U.S. Food and Drug Administration (FDA) approved MARGENZA (margetuximab-cmkb), a human epidermal growth factor receptor 2 (HER2) receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. We expect to launch MARGENZA in collaboration with our commercialization partner, Eversana Life Science Services, LLC (EVERSANA), in March 2021. In addition, we have a pipeline of product candidates in human clinical testing, including eight immuno-oncology programs, that have been created primarily using our proprietary, antibody-based technology platforms. We believe our product candidates have the potential to have a meaningful effect on treating patients' unmet medical needs as monotherapy or, in some cases, in combination with other therapeutic agents.

We are developing product candidates that target various tumor-associated antigens. These include tumor-associated antigens that have been well characterized, such as HER2, which is expressed on some breast, gastroesophageal and other cancer types. Other product candidates that we are developing, with our collaboration partners in certain cases, target tumor-associated antigens against which there are currently no approved products, such as B7-H3, a molecule in the B7 family of immune regulator proteins widely expressed by several different tumor types, and ADAM9, a cell surface protein over-expressed in several solid tumor types. We are also developing molecules that target programmed cell death protein 1 (PD-1), a protein that is important in the regulation of the immune system's response to cancer. Monoclonal antibodies that inhibit PD-1 have been approved by the FDA for the treatment of numerous cancers. Our clinical pipeline includes an anti-PD-1 monoclonal antibody that we have out-licensed to a partner, for which a Biologics License Application (BLA) filed with the FDA is subject to a Prescription Drug User Fee Act (PDUFA) target action date of July 25, 2021, and two bispecific DART product candidates that co-engage PD-1 and LAG-3, or PD-1 and CTLA-4. We are also developing a bispecific DART molecule that engages CD3 on immune effector cells to kill CD123-expressing cancer cells in certain hematological malignancies, including acute myeloid leukemia (AML).

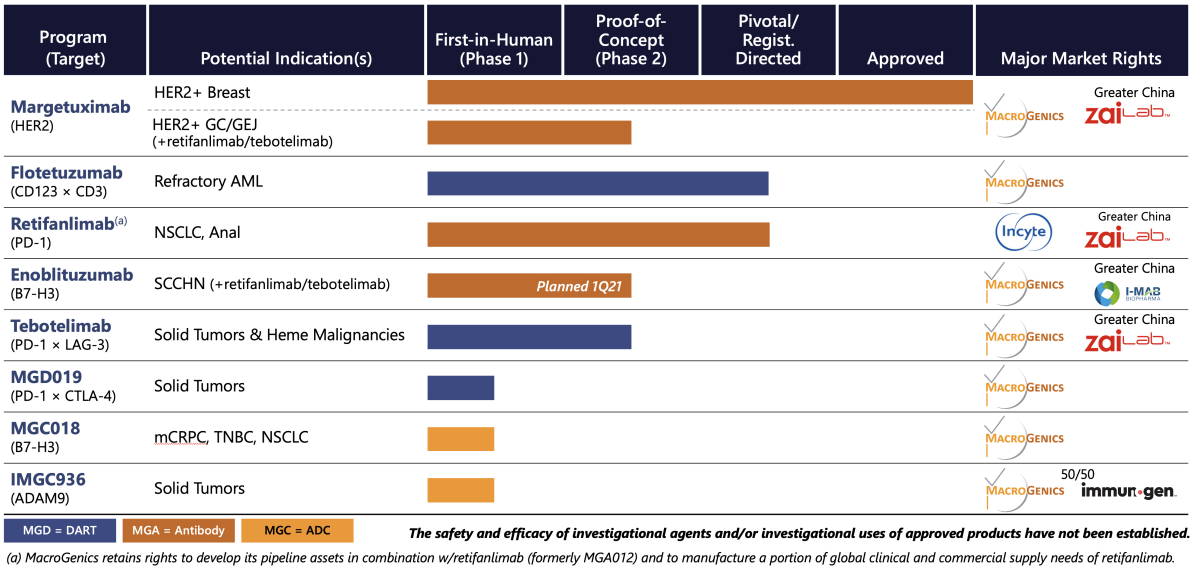
We have created our product candidates based on the following antibody-based technologies:

- Fc Optimization platform, which introduces certain mutations into the Fc domain of a monoclonal antibody in order to modulate antibody interaction with immune effector cells to enhance the killing of cancer cells;
- Multi-specific platforms, which enable us to design antibodies that can bind to two (in the case of our bispecific DART product candidates) or more distinct targets; and
- Antibody drug conjugate (ADC) platforms, which we have licensed from collaboration partners, and which link monoclonal antibodies that specifically target cytotoxins to cancer cells that are designed to trigger cell death in the cancer cell.

Our goal is to be a fully-integrated biotechnology company leading in the discovery, development and commercialization of breakthrough antibody-based biologics for the treatment of patients with cancer.

Our Pipeline of Immuno-Oncology Product Candidates

The table below depicts the current status of our immuno-oncology product candidates that are in clinical development and for which we retain all or some commercial rights:



Margetuximab

Margetuximab is an Fc-engineered, monoclonal antibody that targets the HER2 oncoprotein. HER2 is expressed by tumor cells in breast, gastroesophageal and other solid tumors. Similar to trastuzumab, margetuximab inhibits tumor cell proliferation, reduces shedding of the HER2 extracellular domain and mediates antibody-dependent cellular cytotoxicity (ADCC). However, through our Fc Optimization technology, margetuximab has been engineered to enhance the engagement of the immune system. In vitro, the modified Fc region of margetuximab increases binding to the activating Fc receptor FCGR3A (CD16A) and decreases binding to the inhibitory Fc receptor FCGR2B (CD32B). These changes lead to greater in vitro ADCC and natural killer (NK) cell activation. The clinical significance of in vitro data is unknown.

In December 2020, we announced that the FDA approved MARGENZA (margetuximab-cmkb), in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. MARGENZA is the first product approved from our promising pipeline. The approval was based on safety and efficacy results from the pivotal Phase 3 SOPHIA trial, as described below. We expect to launch MARGENZA in March of 2021.

Margetuximab is being evaluated in combination with checkpoint blockade in the Phase 2/3 MAHOGANY trial for the treatment of patients with HER2-positive gastroesophageal cancer, and in combination with tebotelimab (our PD-1 × LAG-3 bispecific DART molecule) in various HER2-positive tumors. We are partnered with Zai Lab for the development and commercialization of margetuximab in Greater China.

HER2-positive Breast Cancer.

HER2 is a protein found on the surface of some cancer cells that promotes growth and is associated with aggressive disease and poor prognosis. Approximately 15-20% of breast cancer cases are HER2-positive, representing approximately 45,000 new cases annually in the U.S. according to the American Cancer Society *Breast Cancer Facts & Figures 2019-2020*. Monoclonal antibody-based therapies targeting HER2 have greatly improved outcomes of patients with HER2-positive breast cancer and are now standard of care in both early- and late-stage disease. Ongoing HER2 blockade is recommended for patients who have relapsed or refractory HER2-positive disease; after progression occurs during treatment with other HER2-directed therapies, the need for additional agents in later lines remains.

The FDA approval of MARGENZA was based on safety and efficacy results from the SOPHIA study, a randomized, open-label Phase 3 clinical trial evaluating MARGENZA plus chemotherapy compared to trastuzumab plus chemotherapy in patients with HER2-positive metastatic breast cancer, who have previously been treated with anti-HER2-targeted therapies. All study patients had previously received trastuzumab; all but one patient had previously received pertuzumab, and 91% had previously received ado-trastuzumab emtansine, or T-DM1.

The study enrolled 536 patients who were randomized 1:1 to receive either MARGENZA (n=266) given intravenously at 15 mg/kg every three weeks or trastuzumab (n=270) given intravenously at 6 mg/kg (or 8 mg/kg for loading dose) every three weeks in combination with one of four chemotherapy agents (capecitabine, eribulin, gemcitabine or vinorelbine) given at the standard doses. Intent-to-treat progression-free survival (PFS) analysis occurred after 265 PFS events.

The primary endpoint of the study was PFS, determined by blinded, centrally-reviewed radiological review, followed by a second sequential endpoint of overall survival (OS). Additional key secondary endpoints are PFS by investigator assessment, objective response rate (ORR) and duration of response. Tertiary endpoints include ORR by investigator assessment and safety. PFS and ORR were assessed according to Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST).

The SOPHIA study showed a statistically significant 24% reduction in the risk of disease progression or death with MARGENZA plus chemotherapy compared with trastuzumab plus chemotherapy (hazard ratio [HR]=0.76; 95% CI, 0.59-0.98; P=0.033; median PFS 5.8 vs 4.9 months). The objective response rate for MARGENZA plus chemotherapy was 22% and for trastuzumab plus chemotherapy was 16%. The final OS analysis is expected in the second half of 2021.

Adverse reactions occurring in greater than twenty percent of patients with MARGENZA in combination with chemotherapy were fatigue/asthenia (57%), nausea (33%), diarrhea (25%), and vomiting (21%). The MARGENZA U.S. Prescribing Information has a BOXED WARNING for left ventricular dysfunction and embryo-fetal toxicity. In addition, MARGENZA can cause infusion-related reactions (IRRs). IRRs occurred in 13% of patients treated with MARGENZA, with the majority reported as Grade 2 or less. Grade 3 IRRs occurred in 1.5% of patients.

Gastric Cancer.

Cancer of the stomach, also called gastric cancer (GC), and cancer of the gastroesophageal junction (GEJ), which is where the esophagus joins the stomach, are collectively referred to as gastroesophageal adenocarcinoma, which is the third leading cause of cancer death worldwide according to the World Health Organization in 2020. Both GC and GEJ cancer are often diagnosed at an advanced stage and therefore have very poor prognosis, with a 5-year survival of 5-20%. Chemotherapy is the standard of care for first-line therapy and may be combined with trastuzumab for the approximately 20% of patients whose tumors are HER2-positive.

We are evaluating the combination of margetuximab plus PD-1 checkpoint blockade as a chemotherapy-free regimen in patients with advanced HER2-positive GC or GEJ cancer in two separate clinical studies. We believe that combining checkpoint blockade and margetuximab may create synergistic anti-tumor activity through enhanced tumor-specific T-cell immunity.

In July 2020, results were published in *Lancet Oncology* from our Phase 2 study of margetuximab plus pembrolizumab as a chemotherapy-free regimen for patients with advanced HER2-positive gastroesophageal adenocarcinoma (GEA) who have previously been treated with chemotherapy and trastuzumab. The Phase 2 study enrolled patients with GC or GEJ cancer whose tumors were IHC3-positive or IHC2-positive/FISH-positive at diagnosis. Enrollment was regardless of PD-L1 expression status, which was subsequently determined from available archived tumor tissue. Safety and activity analyses were based on data from a July 10, 2019, data cutoff.

Tolerability of margetuximab and pembrolizumab was acceptable in patients treated in this study. Grade 3 or higher treatment-related adverse events (TRAEs) were reported in 20% of patients, with anemia (4%) and IRRs (3%) being the most common. No treatment-related deaths were reported.

In this study, patients who had received margetuximab plus pembrolizumab at the recommended Phase 2 dose of 15 mg/kg every three weeks were evaluable for response. In this overall population, the ORR was 18% (17/92 patients), including complete responses and partial responses. The disease control rate (DCR), which includes complete responses, partial responses, and stable disease, was 53% (49/92 patients). Median PFS was 2.7 months (95% CI 1.6–4.3) and median OS was 12.5 months (95% CI 9.1–14.1).

Activity of margetuximab and anti-PD-1 in this study was more pronounced in key biomarker-positive subgroups. The most pronounced benefit was observed in patients whose tumors had high HER2 expression at diagnosis (HER2 IHC3-positive) and were PD-L1-positive. In this double-positive subgroup, the ORR was 44% (11/25 patients) and the DCR was 72% (18/25 patients). Median PFS was 4.8 months (95% CI 1.6–13.9) and median OS was 20.5 months (95% CI 8.1–NR).

Patients with initial HER2-positive GEA may lose HER2 expression after trastuzumab-based therapy. In this second-line study, HER2 amplification was not detectable in circulating tumor DNA (ctDNA) in 42% of patients who were tested, suggesting loss of HER2 following prior trastuzumab and before treatment with margetuximab and pembrolizumab. The presence of HER2 amplification in ctDNA was associated with better response rates in this study. $HER2^{amp}$-positive/HER2 IHC3-positive/PD-L1-positive ORR was 60% (9/15 patients) and DCR was 80% (12/15 patients).

Consistent with prior studies of margetuximab in other tumor types, correlative analyses of samples from GEA patients treated in the study showed an increase in anti-HER2 specific T-cell immunity, suggesting the potential for engagement of both innate and adaptive immune responses.

Based on these results in second-line patients who were refractory to trastuzumab, in September 2019, we initiated the MAHOGANY study, a Phase 2/3 registration-directed clinical trial to evaluate, in Module A, margetuximab in combination with retifanlimab, an anti-PD-1 monoclonal antibody, in patients with tumors that are both HER2 IHC3-positive and PD-L1 positive. This approach is designed as a chemotherapy-free regimen that engages both innate and adaptive immunity for the treatment of patients with GC or GEJ cancer in the first-line setting. The primary outcome measure for efficacy in Module A is ORR per RECIST. We expect to obtain initial data in the first half of 2021 to enable a decision whether to enroll additional patients into the study to support a potential accelerated approval of the U.S. in the future.

We also plan to evaluate margetuximab with chemotherapy and retifanlimab or tebotelimab, a PD-1 × LAG-3 bispecific DART molecule, compared to standard of care therapy of trastuzumab with chemotherapy in Module B of the MAHOGANY study. In this portion of the randomized, controlled study, patients are planned to be enrolled irrespective of PD-L1 expression. The primary outcome measure for efficacy in Module B is planned to be OS.

In November 2018, we licensed the right to develop and commercialize margetuximab in mainland China, Hong Kong, Macau and Taiwan to Zai Lab Limited (Zai Lab). Zai Lab will lead clinical development in its territory by leveraging its regulatory and clinical development expertise and broad regional network of investigators. We are prioritizing enrollment of MAHOGANY Module A in the U.S. Zai Lab initiated Module B in Greater China in 2020. In February 2020, Zai Lab announced that it had dosed a first patient in a registrational bridging study of margetuximab, in combination with chemotherapy, for the treatment of patients with metastatic HER2-positive breast cancer.

The FDA has granted Orphan Drug Designation to margetuximab for the treatment of gastric and gastroesophageal junction cancer.

Flotetuzumab

Flotetuzumab is an investigational bispecific, humanized DART molecule that recognizes both CD123 and CD3. CD123, the interleukin-3 receptor alpha chain, has been reported to be over-expressed on cancer cells in a wide range of hematological malignancies, including AML and myelodysplastic syndrome (MDS). CD3 is expressed on immune effector cells, such as T cells. Flotetuzumab is designed to engage and redirect T cells to kill CD123-expressing malignant cells. The molecule is being evaluated in a clinical study of up to 200 AML patients who are refractory to induction therapy or relapse within six months of a complete remission (CR). This study is intended to support registration in the U.S. The FDA has granted Orphan Drug Designation to flotetuzumab for the treatment of AML.

Acute Myeloid Leukemia

AML is a hematopoietic malignancy characterized by uncontrolled clonal proliferation of neoplastic myeloid precursors and differentiation arrest that prevent normal bone marrow hematopoiesis. AML is thought to arise in and be perpetuated by a small population of leukemic stem cells (LSCs) that generally resist conventional chemotherapeutic agents. LSCs are characterized by high levels of CD123 expression that is low or absent in the corresponding hematopoietic progenitors and stem cell populations in normal human bone marrow. Flotetuzumab was designed to redirect T lymphocytes, specialized white blood cells of the human immune system, to kill CD123-expressing cells. To achieve this, the DART molecule combines an arm that recognizes CD123 on the target cells with a portion of an antibody recognizing CD3, an activating protein expressed by T cells.

Approximately 20,000 new cases of AML were diagnosed in the U.S. in 2020, with a median age of 68 years at diagnosis, according to the Surveillance, Epidemiology, and End Results Program of the National Institutes of Health (NIH). Hematopoietic stem cell transplantation represents the only treatment modality with reliable curative potential. Approximately 40-50% of newly diagnosed patients fail to achieve a CR with intensive induction therapy (primary induction failure, or PIF) or experience disease recurrence after an initial remission of short duration of less than six months (early relapsed, or ER6). Only a

very small number of these patients are expected to respond to salvage therapy. While some patients may be eligible to receive new targeted agents that have been approved for the treatment of first-line or relapsed/refractory AML in recent years, approximately 50% of patients have no known targetable mutations.

In December 2020, we presented data from our ongoing open-label Phase 1/2 dose expansion study of flotetuzumab in 44 relapsed/refractory patients having either primary induction failure or early relapsed AML. Of these patients, 72.7% (32 of 44) had adverse risk cytogenetics by ELN Risk Stratification (2017). Patients were treated with flotetuzumab at the recommended Phase 2 dose of 500 ng/kg/day by continuous infusion, following step-up, daily dose escalation during the first week. Data were reported as of the cut-off date of November 10, 2020. The study is ongoing, with a total of up to 200 patients planned for enrollment for registrational purposes.

The median time to achieve a response to flotetuzumab in the study was one cycle (range of 1-3 cycles). Responses, including CR, CRh (CR with partial hematological recovery) and CRi (CR with incomplete hematological improvement) per a modified International Working Group (IWG) Response Criteria for AML, are summarized in the table below.

	PIF/ER6 (n=44)	**PIF (n=27)**	**ER6 (n=17)**
CR/CRh	25.0% (11)	33.3% (9)	11.8% (2)
CR/CRh/CRi	31.8% (14)	37.0% (10)	23.5% (4)
HSCT	57.1% (8/14)	70.0% (7/10)	25.0% (1/4)
Median Duration of Response	8.13 months (n=14)	15.2 months (n=10)	2.4 months (n=4)

Eight of 14 responders (57%) received allogeneic hematopoietic stem cell transplantation (HSCT) as consolidation therapy and remained in remission after 6 to 21 months (median not reached). Overall, among the PIF/ER6 patients who achieved remission (CR, CRh or CRi), the median duration of response was 8.13 months, with a median overall survival of 10.7 months. Within the PIF/ER6 population, five of ten patients with *TP53*-mutated AML, a mutation associated with very poor prognosis, achieved CR/CRh/CRi responses, three of whom went on to receive HSCT.

The most common TRAE was infusion-related reaction/cytokine release syndrome (IRR/CRS). While all patients experienced some levels of IRR/CRS, most events were of short duration and mild to moderate (Grade 1 or 2) in severity, with only a single Grade 3 event reported.

Retifanlimab

Retifanlimab is an investigational monoclonal antibody targeting PD-1. Marketed antibodies targeting this checkpoint molecule have shown clinical efficacy in the treatment of various tumors by releasing the "brakes" of the immune system and help to restore the immune system's ability to detect and kill tumor cells. In 2017, we licensed retifanlimab to Incyte Corporation (Incyte) under a global collaboration and license agreement, although we retain the right to develop the molecule in combination with product candidates from our pipeline. In January 2021, Incyte announced that the FDA had accepted for Priority Review its BLA for retifanlimab as a potential treatment for adult patients with locally advanced or metastatic squamous cell carcinoma of the anal canal (SCAC) who have progressed on, or who are intolerant of, platinum-based chemotherapy. The PDUFA target action date for retifanlimab is July 25, 2021. In addition, Incyte has stated it is pursuing development of retifanlimab as monotherapy in potentially registration-enabling studies in patients with MSI-high endometrial cancer and Merkel cell carcinoma.

In 2020, Incyte initiated two Phase 3 studies of retifanlimab in combination with chemotherapy in patients with advanced or metastatic non-small cell lung cancer (NSCLC) and in patients with metastatic SCAC, known as POD1UM-304 and POD1UM-303, respectively. Incyte is also pursuing development of retifanlimab in combination with multiple product candidates from its pipeline.

We are currently evaluating retifanlimab in combination with margetuximab in a potentially registration-enabling study of patients with HER2-positive GC and GEJ. We plan to initiate a study of retifanlimab in combination with enoblituzumab, an investigational Fc-engineered, anti-B7-H3 mAb, in patients with squamous cell carcinoma of the head and neck (SCCHN).

Enoblituzumab

Enoblituzumab is an investigational monoclonal antibody that targets B7-H3 that has been engineered using our Fc Optimization platform. B7-H3 (CD276) belongs to the B7 family of immune regulator proteins that is widely expressed by different tumor types and may play a key role in regulating the immune response to various cancers. There are no currently approved therapeutic agents directed against B7-H3.

We conducted a Phase 1b/2 clinical study of enoblituzumab and pembrolizumab, an anti-PD-1 monoclonal antibody, to evaluate this combination in patients with B7-H3-expressing melanoma, SCCHN, NSCLC and urothelial cancer. The combination of enoblituzumab and immune checkpoint blockade is designed to engage innate and adaptive immunity to enhance tumor cell killing. A total of 133 patients were treated in the study; the data cut-off date was October 12, 2018.

As presented in November 2018, in the SCCHN dose expansion cohort, confirmed partial responses were observed in 6 of 18 (33%) of patients evaluable for response who had not previously received anti-PD-1 or anti-PD-L1 therapy. For the subset of patients with B7-H3 tumor expression ≥ 10%, 6 of 15 (40%) had confirmed partial responses. ORRs ranging from 13% to 16% have previously been reported in SCCHN patients treated with anti-PD-1 agents alone. The combination of enoblituzumab and an anti-PD-1 monoclonal antibody demonstrated acceptable tolerability, with any adverse event ≥ Grade 3 occurring in 27.1% of patients as of the October 12, 2018 data cut-off date. The rate of immune-related adverse events experienced in the trial was comparable to that historically observed by others in patients who received pembrolizumab as monotherapy.

To further inform the development of enoblituzumab, we expect to initiate a Phase 2 study of this agent in patients with relapsed or metastatic SCCHN not curable by local therapy in the first quarter of 2021. This trial will include enoblituzumab in a chemotherapy-free regimen in combination with either retifanlimab in patients who are PD-L1 positive or with tebotelimab in patients who are PD-L1 negative.

In July 2019, we licensed the right to develop and commercialize enoblituzumab in mainland China, Hong Kong, Macau and Taiwan to I-Mab Biopharma (I-Mab). I-Mab plans to both lead regional studies in its territories as well as participate in global studies conducted by us.

Tebotelimab

Tebotelimab is an investigational, first-in-class bispecific, tetravalent DART molecule targeting PD-1 and LAG-3, or lymphocyte-activation gene 3. We have engineered tebotelimab to concomitantly or independently bind to PD-1 and LAG-3 and disrupt these non-redundant inhibitory pathways to further restore exhausted T-cell function. Tebotelimab is being evaluated in a Phase 1 dose expansion study as both monotherapy in several tumor types as well as in combination with margetuximab in HER2-positive neoplasms.

In May 2020, initial data was presented from a Phase 1 study in which 53 patients with advanced tumors were treated with tebotelimab given intravenously in cohorts of escalating flat doses of 1-1200 mg every two weeks. A maximum tolerated dose was not identified. A flat dose of 600 mg every two weeks was selected for tumor-specific expansion cohorts. At the April 25, 2020 data cut-off, 205 patients with advanced solid and hematologic neoplasms had been treated with tebotelimab monotherapy in the ongoing dose-expansion part of the study, of which 152 were evaluable for response. Anti-tumor activity was assessed by RECIST.

Anti-tumor activity of tebotelimab as monotherapy was observed in evaluable patients across several of the tumor types in the selected dose expansion cohorts. ORRs, including both confirmed and unconfirmed responses, and DCR, comprising both confirmed objective responses and stable disease, were observed as follows: triple negative breast cancer (17% ORR, 4 of 23 patients; 39% DCR, 9 of 23 patients), epithelial ovarian cancer (9% ORR, 2 of 23 patients; 52% DCR, 12 of 23 patients) and NSCLC (checkpoint inhibitor naïve: 21% ORR, 3 of 14 patients; 64% DCR, 9 of 14 patients; and post anti-PD-1: 13% ORR, 2 of 15 patients; 53% DCR, 8 of 15 patients). Response to tebotelimab monotherapy was associated with LAG-3 expression and an IFN-γ gene signature at baseline. The overall safety profile of tebotelimab in the Phase 1 study, including the incidence of immune-mediated adverse events, appeared generally consistent with anti-PD-1 antibody monotherapy with respect to event type and frequency.

Immune effector cell activation and LAG-3, PD-1 and PD-L1 expression has been shown to be enhanced in vitro by Fc-engineered margetuximab. An expansion cohort of patients with advanced HER2-positive tumors is being treated with margetuximab plus tebotelimab to evaluate whether Fc-engineering can enhance tumor responsiveness to checkpoint blockade and improve clinical outcomes in patients. In November 2020, updated data was presented from the ongoing combination study of tebotelimab and margetuximab in patients with advanced HER2-positive neoplasms. In this study, 41 patients had been enrolled. As of the October 5, 2020 data cut-off, there were 28 response-evaluable patients. Evidence of antitumor activity was observed among refractory patients with various HER2-positive tumor types, including eight objective responses (six

confirmed) observed in multiple advanced HER2-positive tumor types. The ORR (including unconfirmed responses) was 28.6%, while 64.3% of response-evaluable patients experienced a decrease in target lesion tumor burden. The duration of response for confirmed responders was 4.21–8.97 months, with three patients remaining on treatment as of the data cut-off. Of particular interest, a majority of responding patients had a baseline PD-L1 combined positive score (CPS) ≤ 1. All responding patients carried the less favorable CD16A-158F allotype (i.e., V/F or F/F). Evaluation of baseline LAG-3 and PD-1 mRNA expression and potential association with clinical response analyses are ongoing, and will be important for defining patient enrichment biomarker strategies for further development. The combination of tebotelimab and margetuximab was generally well tolerated, with a safety profile consistent with that of tebotelimab monotherapy. Enrollment in HER2-positive tumor-specific cohorts is ongoing.

In December 2020, data was presented from the ongoing tebotelimab Phase 1 dose expansion study in patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL). LAG-3 has been shown to be highly expressed in DLBCL and has emerged as a therapeutic target of interest in this population, while PD-1-targeted therapy has yielded modest efficacy. There remains significant unmet need for patients with relapsed/refractory (R/R) DLBCL. In this study, 20 DLBCL patients were enrolled, half of whom were chimeric antigen receptor (CAR) T cell therapy experienced. As of the October 23, 2020 data cut-off, there were 13 response-evaluable patients. A preliminary ORR of 53.8% (7 of 13 patients) was observed, including responses in five of seven CAR T cell-naïve patients and in two of six CAR T cell experienced patients, the latter of whom both had complete responses. A preliminary duration of response of up to 168 days was observed, with six of seven ongoing responses as of the cut-off date. In the study, baseline LAG-3 expression appeared to associate with clinical response, with additional analyses ongoing. Tebotelimab was generally well-tolerated among heavily pre-treated R/R DLBCL patients, with manageable infusion-related reactions and no evidence of tumor lysis syndrome. The most common TRAE was pyrexia, which occurred in three (15%) patients. A single Grade 3 TRAE of anemia was observed.

We expect to provide clinical updates on tebotelimab in 2021, including future development plans.

Under our November 2018 license and collaboration agreement with Zai Lab, we also licensed to them the right to develop and commercialize tebotelimab in mainland China, Hong Kong, Macau and Taiwan. In February 2020, Zai Lab dosed the first patient with niraparib, a PARP (poly [ADP-ribose] polymerase) inhibitor, in the Phase 1b proof-of-concept, China-only study, in combination with tebotelimab. In April 2020, Zai Lab initiated a study of tebotelimab in combination with brivanib in a Phase 1 proof-of-concept China-only dose escalation and expansion trial in patients with advanced hepatocellular carcinoma (HCC). The dose escalation phase to determine the recommended Phase 2 dose of tebotelimab as monotherapy and in combination with brivanib was completed, with related data presented in late 2020. In November 2020, Zai Lab enrolled the first patient in a Phase 1 proof-of-concept clinical trial in China of tebotelimab as second-line therapy for melanoma patients after treatment with checkpoint inhibitors.

MGC018

MGC018 is an investigational ADC with a cleavable peptide linker designed to deliver a DNA-alkylating duocarmycin payload to dividing and non-dividing cells on solid tumors that express B7-H3. The underlying ADC technology was licensed from Byondis B.V. (formerly Synthon Biopharmaceuticals). We are conducting a Phase 1 dose expansion study of MGC018.

In May 2020, data from the dose escalation study of MGC018 was presented. At the May 6, 2020 data cut-off, 23 evaluable patients with advanced solid tumors had been enrolled in four dose escalation cohorts of 0.5 mg/kg to 3 mg/kg given intravenously every three weeks. Treatment is ongoing in an expanded fifth cohort of patients at 4 mg/kg every three weeks.

Preliminary evidence of anti-tumor activity by MGC018 has been observed, particularly in patients with advanced metastatic castration-resistant prostate cancer (mCRPC). Reductions in PSA levels of ≥ 50% were observed in five of seven mCRPC patients treated, including one with substantial regression of bone disease. Six mCRPC patients had bone only disease, and one patient with measurable peripheral disease had a 29% reduction in target lesions that did not qualify as a response per RECIST. Four PSA responders remained on therapy as of the data cut-off. Patients with mCRPC had received a median of four therapies prior to MGC018, including taxane chemotherapy (six patients) and next-generation hormonal agents (six patients were treated with both abiraterone and enzalutamide, and one with abiraterone only).

The safety profile of MGC018, which includes hematologic and skin toxicities, has been generally manageable to date. At least one TRAE occurred in 22 of 23 patients (96%), including Grade ≥ 3 reported in 14 of 23 patients (61%). Three treatment-related serious adverse events occurred in one patient each: pneumonitis in a patient with concurrent bacterial pneumonia; non-infectious gastroenteritis; and stasis dermatitis in a patient with chronic venous insufficiency. One dose-limiting toxicity of Grade 4 neutropenia that resolved to baseline was reported. No febrile neutropenia was observed.

We commenced the Phase 1 dose expansion study of MGC018 in patients with mCRPC, triple negative breast cancer (TNBC) and NSCLC in the fourth quarter of 2020 and expects to provide an update on this study in mid-2021.

MGD019

Approved monoclonal antibodies that target the immune checkpoints PD-1 and CTLA-4, or cytotoxic T-lymphocyte-associated protein 4, have shown enhanced clinical antitumor activity when given in combination in various cancers, including renal cell carcinoma and NSCLC with high tumor mutational burden. MGD019 is an investigational, bispecific tetravalent DART molecule designed to enable simultaneous and/or independent blockade of PD-1 and CTLA-4, with potentially enhanced CTLA-4 blockade on T cells co-expressing these immune checkpoint molecules.

In September 2020, data from the Phase 1 dose escalation study of MGD019 were reported. Forty-three patients were enrolled in the study within a dose range of 0.03 – 10.0 mg/kg, administered every three weeks initially, in a population of heavily pre-treated patients representing a broad range of different types (23) of solid tumors. A total of 28 patients were treated at doses ≥ 3.0 mg/kg administered every three weeks initially. Of the 18 evaluable patients who received doses ≥ 3.0 mg/kg as of the July 21, 2020 cut-off date, four objective responses were reported, including a confirmed complete response in mCRPC, confirmed partial responses in microsatellite stable colorectal cancer (MSS CRC) and metastatic type AB thymoma, and an unconfirmed partial response in serous fallopian tube carcinoma. MGD019 was well-tolerated in patients who received less than 10 mg/kg. The most common TRAEs observed were pruritus (23.3%), arthralgia (18.6%), fatigue (18.6%), rash (18.6%), nausea (16.3%) and infusion-related reaction (16.3%). Several Grade 3 adverse events were observed at the 10.0 mg/kg level; however, none were considered dose limiting.

In this study, full and sustained peripheral PD-1 blockade was evident at doses ≥ 1.0 mg/kg over a 3-week dosing interval. In addition, dose-dependent upregulation of the inducible costimulator (ICOS) molecule was evident in treated patients, including those who responded to MGD019 therapy. This is consistent with an observation previously reported in the literature that anti-CTLA-4 therapy increases the frequency of CD4 T cells expressing the ICOS molecule.

We are currently evaluating MGD019 in a Phase 1 dose expansion study initially in patients with MSS CRC and checkpoint-naive NSCLC at the recommended Phase 2 dose of 6.0 mg/kg and expect to provide an update on this study in mid-2021.

IMGC936

IMGC936 is an ADC that targets ADAM9, a cell surface protein over-expressed in several solid tumor types. IMGC936 is being advanced under a co-development agreement with ImmunoGen, Inc. (ImmunoGen). Under the 50/50 collaboration, ImmunoGen is leading clinical development and the Phase 1 dose escalation study is currently enrolling patients with select advanced solid tumors.

Other Clinical Product Candidates (Non-Immuno-Oncology)

In addition to our immuno-oncology programs described above, through collaborations and government contracts, we retain economic rights to other clinical product candidates as described below.

MGD014

We are developing MGD014 under a contract awarded to us in September 2015 by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (contract number HHSN272201500032C). This DART molecule was designed to target the envelope protein of human immunodeficiency virus (HIV) infected cells (Env) and T cells, via their CD3 components, to redirect the immune system's T cells to kill HIV-infected cells. MGD014 could be used independently or become a key part of a "shock-and-kill" strategy in conjunction with HIV latency-reversing agents currently under development. MGD014 is our first clinical DART molecule designed to target virus-infected cells. A Phase 1 dose escalation study of MGD014 is ongoing.

Teplizumab

In 2018, we entered into an asset purchase agreement with Provention Bio, Inc. (Provention) pursuant to which they acquired our interest in teplizumab, a monoclonal antibody we had been developing for the treatment of type 1 diabetes. Teplizumab has been granted Breakthrough Therapy Designation by the FDA and PRIority MEdicines (PRIME) designation by the European Medicines Agency. In January 2021, Provention announced that a BLA for teplizumab for the delay or prevention of clinical type 1 diabetes (T1D) in at-risk individuals had been filed by the FDA, which granted Provention's request for Priority Review and assigned a PDUFA target action date of July 2, 2021. Provention has disclosed that the FDA indicated that

it is planning to hold an advisory committee meeting, tentatively scheduled for May 27, 2021. Provention is currently also evaluating teplizumab in patients with newly diagnosed insulin-dependent T1D in the Phase 3 PROTECT study.

PRV-3279

In 2018, we also entered into a license agreement with Provention pursuant to which we granted them exclusive global rights for the purpose of developing and commercializing PRV-3279 (previously known as MGD010), a CD32B × CD79B DART molecule being developed for the treatment of autoimmune indications. Provention is initially developing PRV-3279 for the interception of systemic lupus erythematosus (SLE), a chronic autoimmune disorder characterized by an abnormal overactivation of B cells and subsequent pathologic production of auto-antibodies. Provention has disclosed that it believes PRV-3279 also has the potential to prevent or reduce the immunogenicity of biotherapeutics, including but not limited to gene therapy vectors and transgenes.

Our Therapeutic Area Focus: Cancer

Cancer is a broad group of diseases in which cells divide and grow in an uncontrolled manner, forming malignancies that can invade other parts of the body. In normal tissues, the rates of new cell growth and cell death are tightly regulated and kept in balance. In cancerous tissues, this balance is disrupted as a result of mutations, causing unregulated cell division or proliferation that leads to tumor formation and growth. While tumors can grow slowly or rapidly, the dividing cells will nevertheless accumulate, and the normal organization of the tissue will become disrupted. Cancers subsequently can spread throughout the body by processes known as invasion and metastasis. Once cancer spreads to sites beyond the primary tumor, it generally becomes more difficult to treat and may be incurable. Cancer cells that arise in the lymphatic system and bone marrow are referred to as hematological malignancies. Cancer cells that arise in other tissues or organs are referred to as solid tumors. Cancer can arise in virtually any part of the body, with the most common types arising in the prostate gland, breast, lung, colon and skin. Cancer is the second leading cause of death in the United States, exceeded only by heart disease. An increasing number of people are also living longer with cancer.

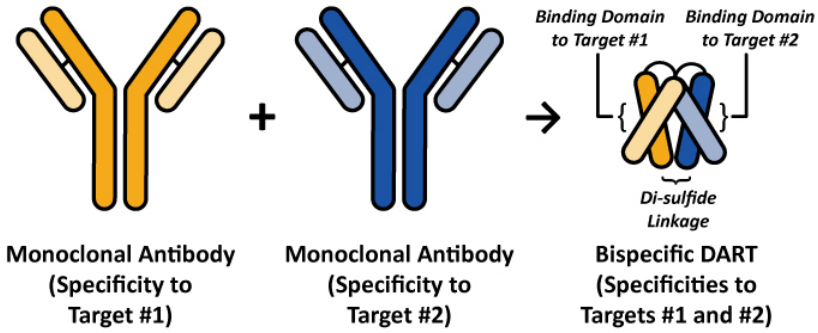
We believe that our platforms position us very well strategically to actively develop approaches for the treatment of both solid tumors and hematologic malignancies.

Our Platforms and Technology Expertise

We apply our understanding of disease biology, immune-mediated mechanisms and next generation antibody technologies to design specifically targeted antibody-based product candidates based on our DART and Fc Optimization platforms. Through these platforms we have designed antibody-based product candidates that have the potential to improve on standard treatments by having one or more of the following attributes: (1) multiple specificities; (2) increased abilities to interact with the body's immune system to fight tumors; (3) capacity to bind more avidly to antigen targets: (4) increased potency; (5) reduced immunogenicity or (6) the ability to target and kill cancer cells that are resistant to standard treatments. Moreover, these technology platforms are complementary and can be combined to address the complex biology of cancer.

DART and TRIDENT Platforms: Our Proprietary Approach to Engineer Multi-Specific Antibodies

We use our DART platform to create derivatives of antibodies with the ability to bind to two distinct targets instead of a single one found in traditional monoclonal antibodies. DART product candidates are therefore bispecific. An example of a bispecific molecule from our DART platform is illustrated below:

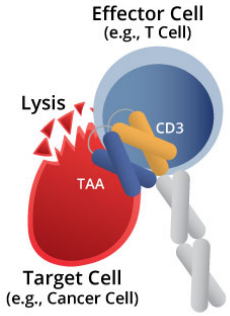


Because cancer cells have developed ways to escape the immune system, we have created DART molecules, which are alternative antibody-like structures with more potent immune properties than the parent antibody molecules from which they are derived. The two variable regions of an antibody are mono-specific and are able to target only a single type structural component of an antigen. For many years, researchers have sought to create recombinant molecules that are capable of targeting two antigens or epitopes (i.e., specific part of an antigen bound by the antibody) within the same molecule. The challenges in creating such molecules have been the instability of the resulting bispecific molecules and their inherently short half-lives, as well as the inefficiencies in manufacturing these compounds. We believe our DART platform has overcome these engineering challenges by incorporating proprietary covalent di-sulfide linkages and particular amino acid sequences that efficiently pair the chains of the DART molecule. This is designed to provide a structure with enhanced manufacturability, long-term structural stability and the ability to tailor the half-lives of the DART molecules to their clinical needs. This engineered antibody-like protein has a compact and stable structure and enables the targeting of two different antigens with a single recombinant molecule.

The DART platform has been specifically engineered to accommodate virtually any variable region sequence with predictable expression, folding and antigen recognition. We believe our multi-specific platforms may provide a significant advantage over current biological interventions in cancer, autoimmune disorders and infectious disease by enabling a range of modalities, including those described below.

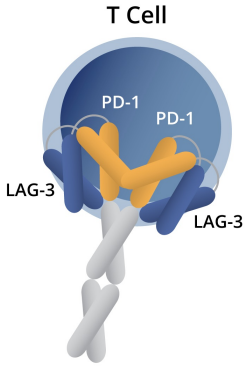
Our DART platform enables us to design multi-specific molecules that seek to exploit different mechanisms of action, including those set forth below.

- *Redirected T cell activation and killing.* In this version of the DART molecule, we are engaging the cancer-fighting properties of the immune effector cells, such as T lymphocytes to: (1) recognize and bind to proteins expressed on a cancer cell, or tumor associated antigens (e.g., CD123), (2) enable the recruitment of all types of cytotoxic, or cell killing, T cells, irrespective of their ability to recognize cancer cells (e.g., CD3, a common component of the T cell antigen receptor) and (3) trigger T cell activation, expansion, and cell killing mechanisms to destroy a cancer cell. The outcome is that any of the body's T cells, in theory, could be recruited to destroy a cancer cell and thus, are not limited to the small numbers of specific T cells that might have been generated in response to cancer to kill tumor cells. Furthermore, given the design of a DART molecule, since any T cell could be recruited for this killing process, relatively small amounts of a DART molecule may be required to trigger this potent immune response. Additionally, the compact structure of the DART protein makes it well suited for maintaining cell-to-cell contact, which we believe contributes to the high level of target cell killing. Our DART molecules that redirect T cells against cancer or other targets, including flotetuzumab, are manufactured using a conventional antibody platform without the complexity of having to genetically modify T cells from individual patients, as would be required by approaches such as CAR T cells. We have continued to evolve our bispecific platform with the introduction of a next-generation CD3-engaging DART technology designed to recruit, engage and activate T cells to kill tumor target cells with reduced release of pro-inflammatory cytokines. This next-generation CD3 DART platform is aimed at addressing cytokine-release syndrome, the most frequent and often dose-limiting adverse event associated with CD3-engaging molecules. We believe the next-generation CD3 DART platform could expand the therapeutic window of CD3-engaing DART molecules and further increase their potential application in oncology.



Product Candidates:
Flotetuzumab (CD123 x CD3)
MGD014 (HIV x CD3)

- *Targeting of multiple co-inhibitory receptors or checkpoints, such as those involved in inhibiting T cell responses.* The immune system generally prevents the development of autoimmune phenomena by regulating activated immune cells that have responded to non-self or foreign antigens. This negative feedback loop is triggered by the interactions of co-inhibitory receptors, or checkpoint molecules, expressed on the immune cells with ligands expressed by other cells, such as antigen-presenting cells. This phenomenon is exploited by cancer, whereby tumor cells express checkpoint ligands that block the development of an immune response against the tumor. Antibodies that block the interaction of checkpoint molecules with their ligands have been shown to significantly improve the clinical outcomes of patients with certain advanced cancers. Because of the diversity of immune checkpoint pathways, blockade of a single axis, while clinically significant, as shown in the case of the blockade of the PD-1/PD-L1 axis with pembrolizumab or nivolumab, will not benefit all patients. In fact, combinations of checkpoint inhibitors, such as nivolumab and ipilimumab, a CTLA-4 blocker, have resulted in significantly enhanced benefit compared to ipilimumab or nivolumab alone. We believe that DART molecules targeting two immunoregulatory pathways, such as two checkpoints in a single molecule, could afford the clinical benefit of the combination together with the potential for synergistic activity, as well as significant advantages in manufacturing, simplified clinical development, and enhanced patient convenience.



Product Candidates:
Tebotelimab (PD-1 x LAG-3)
MGD019 (PD-1 x CTLA-4)

In addition to the ability to tailor a DART molecule's valency, we have the capacity to modify the strength by which the binding sites attach to their targets and the molecule's half-life in the blood circulation after delivery to a patient. Furthermore, when an Fc domain is coupled with a DART molecule, additional changes can be included that can modulate the DART molecule's engagement with different immune cells.

We are currently developing specific product candidates using this technology, including flotetuzumab, tebotelimab, MGD019 and MGD014 in clinical trials, as well as others in preclinical development.

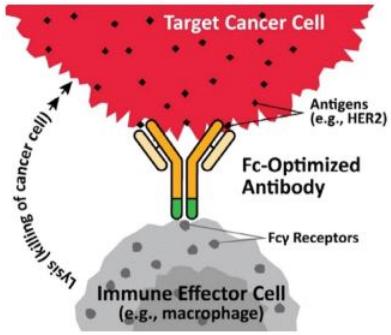
We have also advanced beyond our DART platform to establish a TRIDENT platform, which reflects the continuing evolution of our multi-specific antibody-based targeting expertise. Built on the DART module, the trivalent TRIDENT platform incorporates in an Ig-like format an additional domain capable of engaging an independent antigen. With the inclusion of a third targeting arm, TRIDENT molecules enable a broader range of mechanisms of action than bispecific targeting, allowing, for instance, the engagement of multiple antigens on a single or on different cells or enabling enhanced target selectivity by

modulating the avidity of one of two antigens. Product candidates using this technology are currently in preclinical development.

Fc Optimization Platform: Our Proprietary Approach to Enhance Immune-Mediated Cancer Cell Killing

To enhance the body's immune ability, we developed our Fc Optimization platform which introduces certain mutations into the Fc region of an antibody and is able to modulate antibody interaction with immune effector cells. Such interaction enhances the body's immune ability to mediate the killing of cancer cells through ADCC.

ADCC



The Fc region mediates the function of IgG antibodies by binding to different activating and inhibitory receptors, referred to as FcγRs, on immune effector cells found within the innate immune system. By engineering Fc regions to bind with an increased affinity to the activating FcγRs and with a reduced affinity to the inhibitory FcγRs, we have been able to impart a more effective immune response and improve effector functions, such as ADCC. This is another example in which small changes in antibody structure can confer improvements on normal immune processes.

We have established a proprietary platform to engineer, screen, identify and test antibodies' Fc regions with customizable activity. In particular, we have licenses to use transgenic mice that express human FcγRs. These mice can be used for in vivo testing of antibodies that incorporate Fc domain variants, including those antibodies intended for cancer therapy.

To date, we have successfully incorporated our Fc variants in two of our antibody-based molecules, margetuximab and enoblituzumab. In vitro, the modified Fc region of margetuximab increases binding to the activating Fc receptor FCGR3A (CD16A) and decreases binding to the inhibitor Fc receptor FCGR2B (CD32B). These changes lead to greater in vitro ADCC and NK cell activation. The clinical significance of in vitro data is unknown.

Our Collaborations

Throughout our company's history, we have entered into collaborations with other biopharmaceutical companies and plan to continue to do so. We enter into collaborations when there is a strategic advantage to us and when we believe the financial terms of the collaboration are favorable for meeting our short-term and long-term strategic objectives. We are not dependent upon any one of these collaborations, but in many cases we have rights to receive sales royalties and other significant financial payments if the partnered product candidates achieve certain development and sales milestones. We endeavor to establish collaborations that preserve our right to participate in future commercialization, for example by securing co-promotion or profit-sharing rights under certain circumstances.

We pursue a balanced approach between product candidates that we develop ourselves and those that we develop with our collaborators. Under our strategic collaborations to date, we have received significant non-dilutive funding and continue to have rights to additional funding upon completion of certain research, achievement of key product development milestones and royalties and other payments upon the commercial sale of products. Each of our collaborations has a unique set of terms and conditions.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patents intended to protect, for example, the composition of matter of our product candidates, their methods of use, the technology platforms used to generate them, related technologies and/or other aspects of the inventions that are important to our business. We also rely on trade secrets, confidentiality and invention assignment agreements and careful monitoring of our

proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business. In addition, there is cost and risk to our business in defending and enforcing our patents, maintaining our licenses to use intellectual property owned by third parties and preserving the confidentiality of our trade secrets and operating without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary positions. We currently use multiple industry-standard patent monitoring systems to monitor new United States Patent and Trademark Office (USPTO) filings for any applications by third parties that may infringe on our patents.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted by the courts after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, narrowed, circumvented or invalidated by third parties.

A third party may hold patents or other intellectual property rights that are important to or necessary for the development of our product candidates or use of our technology platforms. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. For example, certain patents held by third parties cover Fc engineering methods and mutations in Fc regions to enhance the binding of Fc regions to Fc receptors on immune cells. Although we believe that these patents are not infringed, invalid, and unenforceable, should a court find that they cover margetuximab or enoblituzumab and we are unable to invalidate them, or if licenses for them are not available on commercially reasonable terms, our business could be harmed, perhaps materially.

Because patent applications in the United States and certain other jurisdictions can be maintained in secrecy for 18 months or potentially even longer, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention. In the ordinary course of business we participate in post-grant challenge proceedings, such as oppositions, that challenge the patentability of third party patents. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

Pipeline Patent Protection

As of December 31, 2020, we held 82 patents in the United States with 50 patent applications pending and 534 patents in other countries of the world with 563 patent applications pending. In addition to patents and patent applications generally providing protection for various aspects of our Fc Optimization, DART, and TRIDENT platforms, we have patent and patent applications for the composition of matter of each of our clinical pipeline product candidates and, in some cases, we also have other patents and patent application related to various aspects of the technology underlying these product candidates or their methods of use.

Patent terms may be adjusted or extended, as described in greater detail below, in certain circumstances. However, assuming no adjustments or extensions, the primary composition of matter patent for each of our clinical pipeline product candidates is expected to expire in the following timeframes:

Product Candidate	Expiration Date
margetuximab	2029
enoblituzumab	2031
flotetuzumab	2034
retifanlimab	2036
tebotelimab	2036*
MGD019	2036*
MGC018	2037*

* *pending*

Patent Term Extension and Reference Product Exclusivity

The Hatch-Waxman Act permits a patent term extension for FDA-approved drugs, including biological products, of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our pharmaceutical product candidates receive FDA approval, we have applied or expect to apply for patent term extensions on patents covering those products. We intend to seek, and are seeking, patent term extensions to our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Affordability Reconciliation Act (collectively the ACA) created a regulatory scheme authorizing the FDA to approve biosimilars via an abbreviated licensure pathway. In many cases, this allows biosimilars to be brought to market without conducting the full suite of clinical trials typically required of originators. Under the ACA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." The "biosimilar" application must include specific information demonstrating biosimilarity based on data derived from: (1) analytical studies, (2) animal studies, and (3) a clinical study or studies that are sufficient to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed, except that FDA may waive some of these requirements for a given application. Under this new statutory scheme, an application for a biosimilar product may not be submitted to the FDA until four years after the date of first licensure. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was first licensed. The law does not change the duration of patents granted on biological products. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. There have been recent proposals to repeal or modify the ACA and it is uncertain how any of those proposals, if approved, would affect these provisions.

Trade Secrets

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In many cases our confidentiality and other agreements with consultants, outside scientific collaborators, sponsored researchers and other advisors require them to assign or grant us licenses to inventions they invent as a result the work or services they render under such agreements or grant us an option to negotiate a license to use such inventions.

In-Licensed Intellectual Property

We have entered into patent and know-how license agreements that grant us the rights to use certain technologies related to biological manufacturing for our clinical product candidates. We anticipate using these technologies for future product candidates. These licensors have businesses dedicated to licensing this type of technology and we anticipate that licenses to use these technologies for our future products will be available. The licenses typically include yearly maintenance payments and sales royalties, and may also include upfront payments or milestone payments.

Manufacturing

We currently manufacture drug substance for most of our clinical trials at our manufacturing facilities located in Rockville, Maryland. We also rely on contract manufacturers, primarily Byondis, for production of our ADC candidates. We have supplemented our drug substance manufacturing capacity through an arrangement with AGC Biologics, Inc. (AGC, formerly CMC Biologics, Inc.), a contract manufacturing organization, and are commercially producing margetuximab at AGC. We also intend to commercially produce material for our and our partner's product candidates, when and if approved by the FDA. In addition, we currently rely on and will continue to rely on contract fill-finish service providers, primarily Ajinomoto Bio-Pharma Services and Baxter Healthcare Corporation, to fulfill our fill-finish needs for our current and future product candidates.

Most of the principal materials we use in our manufacturing operations are available from more than one source. However, we obtain certain raw materials principally from only one source. In the event one of these suppliers was unable to provide the materials or product, we generally seek to maintain sufficient inventory to supply the market until an alternative source of supply can be implemented. However, in the event of an extended failure of a supplier, it is possible that we could experience an interruption in supply until we established new sources or, in some cases, implemented alternative processes.

Production processes for biological therapeutic products are complex, highly regulated, and vary widely from product to product. Shifting or adding manufacturing capacity can be a very lengthy process requiring significant capital expenditures, process modifications, and regulatory approvals. Accordingly, if we were to experience extended plant shutdowns at one of our own facilities, extended failure of a contract supplier or contract manufacturing organization, or extraordinary unplanned increases in demand, we could experience an interruption in supply of certain products or product shortages until production could be resumed or expanded.

Commercialization

MARGENZA is currently our only approved product in the U.S. In November 2020, we partnered with EVERSANA, a pioneer of next-generation commercial services to the global life sciences industry, to commercialize margetuximab in the U.S. by leveraging their integrated commercial services. Under the terms of the agreement, we maintain ownership of margetuximab, including all manufacturing, regulatory and development responsibilities for the product. EVERSANA received a co-exclusive right to conduct approved commercialization activities. EVERSANA will utilize its internal capabilities to support sales and marketing, market access, channel management services, data and analytics, medical affairs, and other patient access related services; we will book MARGENZA sales. We and EVERSANA equally share in funding EVERSANA's commercialization expenses. In exchange for co-funding these expenses, EVERSANA will earn future revenue share payments which shall be capped at 125% of EVERSANA's cumulative service fees. The term of the agreement is five years following the date of FDA approval, subject to predefined termination provisions.

We cannot market or promote a new product in a country until a marketing application has been approved by the appropriate regulatory authority for that jurisdiction. Subject to receiving marketing authorization in a jurisdiction, we believe we will be able to commercialize in that market through arrangements with third-party commercial partners. Other than through our arrangement with EVERSANA for MARGENZA, we have not established a sales, marketing or distribution capabilities. If we are unable to enter into third-party commercial arrangements for other product candidates with respect to the United States, we believe that we could potentially put in place an appropriately sized organization to commercialize our approved product or products. Outside the United States, our strategy is to enter into arrangements with third-party commercial partners for any of our product candidates that obtain marketing approval.

Competition

There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. These treatments consist both of small molecule drug products, as well as biologic therapeutics that work by using next-generation antibody technology platforms to address specific cancer targets. In particular, MARGENZA is directed against HER2 and several companies have cancer therapeutics directed against HER2 that are either currently approved and on the market or in development, such as F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (Roche), particularly through its affiliate, Genentech, Inc., as well as Puma Biotechnology, Inc., Daiichi Sankyo

Company, Limited and AstraZeneca plc. (AstraZeneca), Seagen Inc., Zymeworks, Inc., and Byondis, many of which have significantly greater resources than we do. Market competition may limit the utilization of MARGENZA as a therapeutic, even if market approval and adequate reimbursement is obtained, and competition among development-stage programs for patients enrolling in clinical trials for HER2-directed therapies may delay expected timelines for our clinical trials.

In addition, the immuno-oncology field is competitive, with treatments currently approved and on the market or in development for various tumor types and patient populations from a variety of different companies such as Merck & Co., Inc. (Merck), The Bristol-Myers Squibb Company (BMS), and Roche, all of which have significantly greater resources than we do. Many of our pipeline programs, if successful, will likely face significant competition both by therapeutics that are already being marketed as well as those that will be approved for marketing before our programs. In particular, we are developing PD-1-directed product candidates, including a monoclonal antibody that we have outlicensed and two DART molecules. Merck, BMS, Roche, AstraZeneca, Pfizer Inc., Merck KGaA, and Regeneron Pharmaceuticals, Inc. all have approved products that target either the PD-1 receptor or its ligand, PD-L1, and there are several other companies that have anti-PD-1 or anti-PD-L1 antibodies in clinical development, all of which would compete with our PD-1-directed programs. In addition, these and other companies are developing product candidates directed against other immuno-oncology targets that we are pursuing through our bispecific approaches.

Finally, several companies are also developing therapeutics that work by targeting multiple specificities using a single recombinant molecule. Amgen Inc. has obtained marketing approval for one product that works by targeting antigens both on immune effector cell populations and those expressed on certain cancer cells, and has other product candidates in development that use this mechanism. In addition, other companies are developing new treatments for cancer that utilize multi-specific approaches, including Abbvie Inc., Affimed Therapeutics AG Corporation, Eli Lilly and Company, Genmab A/S, Merus B.V., Regeneron, Roche, AstraZeneca, Xencor, Inc. and Zymeworks, Inc.

Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic 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. These competitors also compete with us in recruiting and retaining top qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting the success of all of our therapeutic product candidates, if approved, are likely to be their efficacy, safety, dosing convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic or biosimilar competition and the availability of reimbursement from government and other third-party payors. In addition, the standard of medical care provided to cancer patients continues to evolve as more scientific and medical information becomes available. These changes in medical care relate to pharmaceutical products, but are also affected by other factors, and such changes can positively or negatively affect the prospects of our product candidates as well as those of our competitors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe effects, are more convenient or are less expensive than any products that we may develop, or the standards of care for cancer patients change while our clinical trials are ongoing. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third party payors seeking to encourage the use of biosimilar products. Biosimilar products are expected to become available over the coming years. For example, trastuzumab biosimilars have been approved in the U.S. by FDA.

The most common methods of treating patients with cancer are surgery, radiation and drug therapy. There are a variety of available drug therapies marketed for cancer. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third party payors. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates may compete with many existing drug and other therapies, to the extent an approved drug is ultimately used in combination with or as an adjunct to these therapies, our product candidates will not be competitive with the approved drug.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing.

The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

FDA Regulation

All of our current product candidates are subject to regulation in the United States by the FDA as biological products (biologics). The FDA subjects biologics to extensive pre- and post-market regulation. The Public Health Service Act, the Federal Food, Drug, and Cosmetic Act (FDCA) and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of biologics. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending BLAs, withdrawal of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, or criminal penalties.

Preclinical Studies. Drug development in our industry is complex, challenging and risky; failure rates are high. Product development cycles are long - approximately 10 to 15 years from discovery to market. A potential new biological product must undergo many years of preclinical and clinical testing to establish it is pure, potent and safe.

Preclinical studies include laboratory evaluation of product chemistry, formulation and toxicity, pharmacology, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including FDA's good laboratory practice (GLP) regulations and the U.S. Department of Agriculture's regulations implementing the Animal Welfare Act. After laboratory analysis and preclinical testing in animals, we file an Investigational New Drug (IND) application with the FDA to begin human testing. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature, and a proposed clinical trial protocol, among other things, to the FDA as part of an IND application. Certain preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue even after the IND application is submitted. An IND application 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 clinical trial on a clinical hold or agrees on an alternate approach with us. 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 application may not result in the FDA allowing clinical trials to commence.

Clinical Development. Clinical trials involve the administration of the investigational drug to human subjects (healthy volunteers or patients) under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with all applicable federal regulations and guidance, including those pertaining to good clinical practice (GCP) standards that are meant to protect the rights, safety, and welfare of human subjects and to define the roles of clinical trial sponsors, investigators, and monitors; as well as (ii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing of a new drug in the United States (whether in patients or healthy volunteers) must be included in the IND application submission, and FDA must be notified of subsequent protocol amendments. In addition, the protocol must be reviewed and approved by an institutional review board (IRB) and all study subjects must provide informed consent prior to participating in the study. Typically, each institution participating in the clinical trial will require review of the protocol before any clinical trial commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health (NIH) for public dissemination on their ClinicalTrials.gov website. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and there are additional, more frequent reporting requirements for suspected unexpected serious adverse events.

A study sponsor might choose to discontinue a clinical trial or a clinical development program for a variety of reasons. The FDA may impose a temporary or permanent clinical hold, or other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support BLAs for marketing approval are typically conducted in three pre-approval phases, but the phases may overlap or be combined, particularly in testing for oncology indications. In Phase 1, testing is conducted in a small group of subjects who may be patients with the target disease or condition or healthy volunteers, to evaluate its safety, determine a safe dosage range, and identify side effects. In Phase 2, the drug is given to a larger group of subjects with the target condition to further evaluate its safety and gather preliminary evidence of efficacy. Phase 3 studies typically last multiple years for oncology indications. In Phase 3, the drug is given to a large group of subjects with the target disease or condition (several hundred to several thousand), often at multiple geographical sites, to confirm its effectiveness, monitor side effects, and

collect data to support drug approval. In some cases, FDA may require post-market studies, known as Phase 4 studies, to be conducted as a condition of approval in order to gather additional information on the drug's effect in various populations and any side effects associated with long-term use. Depending on the risks posed by the drugs, other post-market requirements may be imposed. Only a small percentage of investigational drugs complete all three phases and obtain marketing approval.

Product Approval. After completion of the required clinical testing, a BLA can be prepared and submitted to the FDA. FDA approval of the BLA is required before marketing of the product may begin in the United States. The BLA must include the results of preclinical, clinical and other testing and a compilation of data relating to the product's chemistry, manufacture and controls. The cost of preparing and submitting a BLA is substantial. Under federal law, the submission of most BLAs is additionally subject to a substantial application user fee, and annual program user fees also apply. These fees are typically increased annually.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the FDA's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins a substantive review, and the review period under the PDUFA begins. The standard for reviewing a BLA is whether the product is safe, pure and potent, which has been interpreted to include that the product is safe and effective and has a favorable benefit-risk profile. FDA's current performance goals call for FDA to complete review of 90 percent of standard (non-priority) BLAs within 10 months of filing and within six months for priority BLAs, which is 12 months and eight months, respectively, if the 60-day review of the initial application is included in the timeline. In addition, the FDA has developed approaches intended to make certain qualifying products available to patients rapidly - Priority Review, Breakthrough Therapy, Accelerated Approval, and Fast Track. While the timelines for approval under these pathways may be shorter, there are requirements and conditions associated with each pathway, and there can be no assurance that any of our investigational products will be able to meet the conditions or requirements necessary to receive any such designation or be able to receive the review or approval benefits associated with such designations.

The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes outside clinicians and other experts, for review, evaluation and a recommendation as to whether sufficient data exist in the application to support product approval. The FDA is not bound by the recommendation of an advisory committee, but it generally gives significant deference to such recommendations.

Before approving a BLA, the FDA will typically inspect one or more clinical sites and possibly the sponsor itself to assure compliance with GCP. Additionally, the FDA will typically inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current Good Manufacturing Practices (cGMPs) is satisfactory. FDA also reviews the proposed labeling submitted with the BLA and typically requires changes in the labeling text.

After the FDA evaluates the BLA and the manufacturing and testing facilities, it issues either an approval letter or a complete response letter. Complete response letters generally outline the deficiencies in the submission and delineate the additional testing or information needed in order for the FDA to reconsider the application. If and when deficiencies outlined in a complete response letter have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing 90 percent of resubmissions within two or six months from receipt depending on the type of information included.

An approval letter authorizes commercial marketing of the drug for the approved indication or indications and the other conditions of use set out in the approved prescribing information. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

As a condition of BLA approval, the FDA may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions that can materially affect the potential market and profitability of the product. As a condition of approval, or after approval, the FDA also may require submission of a risk evaluation and mitigation strategy (REMS) to mitigate any identified or suspected serious risks. The REMS may include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

Other U.S. Post-Marketing Regulatory Requirements. Once a BLA is approved, a product will be subject to certain post-approval requirements, including those relating to advertising, promotion, adverse event reporting, recordkeeping, and cGMPs, as well as registration, listing, and inspection. There also are continuing, annual program user fee requirements for marketed products, as well as new application fees for supplemental applications with clinical data.

FDA regulates the content and format of prescription drug labeling, advertising, and promotion, including direct-to-consumer advertising and promotional Internet communications. FDA also establishes parameters for permissible non-

promotional communications between industry and the medical community, including industry-supported scientific and educational activities. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion for uses not consistent with the approved labeling, and a company that is found to have improperly promoted off-label uses or otherwise not to have met applicable promotion rules may be subject to significant liability under both the FDCA and other statutes, including the False Claims Act. See "Other Healthcare Laws and Compliance Requirements" below for more information.

All aspects of pharmaceutical manufacture must conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA during which the FDA inspects manufacturing facilities to assess compliance with cGMPs. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs.

Products may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, product formulation or manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement, in some cases before the change may be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

Manufacturers are subject to requirements for adverse event reporting and submission of periodic reports following FDA approval of a BLA. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, or failure of Phase 4 studies to meet their specified endpoints, may result in revisions to the approved labeling to add new safety information, the need to conduct additional post-market studies or clinical trials to assess new safety risks, imposition of distribution or other restrictions under a REMS program, or recall of the product and withdrawal of the BLA.

Noncompliance with post-marketing requirements can result in one or more of the following consequences:

- Restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- Warning letters;
- Holds on post-approval clinical trials;
- Refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;
- Product seizure or detention, or refusal to permit the import or export of products; or
- Injunctions or the imposition of civil or criminal penalties.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (PDMA) which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Approval of Biosimilars. The ACA authorized the FDA to approve biosimilars via a separate, abbreviated pathway. In many cases, this allows biosimilars to be brought to market without conducting the full suite of clinical trials typically required of originators. The law establishes a period of 12 years of exclusivity for reference products in order to preserve incentives for future innovation, and outlines statutory criteria for science-based biosimilar approval standards that take into account patient safety considerations. Under this framework, exclusivity protects innovator products by prohibiting others, for a period of 12 years, from being granted FDA approval based in part on reliance on or reference to the innovator's data in their application to the FDA. The law does not change the duration of patents granted on biological products. There are regular legislative proposals to rescind or reduce the biologics exclusivity provisions of the ACA and it is uncertain whether or if any of those proposals may be approved, and if approved, how exclusivity for biologics would be affected.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by federal, state, and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments.

For example, certain financial interactions with healthcare professionals may be subject to the anti-kickback and fraud and abuse provisions of the Social Security Act and the False Claims Act, and in addition our activities may be affected by the privacy regulations issued under the Health Insurance Portability and Accountability Act, as amended, and similar state laws.

International Regulation

In addition to regulations in the United States, we and our collaborators, may be subject to a variety of foreign regulations governing clinical trials, drug registration, commercial sales and distribution of our product candidates outside the United States. These regulations can vary between jurisdictions and can be more onerous than regulations in the United States. Whether or not we obtain FDA approval for a product candidate, we must obtain approval from the comparable regulatory authorities of foreign countries or economic areas, such as the European Union (EU) before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time to approval may be longer or shorter than that required for FDA approval.

Certain countries outside of the United States have a process that requires the submission of a clinical trial application (CTA) much like an IND prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country. In all cases, the clinical trials must be conducted in accordance with GCP, and other applicable regulatory requirements. A separate CTA must be submitted for each clinical trial to be conducted.

In the EU, for example, to obtain regulatory approval of an investigational medicinal product, we must submit a marketing authorisation application (MAA). The content of the MAA is similar to that of a New Drug Application or BLA filed in the United States, with the exception of, among other things, EU-specific document requirements. Under the EU regulatory system, a company may submit marketing authorisation applications either under a centralised or decentralised procedure. Under the centralised procedure in the EU, a MAA is submitted to the European Medicines Agency (EMA) where it will be evaluated by the Committee for Medicinal Products for Human Use (CHMP). The maximum timeframe for a CHMP evaluation of an MAA that has been validated is 210 days, excluding time taken by an applicant to respond to questions. A favorable opinion on the application by the CHMP will typically result in the granting of the marketing authorisation by the European Commission within 67 days of receipt of the opinion. Generally, the entire review process takes approximately 13-14 months. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days, excluding time taken by an applicant to respond to questions.

As in the United States, we or our collaborators may apply for designation of a product as an orphan drug for the treatment of a specific indication in the EU before the MAA is made. Orphan drugs in Europe enjoy certain benefits, including up to 10 years of exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan designated product. The PRIME initiative was established by the EMA to help promote and foster the development of new medicines in the EU that demonstrate potential for a major therapeutic advantage in areas of unmet medical need. Benefits from the PRIME designation include early confirmation of potential for accelerated assessment, early dialogue and increased interaction with relevant regulatory committees to discuss development options, scientific advice at key development milestones, and proactive regulatory support from the EMA.

If we, or our collaborators, 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.

BioPharmaceutical Coverage, Pricing, and Reimbursement

In the United States and other countries, sales of any future products for which we receive regulatory approval for commercial sale will depend in part on the availability of adequate reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers, and other organizations. Third-party payors are increasingly examining the medical necessity and cost effectiveness of medical products and services in addition to safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved

therapeutics. Third-party reimbursement adequate to enable us to realize an appropriate return on our investment in research and product development may not be available or optimal for our products.

Drug prices have become a subject of increased focus in recent years. Although there are currently no direct government price controls over private sector purchases in the U.S., federal law requires pharmaceutical manufacturers to pay prescribed rebates on certain government or Medicaid-reimbursed drugs to enable them to be eligible for reimbursement under certain public healthcare programs such as Medicaid and Medicare Part B. Various states have adopted further mechanisms that seek to control drug prices, including by disfavoring certain higher priced drugs or by seeking supplemental rebates from manufacturers. Managed care has also become a potent force in the market place that increases downward pressure on the prices of pharmaceutical products.

Public and private healthcare payers control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payers also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered.

Employees

As of December 31, 2020, we had 370 full-time employees, 314 of whom were primarily engaged in research, development and manufacturing activities, and 73 of whom had an M.D. and/or Ph.D. Our employees are critically important to the achievement of our company's mission and goals. We periodically conduct employee engagement surveys to understand our employees' perspectives and endeavor to address, improve, or build on how we work together in response to these perspectives. We face significant competition for experienced and talented individuals in our area due to the growth of local companies. We monitor our compensation, benefits, and exit interview data and make changes as needed to enable the ongoing recruitment and selection of talented new employees, as well as to retain existing talent. We strive to offer our employees an intellectually challenging and diverse work environment, opportunities to expand their knowledge and skills and receive feedback on performance, and for career advancement. Our Living Values, which focus on patients, honest and transparent communications, innovation, ethics, collaboration, our sense of urgency and getting results, set the tone for how we work together.

We empowered a cross-functional team in the early days of the ongoing pandemic to recommend safety protocols, ensure timely communications, and make decisions related to the effect of COVID-19 on our employees and work environment. We believe management's relationships with our employees is very positive and they are not subject to a collective bargaining agreement or represented by a trade or labor union.

Available Information

Our website address is www.macrogenics.com. We post links to our website to the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission (SEC): annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, and any amendments to those reports filed or furnished pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. All such filings are available through our website free of charge. In addition, the SEC makes available at its website (www.sec.gov), free of charge, reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

ITEM 1A. RISK FACTORS

The discussion below addresses material factors, of which we are currently aware, that could have a material and adverse effect on our business, results of operations and financial condition. Many of the following risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. These risk factors and other forward-looking statements that relate to future events, expectations, trends and operating periods involve certain factors that are subject to change, and important risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties should not be considered a complete discussion of all the risks and uncertainties we may face and although the risks are organized by headings and each risk is discussed separately, many are interrelated.

Summary of Risk Factors Affecting Our Business

Our business is subject to numerous risks. The following summary highlights some of the risks you should consider with respect to our business and prospects. This summary is not complete and the risks summarized below are not the only risks we face. You should review and consider carefully the risks and uncertainties described in the "Risk Factors" section of this Annual Report on Form 10-K, which includes a more complete discussion of the risks summarized below as well as a discussion of other risks related to our business and an investment in our common stock, as well as our other SEC filings.

- We depend substantially on the success of the clinical development of our products and product candidates. If we are unable to successfully complete clinical development, obtain additional regulatory approvals and commercialize our products and product candidates, or experience significant delays in doing so, our business will be materially harmed.

- MARGENZA, or any other product candidate that we may develop, may fail to achieve market acceptance by physicians, patients, third-party payors and others in the medical community necessary, diminishing any potential commercial success.

- We have limited experience in launching and marketing biopharmaceutical products. If we are unable to further develop marketing and sales or other commercialization capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate substantial product sales revenue.

- We face significant competition and if our competitors develop and market products that are more effective, have a more favorable safety profile, or are less expensive than MARGENZA and our product candidates, our commercial opportunities may be negatively impacted.

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

- If clinical trials for our product candidates are prolonged, delayed or stopped, for any reason, we may be unable to obtain regulatory approval and commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any product revenue.

- The results of previous clinical trials may not be predictive of future results, and interim or top line data may be subject to change or qualification based the complete analysis of data. In addition, the results of our current or planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities for product approval.

- We use or may use novel technologies in the development of our product candidates and the FDA and other regulatory authorities have not approved or may not approve products that utilize these technologies.

- We may not be successful in our efforts to use and expand our technology platforms to build a pipeline of product candidates. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

- We and/or our collaboration partners may never obtain approval of, or commercialize, our products outside of the United States, which would limit our ability to realize the products full market potential.

- Our product candidates may have undesirable side effects which may delay or prevent further clinical development or marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

- The manufacture of MARGENZA and our product candidates, for ourselves and our collaborators, is complex, and we may encounter difficulties in production.

- We have limited experience in large-scale or commercial manufacturing, and there can be no assurance that we will be able to effectively manufacture clinical or commercial quantities of our products.

- Our manufacturing facilities are subject to significant government regulations and approvals, which are often costly and could result in adverse consequences to our business if we fail to comply with the regulations or maintain the approvals.

- Reimbursement decisions by third-party payors, including government payors, may have an adverse effect on pricing and market acceptance.

- Actual or anticipated changes to the laws and regulations governing the health care system may have a negative impact on cost and access to health insurance coverage and reimbursement of healthcare items and services.

- If any product liability lawsuits are successfully brought against us or any of our collaborators, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

- The current or future impact of the COVID-19 (or any variant thereof) pandemic may have significant negative impact on our clinical trials, preclinical studies, commercialization of MARGENZA, development, manufacturing and commercialization of our product candidates and other aspects of our business, staff, and operations. The extent to which the COVID-19 pandemic, both now and in the future, adversely affects our financial condition, results of operations, and liquidity, will depend on future developments, including but not limited to the measures taken by public and private entities in response to the pandemic, which remain highly uncertain and cannot be predicted.

- We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future.

- We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back, or cease our product development programs or operations.

- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish substantial rights.

- Our inability, or the inability of third-party contractors, to successfully develop or commercialize companion diagnostics, assays, or other tests either for use with our product candidates, or to aid physicians and patients in making treatment decisions, could harm our ability to commercialize our product candidates.

- We contract with third parties for the manufacturing, distribution and commercialization of MARGENZA and we may contract with third parties for the manufacture, distribution, or commercialization of some of our product candidates for clinical testing in the future.

- Our commercial success depends significantly on our ability to operate without infringing the valid patents and other proprietary rights of third parties.

- If we are unable to obtain and enforce adequate patent protection for MARGENZA and our other product candidates and related technologies, our business could be materially harmed.

- If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

- If we do not comply with the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, our business could be adversely affected.

- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

- We are subject to securities litigation, which is expensive and could divert management attention and adversely impact our business.

Risks Related to Our Business and the Development and Commercialization of Our Products and Product Candidates

We depend substantially on the success of the clinical development of our products and product candidates. If we are unable to successfully complete clinical development, obtain additional regulatory approvals and commercialize our products and product candidates, or experience significant delays in doing so, our business will be materially harmed.

Our business depends on the successful development, regulatory approval and commercialization of our products and product candidates, such as MARGENZA, for which in December 2020 we obtained FDA approval, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. MARGENZA is our first product approved for sale and we expect MARGENZA will be available to patients in the U.S. in March 2021. We have invested a significant portion of our efforts and financial resources in the development of our products and product candidates, including MARGENZA. The success of our products and product candidates depends on many factors, including but not limited to:

- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies;

- safety and favorable efficacy and acceptable safety data from our clinical trials and other studies;

- receipt of regulatory approvals;

- establishing commercial manufacturing capabilities, either by building out and expanding our current manufacturing facilities or making arrangements with third-party manufacturers;

- the performance by clinical research organizations (CROs) or other third parties we may retain of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;

- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;

- ensuring we do not infringe, misappropriate or otherwise violate the valid patent, trade secret or other intellectual property rights of third parties;

- successfully launching our products, such as MARGENZA, and our other product candidates, if and when approved;

- obtaining favorable reimbursement from third-party payors for products and product candidates;

- competition with other products;

- post-marketing commitments to regulatory agencies following regulatory approval;

- continued acceptable safety profile following regulatory approval; and

- manufacturing or obtaining sufficient supplies of our products and product candidates that may be necessary for use in clinical trials for evaluation of our product candidates and commercialization of our products.

If we do not achieve and maintain one or more of these factors in a timely manner or at all, we could experience significant delays in our ability to, or be unable to obtain additional regulatory approvals for, and/or to successfully commercialize our products and product candidates, which would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

MARGENZA or any other product candidate that we develop may fail to achieve market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

MARGENZA or any other product candidates that we develop may fail to gain market acceptance by physicians, patients, third-party payors and others in the medical community. If MARGENZA or any such product candidate that we develop does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of MARGENZA or any other product candidates that we develop will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of physicians to prescribe MARGENZA or other new therapies, and of the patient population to try MARGENZA or these therapies;
- the strength of marketing, sales, and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; any safety events that may have occurred in connection with the development of the product candidate; and
- any restrictions on the use of our products together with other medications.

MARGENZA's market acceptance depends significantly on the medical community's determination of clinical benefit and safety compared to alternative therapies available both now and in the future. Several new therapies for the treatment of HER2-positive breast cancer have recently been approved. Certain of these therapies may have or may be perceived to have greater efficacy benefits than MARGENZA in clinical trials. Competition from recently approved therapies may adversely impact the market acceptance of MARGENZA. In addition, market acceptance and the medical community determination of clinical benefit may depend significantly on the pending results of the final Overall Survival (OS) endpoint data from the SOPHIA trial, which MARGENZA result may not be favorable compared to trastuzumab, or, even if favorable compared to trastuzumab, may not be statistically significant, clinically meaningful or favorable when compared to other available or future therapies.

In addition, the potential market opportunity for MARGENZA is difficult to precisely estimate. Our internal estimates of the potential market opportunity for MARGENZA include several key assumptions based on our industry knowledge, industry publications, third-party research reports, assessment of competition, and other surveys. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of these assumptions proves to be inaccurate, then the actual market for MARGENZA could be smaller than our estimates of our potential market opportunity. If the actual market for MARGENZA is small, and/or smaller than we expect, our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

We have limited experience in launching and marketing our internally developed products. If we are unable to further develop marketing and sales capabilities or enter into agreements with third parties to market and sell our products, or our existing arrangements are not successful, we may not be able to generate substantial product sales revenue.

In December 2020, the FDA approved MARGENZA, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. We expect to launch MARGENZA in March 2021. In conjunction with EVERSANA we continue to build commercialization support in United States to commercialize MARGENZA. We have limited internal commercialization capabilities, and any additional products or product candidates that we may develop or in-license, will require significant capital expenditures, management resources and time.

We have limited experience in commercializing our internally developed products, such as MARGENZA. For example, we have limited experience in building and managing a commercial team, conducting a comprehensive market analysis, obtaining state licenses and reimbursement, or managing distributors and a sales force for our products. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. As a result, although we have partnered with EVERSANA to commercialize MARGENZA, our ability to successfully commercialize

MARGENZA or any of our products may involve more inherent risk, take longer, and cost more than it would if we were a company with substantial experience launching products.

For commercialization of any or all of our product candidates, 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 to, or decide not to, further develop internal sales, marketing, and commercial distribution capabilities for any or all of our products, we will likely pursue additional 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. We would 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 products ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our products.

There can be no assurance that we will be able to further develop and successfully maintain internal sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and as a result, we may not be able to generate substantial product sales revenue.

We face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than MARGENZA and our product candidates, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive and subject to rapid and significant technological change. Our approved product, MARGENZA, competes with, and our product candidates under development (if approved) will compete with, drugs and therapies that currently exist or are being developed. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed, or may have succeeded, in obtaining patent protection and/or FDA approval or discovering, developing and commercializing products in our field before we do.

Specifically, there are a large number of companies developing or marketing potential treatments for cancer, including many major pharmaceutical and biotechnology companies. These treatments consist both of small molecule drug products, as well as biologic therapeutics that work by using next-generation antibody technology platforms to address specific cancer targets. In addition, several companies are developing therapeutics that work by targeting multiple specificities using a single recombinant molecule. See “Competition” above for additional information.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. For example, Daiichi Sankyo Inc.'s product ENHERTU® (fam-trastuzumab deruxtecan-nxki) and Seagen’s product TUKYSA™ (tucatinib) both recently launched in the United States in patient populations that potentially compete with the patient population for MARGENZA. This could result in, or has resulted in, our competitors establishing a strong market position before we are able to enter the market. In addition, both ENHERTU and TUKYSA demonstrated greater efficacy results than MARGENZA in clinical trials. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of biosimilar products. For example, certain HER2 biosimilar products are approved in certain countries, including the United States, and others may be approved prior to commercialization of, or market acceptance of, MARGENZA. MARGENZA and product candidates, if approved, may be priced at a significant premium over competitive biosimilar products.

Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be

unable to compete effectively. Technological advances or products developed by our competitors may render our technologies, products or product candidates obsolete, less competitive or not economical.

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

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and non-U.S. regulatory authorities, which regulations differ from country to country. We are not permitted to market our product candidates in the United States or in other countries until we receive approval of a Biologics License Application (BLA) from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in drug development. For example, in December 2020, the FDA approved the BLA for MARGENZA. MARGENZA is our first product approved for sale in any jurisdiction. In addition, our collaborator Incyte submitted a BLA for retifanlimab in January 2021. Obtaining approval of a BLA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and non-U.S. regulatory requirements may, either before or after product approval, subject our company or our collaborators to administrative or judicially imposed sanctions, including:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers, manufacturing facilities or manufacturing process;
- warning letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending BLAs or supplements to approved BLAs or analogous marketing approvals outside the United States.

The FDA and foreign regulatory authorities also have substantial discretion in the drug approval process. The number of preclinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular drug candidate. Regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including:

- a product candidate may not be deemed safe or effective;
- the results may not confirm the positive results from earlier preclinical studies or clinical trials;
- regulatory agencies may not find the data from preclinical studies and clinical trials sufficient or meaningful;
- regulatory agencies might not approve or might require changes to our manufacturing processes or facilities; or
- regulatory agencies may change their approval policies or adopt new regulations.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price. Furthermore, any regulatory approval to market a product may be subject to limitations on the

indicated uses for which we may market the product. These limitations may limit the size of the potential market for a product candidate, if approved.

Even if we and our collaborators obtain regulatory approvals to market our current and any future approved products, we and our collaborators will remain subject to extensive ongoing regulatory obligations and oversight, including post-approval requirements, that could result in significant additional expense and could negatively impact our and our collaborators' ability to commercialize our current and any future approved products.

We and our collaborators are subject to extensive ongoing obligations and continued regulatory review from applicable regulatory agencies with respect to any product obtaining regulatory approval, including MARGENZA, such as continued adverse event reporting requirements and post-marketing commitments, all of which may result in significant expense and limit our and our collaborators' ability to commercialize our current and any future approved products. For example, the FDA's approval of MARGENZA included a requirement that we provide to the FDA the data from the final overall survival endpoint from our SOPHIA study, when available. Unfavorable overall survival results could result in the withdrawal of approval of MARGENZA or the inclusion of unfavorable safety information in our product labeling, or diminished market opportunity or acceptance, which could seriously harm our business. Moreover, in connection with MARGENZA's approval, the labeling and advertising and promotion of MARGENZA are subject to additional regulatory requirements, which could entail significant expense and could negatively impact the potential commercialization of MARGENZA. In addition, the use of MARGENZA may uncover additional adverse events that limit or prevent MARGENZA's widespread use or that force us to withdraw MARGENZA from the market, and any problems with MARGENZA or any violation of ongoing regulatory obligations could result in restrictions on MARGENZA, including its withdrawal from the market. To the extent other product candidates or those of our partners are approved by the FDA, we or our collaborators may be subject to similar post-marketing obligations.

We and the manufacturers of our current and any future approved products are also required, or will be required, to comply with current Good Manufacturing Practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products and product candidates, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject an approved product, its manufacturer and the manufacturer's facilities to continual review and inspections, including periodic unannounced inspections. The subsequent discovery of previously unknown problems with our current or any future approved products, including adverse events of unanticipated severity or frequency, or problems with the facilities where our current or any future approved products are manufactured, may result in restrictions on the marketing of our current or any such future approved products, up to and including withdrawal of the affected product from the market. If our manufacturing facilities, our collaborators' manufacturing facilities, or those of our respective suppliers, fail to comply with applicable regulatory requirements, such noncompliance could result in regulatory action and additional costs to us.

Failure to comply with applicable FDA and other regulatory requirements may subject us to administrative or judicially imposed sanctions, including:

- issuance of Form FDA 483 notices or Warning Letters by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties;
- criminal prosecutions;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing clinical trials;
- total or partial suspension of manufacturing;
- delays in commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us;
- refusals to permit drugs to be imported into or exported from the United States;
- restrictions on operations, including costly new manufacturing requirements; and

- product recalls or seizures.

The policies of the FDA and other regulatory agencies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or of MARGENZA in any additional indications or territories, or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we or our collaborators might not be permitted to market our current or any future approved products and our business would suffer.

If clinical trials for our product candidates are prolonged, delayed or stopped, for any reason, we may be unable to obtain regulatory approval and commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any product revenue.

We are either currently enrolling patients in clinical trials or anticipate initiating or continuing clinical trials for molecules that include margetuximab, enoblituzumab, flotetuzumab, retifanlimab, tebotelimab,MGC018, MGD014, and MGD019, as monotherapies or in combination with other product candidates in 2021. In addition, Incyte Corporation is currently enrolling patients in clinical trials for retifanlimab, and other collaborators outside the United States are developing our product candidates and enrolling patients in clinical trials. We anticipate our collaborators will initiate or continue clinical trials including our other product candidates. The continuation, modification, or commencement of existing or new clinical trials could be substantially delayed or prevented by several factors, including:

- further discussions with the FDA or other regulatory agencies regarding the scope or design of our clinical trials;
- the limited number of, and competition for, suitable sites to conduct our clinical trials, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- any delay or failure in patient recruitment or enrollment in our or our collaborators' trials for any reason, including as a result of public health crises such as the evolving COVID-19 pandemic;
- any delay or failure to obtain regulatory approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required for a clinical trial;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to manufacture sufficient supplies of the product candidate for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial terms or clinical trial protocols with prospective sites or CROs the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs; and
- delay or failure to obtain institutional review board (IRB) approval to conduct a clinical trial at a prospective site.

The progress or completion of our, or our collaborators', clinical trials could also be substantially delayed or prevented by many factors, including:

- delays in expected site initiation, patient recruitment and enrollment, for any reason, including as a result of public health crises such as the evolving COVID-19 pandemic
- failure of patients to complete the clinical trial;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;
- lack of efficacy during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;

- inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment by us, our collaboration partners and/or our CROs; and
- the need to repeat or terminate clinical trials as a result of inconclusive or negative results or unforeseen complications in testing.

Changes in regulatory requirements and guidance may also occur and we may need to significantly amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us, due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;
- lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions; and
- upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates.

Clinical trials of our product candidates are subject to partial or full clinical holds from time to time. A clinical hold may delay the timing of a clinical trial, or may require us to modify or discontinue such trial. Any failure or significant delay in completing clinical trials for our product candidates would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

The results of previous clinical trials may not be predictive of future results, and interim or top line data may be subject to change or qualification, based on several factors, including a complete analysis of data, or in the case of interim analysis, the continued or ongoing accrual of data. In addition, the results of our current and planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities.

Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or preclinical testing. Success in early clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through initial clinical trials. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

We may publicly disclose top line or interim data from time to time, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, in October 2019 we announced second interim overall survival data for the SOPHIA trial of margetuximab for the treatment of certain metastatic breast cancer patients. The top line or interim results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top line and interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. In addition, the achievement of one primary endpoint for a trial does not guarantee that additional co-primary endpoints or secondary endpoints will be achieved. For example, the achievement by margetuximab of its first sequential endpoint for progression-free survival events in the SOPHIA trial does not indicate whether the second sequential endpoint of overall survival will be achieved. In particular, the second interim overall survival analysis, based on 270 events, did not show statistically significant results. We currently expect to receive final overall survival analysis in the second half of 2021, and such results may not show statistical significance. Failure to achieve statistical significance in this second sequential endpoint of overall survival in the SOPHIA trial may have an adverse effect on our ability to obtain or retain regulatory approval of margetuximab in the U.S. or in other jurisdictions.

We use novel technologies in the development of our product candidates and the FDA and other regulatory authorities have not approved products that utilize these technologies.

Our products in development are based on our technology platforms, including Fc Optimization, DART and TRIDENT technologies. Given the novelty of these technologies, we intend to work closely with the FDA and other regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates. Even though MARGENZA, which incorporates an Fc variation created using our Fc Optimization platform, was approved by the FDA, there is no assurance that the FDA will approve future product candidates using such technology. The validation process takes time and resources, may require independent third-party analyses, and may not be accepted by the FDA and other regulatory authorities. For some of our product candidates that are based on these technology platforms, the regulatory approval path and requirements may not be clear or evolve as more data becomes available for this product candidates, which could add significant delay and expense. Delays or failure to obtain regulatory approval of any of the product candidates that we develop would adversely affect our business.

We may not be successful in our efforts to use and expand our technology platforms to build a pipeline of product candidates. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

A key element of our strategy is to use and expand our technology platforms to build a pipeline of product candidates and progress several of these product candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have resulted in a pipeline of product candidates directed at various cancers, as well as autoimmune disorders and infectious diseases, we may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for initial or continued clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenues in future periods, which could result in significant harm to our financial position and adversely affect our stock price.

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 capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

We and/or our collaboration partners may never obtain approval or commercialize our products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we and our current and potential collaboration partners must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and may require additional preclinical studies or clinical trials or additional administrative review periods, which could result in significant delays, difficulties and costs for us. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. Although we obtained FDA approval or MARGENZA in December 2020, we do not have any product candidates approved for sale in any international market. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Our product candidates may have undesirable side effects which may delay or prevent further clinical development or marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Although all of our product candidates have undergone or will undergo safety testing, not all adverse effects of drugs can be predicted or anticipated. Unforeseen side effects from any of our product candidates could arise either during clinical development or after the approved product has been marketed. Ongoing or future trials of our product candidates may not support the conclusion that one or more of these product candidates have acceptable safety profiles. The results of future clinical or preclinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings or potential product liability claims.

If we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, impose other risk-management measures, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

For example, the prescribing information for MARGENZA include warnings and precautions for infusion-related reactions, as well as a boxed warning related to left ventricular dysfunction and embryo-fetal toxicity. Further, based on the identification of future adverse events, we may be required to further revise the prescribing information, including MARGENZA's boxed warning, which could negatively impact sales of MARGENZA or adversely affect MARGENZA's acceptance in the market.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products.

The manufacture of MARGENZA and our product candidates, for ourselves and our collaborators, is complex, and we may encounter difficulties in production. If we encounter any such difficulties, our ability to supply MARGENZA and our product candidates for clinical trials or, if approved, for commercial sale could be delayed or halted entirely, and our business, financial results, and reputation could be materially harmed.

MARGENZA is currently manufactured by a third party, and we are currently manufacturing retifanlimab and other product candidates for ourselves and our collaborators. The process of manufacturing MARGENZA and our product candidates for ourselves and our collaborators is extremely susceptible to delays or product loss due to a variety of factors, including but not limited to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, difficulties in scaling the production process, and vendor supply chain disruptions or fluctuations. Even minor deviations from manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in MARGENZA and our product candidates or in the manufacturing facilities in which MARGENZA and our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any adverse developments affecting manufacturing operations for MARGENZA and our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. In addition, if we fail to supply required quantities of MARGENZA and a product candidate for one of our collaborators, our collaborator may terminate our agreement.

Although we currently maintain insurance coverage against damage to our property and to cover business interruption and research and development restoration expenses, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. If there were to be a catastrophic event or failure of our manufacturing facilities or processes, we may be unable to meet our requirements for supply of MARGENZA and our product candidates.

We have limited experience in large-scale or commercial manufacturing, and there can be no assurance that we will be able to effectively manufacture clinical or commercial quantities of our products.

We currently have two current Good Manufacturing Practice (cGMP) manufacturing facilities located in Rockville, Maryland, one of which is a commercial scale facility which is intended to support future clinical and commercial production of our and our collaborators' product candidates. Although some of our employees have experience in the manufacturing of pharmaceutical products from prior employment at other companies, we as a company have limited experience in large-scale manufacturing and no experience in commercial manufacturing. The design and build of a large scale manufacturing facility was time-consuming and expensive, and we may not realize the benefit of this investment. As a manufacturer of pharmaceutical products, we are required to demonstrate and maintain compliance with cGMPs which include requirements related to production processes, quality control and assurance and recordkeeping. Furthermore, establishing and maintaining manufacturing operations requires a reallocation of other resources, particularly the time and attention of certain of our senior management. Any failure or delay in our manufacturing capabilities could adversely impact the clinical development or commercialization of our or our collaborators' product candidates.

Our manufacturing facilities are subject to significant government regulations and approvals, which are often costly and could result in adverse consequences to our business if we fail to comply with the regulations or maintain the approvals.

We must comply with the FDA's cGMP requirements, as set out in statute, regulations and interpreted through guidance. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. See "Other U.S. Post-Marketing Regulatory Requirements" above for additional information. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product or product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product or product candidates, including leading to significant delays in the availability of drug product for sale and our clinical trials or the termination or hold on a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation or negatively impact a product's commercial success. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that our products will be widely used.

Market acceptance and sales of our products and product candidates, if approved for sale by the appropriate regulatory authorities, may depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will reimburse and establish payment levels and, in some cases, utilization management strategies, such as tiered formularies and prior authorization. We cannot be certain that reimbursement will be available for our products or any products that we develop or that the reimbursement level will be adequate to allow us to operate profitably. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. Our ability to commercialize our products may depend, in part, on the extent to which reimbursement for the products will be available from government authorities and third-party payors. If reimbursement for our products is not available or is available on a limited basis, or if the reimbursement amount for our products is inadequate, we may not be able to successfully commercialize any of our approved products.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party

payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage and reimbursement determination process is often time-consuming and costly. This process may require us to provide scientific and clinical information to support the coverage or reimbursement of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

As federal and state governments implement additional health care cost containment measures, including measures to lower prescription drug pricing, we cannot be sure that MARGENZA and our product candidates, if approved, will be covered, or remain covered, by private or public payors, and if covered, whether the reimbursement will be perceived by product purchasers as adequate. Health reform actions by federal and state governments and health plans may put additional downward pressure on pharmaceutical pricing and health care costs, which could negatively impact coverage and reimbursement for MARGENZA and our product candidates, if approved, our revenue, and our ability to compete with other marketed products and to recoup the costs of our research and development.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical products . There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific products and product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our products may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any approved product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Further, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Actual or anticipated changes to the laws and regulations governing the health care system may have a negative impact on cost and access to health insurance coverage and reimbursement of healthcare items and services.

The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any of our future approved products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs through lowering prescription drug prices, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), which became law in 2010. While it is difficult to assess the impact of the ACA in isolation, either in general or on our business specifically, it is widely thought that the ACA increases the likelihood of downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of, and the price we may charge for, any products we develop that receive regulatory approval. Further, the United State and foreign governments regularly consider additional reform measures that affect healthcare coverage and costs. Such reforms may include changes to the coverage and reimbursement of healthcare services and products. In particular, there have been recent executive, judicial and Congressional challenges to the ACA, which could have an impact on coverage and reimbursement for healthcare services covered by plans authorized by the ACA.

While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." The United States Supreme Court is currently reviewing the constitutionality of the ACA, although it is unclear when a decision will be made. Although the U.S. Supreme Court has yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or

the Affordable Care Act. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, on November 20, 2020, CMS issued an interim final rule implementing former President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, however, government and other regulatory oversight and future regulatory and government interference with the healthcare systems could adversely impact our business and results of operations.

We expect to experience pricing pressures in connection with the sale of any products that we develop, due to the trend toward managed healthcare, the increasing influence of various and evolving payor models and additional legislative proposals.

Inadequate funding for the FDA and other government agencies 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. In addition, government funding of 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 drugs 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 agencies, such as the FDA, have had to furlough critical FDA, and other government employees and pause or 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.

If any product liability lawsuits are successfully brought against us or any of our collaborators, we may incur substantial liabilities and may be required to limit commercialization of our products or product candidates.

We face an inherent risk of product liability lawsuits related to the sale of our products to, use of our products by, and testing of our product candidates in, seriously ill patients. Product liability claims may be brought against us or our collaborators by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling any of our approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, liability claims may result in:

- decreased demand for our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- increased regulatory scrutiny;

- significant litigation costs;
- substantial monetary awards to or costly settlement with patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

With respect to MARGENZA and any of our other product candidates that are approved for commercial sale, we are, and will be, highly dependent upon physician and patient perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations.

As of December 31, 2020, we hold $20 million in product liability insurance coverage in the aggregate, with a per incident limit of $20 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage when we begin the commercialization of our product candidates. Insurance coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. A successful product liability claim or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operation.

Our contract with the National Institute of Allergy and Infectious Diseases (NIAID) makes us a government contractor. Laws and regulations affecting government contracts may make it more costly and difficult for us to successfully conduct our business.

We must comply with numerous laws and regulations relating to the procurement, formation, administration and performance of government contracts. Failure to comply with these laws could result in significant civil and criminal penalties. Among the most significant government contracting regulations that may affect our business are: the Federal Acquisition Regulation (FAR) and NIH-NIAID-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts; business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act, the Procurement Integrity Act, and the False Claims Act; export and import control laws and regulations; and laws, regulations and executive orders restricting the use and dissemination of sensitive information we may receive pursuant to our performance of the government contract. U.S. government agencies routinely audit and investigate government contractors for compliance with applicable laws and standards. If we are audited, such audit could result in disallowance of expected cost reimbursement, or if such audit were to uncover improper or illegal activities, we could be subject to civil and criminal penalties, administrative sanctions, including suspension or debarment from government contracting and significant reputational harm.

Changes in U.S. tax law may have a material adverse effect on our business, financial condition and results of operations, and changes in international trade relations may have a material adverse effect on the commercialization of some or all of our product candidates.

Changes in laws and policy relating to taxes may have an adverse effect on our business, financial condition and results of operations. Recent tax reforms in the United States have resulted in significant changes to preexisting U.S. tax rules and regulations. These changes may trigger an adverse effect on our business, financial conditions and results of operations.

Additionally, the U.S. government may seek to implement more protective trade measures with countries in which we plan to conduct business in, with great deal of uncertainty regarding trade policies, tariffs and government regulations, which if altered could have the potential to create a significant adverse effect on trade between the United States and other countries. Overall, changes in international trade relations, such as the imposition of or increase in tariffs or other trade barriers, could

materially and adversely impact our costs, the ability to make sales of our product candidates to any of our significant customers in other countries, and reduce the competitiveness of our product candidates.

The COVID-19 pandemic has had, and may continue to have, a material impact on our clinical trials, preclinical studies, commercialization of MARGENZA, manufacturing, development and commercialization of our product candidates and other aspects of our business, staff, and operations, which in turn may, materially adversely affect our financial condition, results of operations and liquidity. The extent to which the COVID-19 pandemic continues to adversely affect our business, staff, operations, financial condition, results of operations and liquidity, will depend on future developments, including the measures taken by public and private entities in response to the pandemic, which remain highly uncertain and cannot be predicted.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. The COVID-19 pandemic, which is continuing to evolve, and to date has led to the implementation of various responses, including government-imposed quarantines, work and travel restrictions and other public health safety measures at the federal, state and local levels.

The continued spread of the COVID-19 pandemic has had, and may continue to have, a material impact on our clinical trials, preclinical studies, commercialization efforts, manufacturing and development of our product candidates and other aspects of our business, staff, and operations, which in turn may impact our financial condition, results of operations and liquidity. For instance, the COVID-19 pandemic impaired the ability to enroll patients in clinical trials, continue ongoing clinical trials or activate clinical trial sites, and MARGENZA commercialization, due to, for example, heightened exposure to COVID-19 if an outbreak occurs in a specific geography, the shifting of healthcare resources toward the pandemic or the closing of or limiting of access to clinical facilities, and reduced or non-existent in-person access to physicians and health care centers. Furthermore, patients may be unable or unwilling to enroll in our clinical trials or be unable to comply with clinical trial protocols if COVID-19 related restrictions impede patient movement or interrupt healthcare services. Government-imposed quarantines and other restrictions may also require us to temporarily suspend activity at our clinical sites. The COVID-19 pandemic may also negatively affect the operations of third-party CROs that we rely upon to carry out our clinical trials, or the operations of other service providers, which could result in delays or disruptions in the supply of our product candidates or other aspects of our business or that of our collaborators. Any negative impact the COVID-19 pandemic has had, or will have, on patient enrollment or treatment or the timing and execution of our clinical trials could cause delays to our clinical trial activities, which could adversely affect our ability to seek and obtain regulatory approval for and to commercialize any approved product candidates, increase our operating expenses and have a material adverse effect on our business and financial results. In particular, enrollment of our registrational path trial of flotetuzumab has been slower than expected due to the COVID-19 pandemic.

Further, the COVID-19 pandemic has increased the risk that a portion of the workforce, including ours, may suffer illness or otherwise be unable to work due to close contact related precautions. There has been limited business impact from COVID-19 related absences, but there can be no assurance that there will not be additional or significant employee COVID-19 related absences with negative business impact in the future. We have maintained an on-site workforce and implemented stay-at-home orders consistent with the requirements of the jurisdictions in which we operate, with arrangements such as remote work and flexible schedules for certain functions, as well as other measures intended to reduce the risks to our employees from the impact of the pandemic while maintaining our operations.

We may also face increased cybersecurity risks due to the shifting of a majority of our corporate functions operating remotely in regions impacted by stay-at-home orders. Increased levels of remote access may create additional opportunities for cybercriminals to attempt to exploit vulnerabilities, and our employees may be more susceptible to phishing and social engineering attempts.

The extent to which the COVID-19 pandemic impacts our business, staff, operations, financial condition, results of operations and liquidity, or those of our collaborators, will largely depend on future developments, which are highly uncertain and cannot be predicted, such as the duration of the pandemic, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions to contain COVID-19 or treat its impact, among others. We cannot presently predict the scope and severity of any potential government or business shutdowns or disruptions. If we or any of the third parties with whom we engage experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, financial condition and results of operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. Our first commercial product was only recently approved. We may never achieve or sustain profitability.

We have incurred significant losses since our inception. As of December 31, 2020, our accumulated deficit was approximately $771.8 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates, prepare for and begin to commercialize any approved products, and add infrastructure and personnel to support our product development efforts and operations as a public company. The net losses and negative cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our stockholders' deficit and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. For example, our expenses could increase if we are required by the FDA to perform trials in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical trials or in the development of any of our product candidates. Our expenses would significantly increase to the extent we build out a sales force and other commercially relevant functions to support the commercialization of MARGENZA or any of our product candidates.

To become and remain profitable, we must succeed in developing and commercializing products with significant market potential. For example, revenues from MARGENZA may not be sufficient to enable us to reach profitability. In order to commercialize any additional product candidates, we will need to be successful in a range of challenging activities for which we are only in the preliminary stages, including developing product candidates, obtaining regulatory approval for them, and manufacturing, marketing and selling approved products and product candidates for which we may obtain regulatory approval. We may never succeed in these activities and may never generate revenue from product sales that is significant enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates, or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back, or cease our product development programs or operations.

We are advancing our product candidates through clinical development and are commercializing MARGENZA in collaboration with EVERSANA. Developing and commercializing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. In order to obtain such regulatory approval, we will be required to conduct clinical trials for each indication for each of our product candidates. We will continue to require additional funding beyond what was raised in our public offerings and through our collaborations and license agreements to complete the development and commercialization of our product candidates and to continue to advance the development of our other product candidates, and such funding may not be available on acceptable terms or at all. Although it is difficult to predict our funding requirements, based upon our current operating plan, we anticipate that our cash, cash equivalents and marketable securities as of December 31, 2020, combined with anticipated and potential collaboration payments, will enable us to fund our operations into 2023, assuming all of our programs and collaborations advance as currently contemplated. Because successful commercialization of MARGENZA and development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to commercialize MARGENZA and complete research, development and clinical testing to commercialize our product candidates.

Our future funding requirements will depend on many factors, including but not limited to:

- the number and characteristics of other product candidates and indications that we pursue;
- the scope, progress, timing, cost and results of research, preclinical development, and clinical trials;
- the costs, timing and outcome of seeking and obtaining FDA and non-U.S. regulatory approvals;
- the costs associated with manufacturing our product candidates;
- the costs of establishing sales, marketing, and distribution capabilities;

- our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;

- our need and ability to hire additional management, scientific, and medical personnel;

- the effect of competing products that may limit market penetration of our product candidates;

- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and

- the economic and other terms, timing of and success of our existing collaborations, and any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through a combination of public or private equity offerings, debt financings, strategic collaborations, and grant funding. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, scale back or eliminate one or more of our development programs or our business operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish substantial rights.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available at all, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, MARGENZA, product candidates, or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our development programs or grant rights to develop and market MARGENZA or product candidates that we would otherwise prefer to develop and market ourselves.

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

Our ability to utilize our federal net operating losses (NOLs) and federal tax credits is currently limited, and may be limited further, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. The limitations apply if an ownership change, as defined by Section 382, occurs. Generally, an ownership change occurs when certain shareholders increase their aggregate ownership by more than 50 percentage points over their lowest ownership percentage in a testing period, which is typically three years or since the last ownership change. We are already subject to Section 382 limitations due to acquisitions we made in 2002 and 2008. As of December 31, 2020, we had federal and state NOL carryforwards of $648 million and federal research and development tax credits of $69.6 million available. Future changes in stock ownership may also trigger an ownership change and, consequently, another Section 382 limitation. Any limitation may result in expiration of a portion of the net operating loss or tax credit carryforwards before utilization which would reduce our gross deferred income tax assets and corresponding valuation allowance. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards and tax credit carryforwards to reduce United States federal income tax may be subject to limitations, which could potentially result in increased future cash tax liability to us.

Risks Related to Our Dependence on Third Parties

Our existing therapeutic collaborations are important to our business, and future collaborations may also be important to us. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.

We have limited capabilities for drug development and have little to no internal capability for sales, marketing or distribution. We have entered into collaborations with other companies that we believe can provide such capabilities, including our agreements with, for example, Incyte Corporation, Zai Lab Limited and I-Mab Biopharma. These current collaborations also have provided us with important funding for our development programs and technology platforms and we expect to receive

additional funding under these collaborations in the future. Our existing therapeutic collaborations, and any future collaborations we enter into, may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create 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;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products 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;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. For example, each of our collaboration and license agreements may be terminated for convenience upon the completion of a specified notice period.

If our therapeutic 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. For example, in January 2020 our arrangement terminated with Les Laboratoires Servier and Institut de Recherches Servier (collectively, Servier), to which we had previously granted exclusive options to obtain three separate exclusive licenses to develop and commercialize DART molecules. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of our program collaborators.

Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination, the collaborator might de-emphasize or terminate the development or commercialization of MARGENZA or any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators.

For MARGENZA and our product candidates, we may in the future determine to collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization. We face significant competition in seeking appropriate collaborators. Our ability to 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. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for MARGENZA or the subject product candidate, the costs and complexities of manufacturing and delivering MARGENZA or 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 products, 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 MARGENZA or our product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of MARGENZA or a product candidate, reduce or delay one or more of our other development programs, delay the commercialization of MARGENZA or a product candidate 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 fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop MARGENZA or our product candidates or bring them to market or continue to develop our technology platforms and our business may be materially and adversely affected.

We may also be restricted under collaboration agreements from entering into additional agreements on certain terms with potential collaborators. Most of our existing therapeutic collaborations contain a restriction on our engaging in activities that are the subject of the collaboration with third parties for specified periods of time.

Independent clinical investigators and CROs that we engage to conduct our clinical trials may not devote sufficient time or attention to our clinical trials or be able to repeat their past success.

We expect to continue to depend on independent clinical investigators and CROs to conduct our clinical trials. CROs may also assist us in the collection and analysis of data. There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. These investigators and CROs will not be our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. Further, the FDA requires that we comply with standards, commonly referred to as current Good Clinical Practice (GCP) for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. Failure of clinical investigators or CROs to meet their obligations to us or comply with GCP procedures could adversely affect the clinical development of our product candidates and harm our business.

Failure of third-party contractors and/or our inability to successfully develop and commercialize companion diagnostics for use with our product candidates could harm our ability to commercialize our product candidates.

We plan to develop companion diagnostics for our product candidates where appropriate. At least in some cases, the FDA and similar regulatory authorities outside the United States may request or require the development and regulatory approval of a companion diagnostic as a condition to approving one or more of our product candidates. We do not have experience or capabilities in developing or commercializing diagnostics and are relying, and in the future plan to continue to rely, in large part on third parties to perform these functions.

In most cases, we will likely outsource the development, production and commercialization of companion diagnostics to third parties. By outsourcing these companion diagnostics to third parties, we become dependent on the efforts of our third party contractors to successfully develop and commercialize these companion diagnostics. Our contractors:

- may not perform their obligations as expected;
- may encounter production difficulties that could constrain the supply of the companion diagnostic;
- may have difficulties gaining acceptance of the use of the companion diagnostic in the clinical community;
- may not commit sufficient resources to the marketing and distribution of such product; and
- may terminate their relationship with us.

If any companion diagnostic for use with one of our product candidates fails to gain market acceptance, our ability to derive revenues from sales of such product candidate could be harmed. If our third party contractors fail to commercialize such companion diagnostic, we may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with such product candidate or do so on commercially reasonable terms, which could adversely affect and delay the development or commercialization of such product candidate.

We currently contract with third parties for the manufacturing of MARGENZA and we expect to contract with third parties for the manufacture of some of our product candidates for clinical testing in the future in addition to commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently have two cGMP manufacturing facilities located in Rockville, Maryland, one of which was completed in 2018 and is designed to increase our internal capacity to manufacture more drug substance lots, at larger scale and in full compliance with cGMP to support future clinical and commercial production of our and our collaborators' product candidates. We manufacture drug substance lots at these facilities that we use for research and development purposes and for clinical trials of our and our collaborators' product candidates. Although we believe we currently have capacity to produce all of the material required for our and our collaborators' clinical trials, we may not be able to do so in the future, and may rely on arrangements with third parties. Our current facilities may also be insufficient to support our needs for commercial quantities of MARGENZA and such candidates, and we may rely on arrangements with third parties. We have limited experience in manufacturing products at commercial scale.

We have entered into agreements with contract manufacturing organizations to supplement our clinical supply and internal capacity as we commercialize MARGENZA and advance our product candidate pipeline. MARGENZA is currently manufactured by third parties. In the future, we may transition some of the manufacturing of MARGENZA to our internal facilities. We may use third parties for the manufacture of some of our product candidates for clinical testing, as well as for commercial manufacture of some of our product candidates that receive marketing approval and that are not manufactured by us or one of our third party collaborators. We have entered into supply agreements with manufacturers for commercial supply and may in the future enter into one or more additional supply agreements for our product candidates. We may be unable to reach agreement with any of these contract manufacturers, or to identify and reach arrangements on satisfactory terms with other contract manufacturers, to manufacture any of our product candidates. Additionally, the facilities used by any contract manufacturer to manufacture any of our product candidates must be the subject of a satisfactory inspection before the FDA and other regulatory authorities approve a BLA or marketing authorization for the product candidate manufactured at that facility. We will depend on these third-party manufacturing partners for compliance with the FDA's requirements for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA and other regulatory authorities' cGMP requirements, our product candidates will not be approved or, if already approved, may be subject to recalls.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured MARGENZA or the product candidates ourselves, including:

- the possibility of a breach of the manufacturing agreements by the third parties because of factors beyond our control;
- the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer; and
- the possibility that we may not be able to secure a manufacturer or manufacturing capacity in a timely manner and on satisfactory terms in order to meet our manufacturing needs.

Any of these factors could cause adversely impact the commercialization of MARGENZA and the delay of approval or commercialization of our product candidates, cause us to incur higher costs or prevent us from commercializing our product candidates successfully. Furthermore, if contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for MARGENZA or our product candidates and to have any such new source approved by the FDA or any other relevant regulatory authorities.

Our commercialization collaboration with EVERSANA for MARGENZA is important to our business, and future commercialization collaborations may also be important to us. If we are unable to maintain this or other commercialization collaborations, or if commercialization collaborations are not successful, our business could be adversely affected.

We have limited capabilities for drug commercialization, with little to no internal capability for sales, marketing or distribution. We have entered into a collaboration with EVERSANA for the commercialization of MARGENZA in the United States that we believe can provide such capabilities, and may enter into commercial collaborations in the future for MARGENZA or our product candidates. Our existing commercialization collaboration, and any future commercialization collaborations we enter into, may pose a number of risks, including the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue commercialization of MARGENZA or any product candidates that achieve regulatory approval or may elect not to continue commercialization based on clinical trial results, changes in the collaborators' strategic focus or other factors that divert resources or create competing priorities;
- collaborators could independently commercialize products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to MARGENZA or our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements on contract interpretation, commercialization strategy or tactics, might cause delays or termination of the commercialization of MARGENZA or product candidates, might lead to additional responsibilities for us with respect to MARGENZA or product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly utilize our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may violate, or be investigated for potentially violating, health care compliance and related laws and regulations, which may expose us to litigation, enforcement actions or inquiries, or other potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further commercialization of MARGNEZA or applicable product candidates.

All of the risks relating to commercialization, and health care legal compliance described in this Annual Report on Form 10-K also apply to the commercialization activities of our collaborators.

Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination, the collaborator might de-emphasize or terminate the development or commercialization of MARGENZA or any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators. We may also be restricted under commercialization collaboration agreements from entering into future agreements on certain terms with potential collaborators. For example, our collaboration with EVERSANA contains a

restriction on our engaging in activities that are the subject of the collaboration with third parties for specified periods of time among other conditions

Commercialization collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the commercialization of MARGENZA or a product candidate, reduce the scope of any sales or marketing activities, or increase our expenditures and undertake or commercialization activities at our own expense. If in the future we elect to fund and undertake commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations to commercialize our product candidates and do not have sufficient funds or expertise to undertake the necessary commercialization activities, we may not be able to commercialize our product candidates or bring them to market or continue and our business may be materially and adversely affected.

Risks Related to Cybersecurity

A disruption in our computer networks, including those related to cybersecurity, could adversely affect our financial performance as well as our research, development and commercialization efforts.

Security breaches, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches can create system disruptions or shutdowns or the unauthorized disclosure of confidential information. In addition, due to the COVID-19 pandemic a significant portion of our employees have been working remotely, either from home or elsewhere. If personal information or protected health information is improperly accessed, tampered with or disclosed as a result of a security breach, we may incur significant costs to notify and mitigate potential harm to the affected individuals, and we may be subject to sanctions and civil or criminal penalties if we are found to be in violation of the privacy or security federal or state laws protecting confidential personal information. In addition, a cybersecurity breach could hurt our reputation, subject us to liability claims or regulatory penalties for compromised personal information and could have a material adverse effect on our business, financial condition and results of operations. In order to reduce such risks, our information security program employs a policy-driven information systems security architecture based on National Institute of Standards and Technology (NIST) Cybersecurity Framework and references the NIST 800-53 guidelines for risk-based assessments and implementation of information security controls. The program is managed by dedicated Information Security personnel with the primary mission to implement, maintain, and improve the capabilities and practices to ensure the confidentiality, integrity, and availability of the sensitive information it maintains.

Risks Related to Our Intellectual Property

Our commercial success depends significantly on our ability to operate without infringing the valid patents and other proprietary rights of third parties.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position. For example, certain patents held by third parties cover Fc engineering methods and mutations in Fc regions to enhance the binding of Fc regions to Fc receptors on immune cells. Although we believe that these patents are not infringed, and/or are invalid and/or unenforceable, if a court should find that they cover MARGENZA or enoblituzumab and we are unable to invalidate such patents, or if licenses for them are not available on commercially reasonable terms, our business could be harmed, perhaps materially.

Patents that we may ultimately be found to infringe could be issued to third parties. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations. Moreover, our failure to maintain a license to any technology that we require may also materially harm our business, financial condition, and results of operations. Furthermore, we would be exposed to a threat of litigation.

In the pharmaceutical industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;

- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;

- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; and

- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

These lawsuits would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. There is a risk that a court would decide that we or our collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our collaborators may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties and require us to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Any of these outcomes could have a material adverse effect on our business.

The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

If we are unable to obtain and enforce patent protection for our products and our product candidates and related technology, our business could be materially harmed.

Issued patents may be challenged, narrowed, invalidated or circumvented. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by biotechnology companies. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the enforceability and scope of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against

competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives.

Our strategy depends on our ability to identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary.

The issuance of a patent does not ensure that a court or agency finds or will find the patent valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology. Third parties may also seek to market biosimilar versions of any approved products. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid and/or unenforceable. 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.

The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards which the United States Patent and Trademark Office (USPTO) and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries. Outside the United States, patent protection must be sought in individual jurisdictions, further adding to the cost and uncertainty of obtaining adequate patent protection outside of the United States. Accordingly, we cannot predict whether additional patents protecting our technology will issue in the United States or in foreign jurisdictions, or whether any patents that do issue will have claims of adequate scope to provide competitive advantage. Moreover, we cannot predict whether third parties will be able to successfully obtain claims or the breadth of such claims. The allowance of broader claims may increase the incidence and cost of patent interference proceedings, opposition proceedings, and/or reexamination proceedings, the risk of infringement litigation, and the vulnerability of the claims to challenge. On the other hand, the allowance of narrower claims does not eliminate the potential for adversarial proceedings, and may fail to provide a competitive advantage. Our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products, or provide us with any competitive advantage.

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

Even after they have been issued, our patents and any patents which we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our approved products and product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition.

The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we or our collaborators may initiate litigation or other proceedings against third parties to enforce our patent rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;
- third parties may initiate opposition, reexamination or inter partes review proceedings challenging the validity or scope of our patent rights, requiring us or our collaborators and/or licensors to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents currently identified as being owned by or licensed to us;

- the USPTO may initiate an interference between patents or patent applications owned by or licensed to us and those of our competitors, requiring us or our collaborators and/or licensors to participate in an interference proceeding to determine the priority of invention, which could jeopardize our patent rights; or

- third parties may seek approval to market biosimilar versions of our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. There is a risk that a court or administrative body would decide that our patents are invalid or not infringed by a third party's activities, or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents could limit our ability to assert our patents against these or other competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;

- we might not have been the first to make the inventions covered by patents or pending patent applications;

- we might not have been the first to file patent applications for these inventions;

- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or

- we may not develop additional proprietary technologies that are patentable.

If we fail to comply with our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are currently party to various intellectual property license agreements. These license agreements impose, and we expect that future license agreements may impose, various diligence, milestone payment, royalty, insurance and other obligations on us. For example, we have entered into patent and know-how license agreements that grant us the right to use certain technologies related to biological manufacturing to manufacture our clinical product candidates. These licenses typically include an obligation to pay yearly maintenance payments and royalties on sales, and may also include upfront and milestone payments. If we fail to comply with our obligations under the licenses, the licensors may have the right to terminate their respective license agreements, in which event we might not be able to market any product that is covered by the agreements. Termination of the license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, which could adversely affect our competitive business position and harm our business.

If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such

agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, 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, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel or our agents to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. In addition, we may be responsible for the payment of patent fees for patent rights that we license from other parties. If any licensor of these patents does not itself elect to make these payments, and we fail to do so, we may be liable to the licensor for any costs and consequences of any resulting loss of patent rights.

If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Depending upon the timing, duration and conditions of 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. 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 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. 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 that product 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, possibly materially,

Risks Related to Legal Compliance Matters

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development involves, and may in the future involve, the use of potentially hazardous materials and chemicals. Our operations may produce hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by local, state and federal laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations and fire and building codes, including those governing laboratory procedures, exposure to blood-borne pathogens, use and storage of flammable agents and the handling of biohazardous materials. Although we maintain workers' compensation insurance as prescribed by the States of Maryland and California to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

We and our collaborators are subject to various healthcare laws, and our failure, or the failure of our collaborators, to comply with those laws could result in significant penalties and adversely affect our business, operations and financial condition.

In the United States, our operations, and those of our collaborators, are subject to regulation by various local, state, federal authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services ("CMS"), other divisions of HHS (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice ("DOJ") and individual U.S. Attorney offices within the DOJ, and state and local governments. We and our collaborators are or may be subject to broadly applicable "fraud and abuse" laws , such as false claims, anti-kickback laws, transparency laws, and privacy and security laws.. Federal false claims laws, including the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a claim paid.

The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal anti-kickback statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices, or those of our collaborators, may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the federal anti-kickback statute and the criminal healthcare fraud statutes (discussed below) was amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil false claims act.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services 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.

In addition, under the Sunshine Act provisions of the ACA, covered manufacturers of drugs, devices, biological and medical supplies for which payment is available under a federal health care program (with certain exceptions) are subject to

annual federal reporting and disclosure requirements with regard to payments or other transfers of value made to physicians defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals as well as certain ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.

Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which may apply to items such as pharmaceutical products and services reimbursed by private insurers. Some state laws also prohibit certain gifts to healthcare providers, require pharmaceutical companies to report payments to healthcare professionals, and/or require companies to adopt compliance programs or codes of conduct.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, improper consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. At such time as we or our collaborators market MARGENZA or any of our future approved products and these products are paid for by governmental programs, it is possible that some of our business activities could also be subject to challenge under one or more of these “fraud and abuse” laws.

We and our collaborators may also be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business, as well as foreign jurisdictions. In the United States, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, impose requirements on “covered entities,” including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective “business associates” that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors relating to the privacy, security and transmission of individually identifiable health information.

Further, in order to distribute products commercially in the United States, we or our collaborators must also comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers, and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, track, and report gifts, compensation and other remuneration made to physicians and other healthcare providers, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit certain other sales and marketing practices.

If our operations, or those of our collaborators marketing, distributing or commercializing any of our products on our behalf, are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private “qui tam” actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In addition, our operations and those of our collaborators may be subject to analogous foreign health care laws in the jurisdictions in which we operate.

We are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, (FCPA) and other anti-corruption laws that apply in countries where we do business. The FCPA and these other laws generally prohibit us and our

employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We and our commercial partners operate in a number of jurisdictions that pose a risk of potential FCPA violations, and we participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or other anti-corruption laws. There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws. If we violate provisions of the FCPA or other anti-corruption laws or are subject to an investigation or audit pursuant to these laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures and legal expenses, which could have an adverse impact on our business, financial condition and results of operations.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA or other agencies, to comply with federal and state health care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity 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 these laws or 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 significant fines or other sanctions.

Risks Relating to Employee Matters and Managing Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical and business development expertise of Scott Koenig, M.D., Ph.D., our President and Chief Executive Officer, as well as the other members of our senior management team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development, manufacturing and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. In addition, we will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our commercialization of MARGENZA and research, development and commercialization efforts for our existing and future product candidates. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

If we are unable to provide meaningful equity incentives to our key employees, it could adversely affect our ability to retain these key employees, which in turn could affect our ability to implement our business strategies.

We are dependent upon the members of our senior management team and other key employees. In our industry, it is common to attract and retain executive and other key employees with compensation packages that include a significant equity component. As a result, we may have difficulty retaining key personnel, which would have a material adverse effect on our ability to execute our business strategy.

We may need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2020, we had 370 full-time employees. As our development and commercialization plans and strategies develop, we may choose to expand our employee base for managerial, operational, manufacturing, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Any such growth could require significant capital expenditures and may divert financial resources from other projects, such as the commercialization of MARGENZA and the development of existing and additional product candidates. If our management is unable to effectively manage such growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize MARGENZA, our product candidates and compete effectively with others in our industry will depend, in part, on our ability to effectively manage any such growth.

Risks Relating to Our Common Stock

We are subject to securities litigation, which is expensive and could divert management attention and adversely impact our business.

The market price of our common stock has been and may continue to be volatile. Companies that have experienced volatility in the market price of their common stock are often subject to securities class action litigation. For example, on September 13, 2019, a securities class action complaint was filed against us, and certain of our officers and/or directors in the U.S. District Court for the District of Maryland, which case is still pending. This or any future securities litigation could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities.

The market price of our stock may fluctuate unpredictably in response to factors unrelated to our operating performance. The stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology, and other life sciences company stocks. The volatility of pharmaceutical, biotechnology, and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results and timing of our clinical trials and clinical trials of our competitors' products;
- failure or discontinuation of any of our development programs;
- issues in manufacturing our product candidates or future approved products;
- regulatory developments or enforcement in the United States and foreign countries with respect to our product candidates or our competitors' products;
- competition from existing products or new products that may emerge;
- developments or disputes concerning patents or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- changes in estimates or recommendations by securities analysts, if any cover our common stock;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concern over our product candidates or any future approved products;

- threatened or actual litigation;
- future or anticipated sales of our common stock;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key personnel;
- changes in the structure of health care payment systems in the United States or overseas;
- failure of any of MARGENZA or our product candidates, if approved, to achieve commercial success;
- economic and other external factors or other disasters or crises;
- period-to-period fluctuations in our financial condition and results of operations, including the timing of receipt of any milestone or other payments under commercialization or licensing agreements;
- general market conditions and market conditions for biopharmaceutical stocks;
- overall fluctuations in U.S. equity markets; and
- impact of the COVID-19 pandemic as well as mandatory and voluntary actions taken to mitigate the evolving public health impact of the pandemic.

In addition, in the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the company that issued the stock. For example, we currently have one such securities class action lawsuit brought against us. We could incur substantial costs defending this or similar lawsuits, as well as diversion of the time and attention of our management, any or all of which could seriously harm our business

Provisions of our charter, bylaws, third-party agreements and Delaware law may make an acquisition of us or a change in our management more difficult.

Certain provisions of our restated certificate of incorporation and amended and restated bylaws could discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could 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. Stockholders who wish to participate in these transactions may not have the opportunity to do so. Furthermore, since our board of directors is responsible for appointing the members of our management team, these provisions could prevent or frustrate attempts by our stockholders to replace or remove our management by making it more difficult for stockholders to replace members of our board of directors. These provisions:

- allow the authorized number of directors to be changed only by resolution of our board of directors;
- establish a classified board of directors, providing that not all members of the board of directors be elected at one time;
- authorize our board of directors to issue without stockholder approval blank check preferred stock that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;
- establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings;
- limit who may call stockholder meetings; and
- require the approval of the holders of 75% of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our restated certificate of incorporation and restated bylaws.

Furthermore, in the ordinary course of our business, from time to time we discuss and enter into collaborations, licenses and other transactions with various third parties, including other pharmaceutical companies and biotechnology companies. When we deem it appropriate, our agreements with such third parties may include standstill provisions. These standstill provisions, several of which may be in force from time-to-time, typically prohibit such parties from acquiring our securities for a period of time, which may discourage such parties from acquiring MacroGenics even if doing so would be beneficial to our stockholders.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a prescribed period of time. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease a total of approximately 235,000 square feet of manufacturing, office, laboratory and warehouse space in Maryland and California. Our headquarters building in Rockville, Maryland currently houses laboratory, office and manufacturing operations to support clinical, and potentially commercial, quantities and scale. This location is occupied under a lease that expires in 2027. We also lease another space supporting smaller-scale manufacturing operations in Rockville. The lease of that space expires in December 2024. These leases and all of the leases on our other properties include one or more options to renew, with those renewal periods ranging from five to fourteen years. We believe that our properties are generally in good condition, well maintained, suitable and adequate to carry on our business. We believe our capital resources are sufficient to lease any additional facilities required to meet our expected growth needs.

ITEM 3. LEGAL PROCEEDINGS

In the ordinary course of business, we are or may be involved in various legal or regulatory proceedings, claims or class actions related to alleged patent infringements and other intellectual property rights, or alleged violation of commercial, corporate, securities, labor and employment, and other matters incidental to our business. We do not, however, expect such legal proceedings to have a material adverse effect on our business, financial condition or results of operations. However, depending on the nature and timing of a given dispute, an eventual unfavorable resolution could materially affect our current or future results of operations or cash flows.

See note 10, Commitments and Contingencies, to the consolidated financial statements for more information.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

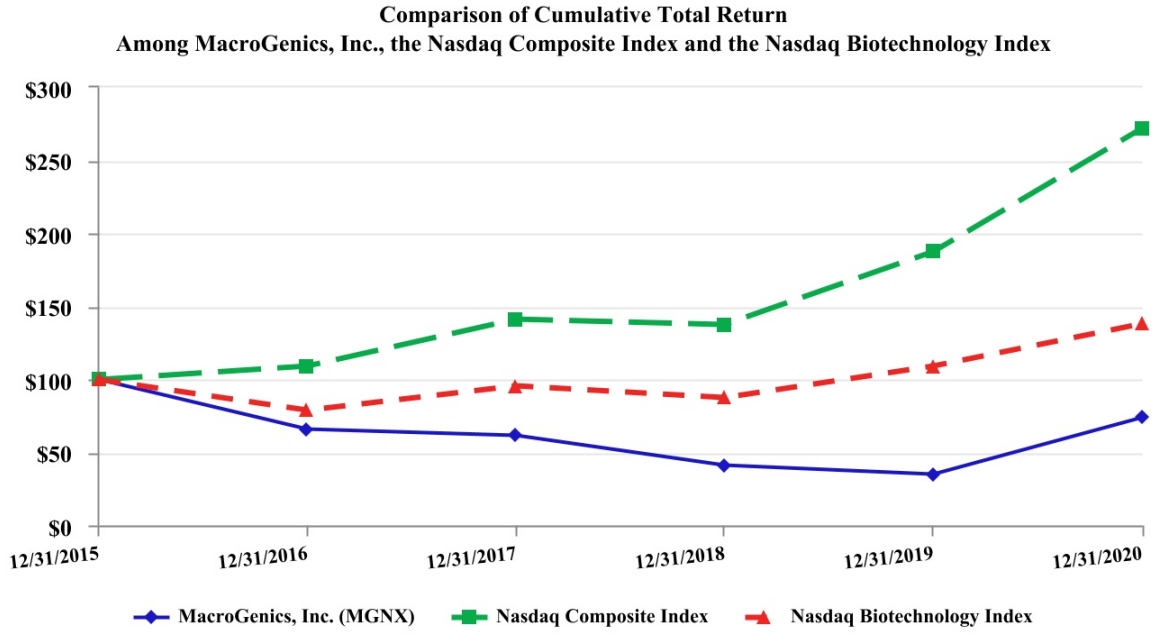
ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on the Nasdaq Global Select Market under the symbol "MGNX". As of February 22, 2021, we had 56,258,468 shares of common stock outstanding held by approximately 63 holders of record, which include shares held by a broker, bank or other nominee. We have never declared or paid any cash dividends. We do not anticipate declaring or paying cash dividends for the foreseeable future. Instead, we will retain our earnings, if any, for the future operation and expansion of our business.

Performance Graph

The following graph compares the five-year cumulative total return of our common stock with the Nasdaq Composite Index (U.S.) and the Nasdaq Biotechnology Index. The comparison assumes a $100 investment on December 31, 2015 in our common stock, the stocks comprising the Nasdaq Composite Index, and the stocks comprising the Nasdaq Biotechnology Index, and assumes reinvestment of the full amount of all dividends, if any. Historical stockholder return is not necessarily indicative of the performance to be expected for any future periods.



The information set forth under the heading "Performance Graph" shall not be deemed to be "soliciting material" or to be "filed" with the SEC or subject to liabilities of Section 18 of the Exchange Act, except to the extent that we specifically request that such information be treated as soliciting material or specifically be incorporated by reference into a filing under the Securities Act of 1933, as amended, or the Exchange Act.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

The following discussion of our financial condition and results of operations should be read together with our selected consolidated financial data and the consolidated financial statements and related notes included elsewhere herein. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors including, but not limited to, those set forth under the sections entitled "Risk Factors" and "Forward-Looking Statements", our actual results may differ materially from those anticipated in such forward-looking statements.

For the discussion of our financial condition and results of operations for the year ended December 31, 2019 compared to the year ended December 31, 2018, please refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on February 25, 2020.

Overview

We are a biopharmaceutical company focused on developing and commercializing innovative antibody-based therapeutics designed to modulate the human immune response for the treatment of cancer. In December 2020, the U.S. Food and Drug Administration (FDA) approved MARGENZA (margetuximab-cmkb), a human epidermal growth factor receptor 2 (HER2) receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. We expect to initiate the commercial launch of MARGENZA late in the first quarter of 2021. In addition, we have a pipeline of product candidates in human clinical testing, including eight immuno-oncology programs, that have been created primarily using our proprietary, antibody-based technology platforms. We believe our product candidates have the potential to have a meaningful effect on treating patients' unmet medical needs as monotherapy or, in some cases, in combination with other therapeutic agents.

We commenced active operations in 2000, and have since devoted substantially all of our resources to staffing our company, developing our technology platforms, identifying potential product candidates, undertaking preclinical studies, conducting clinical trials, developing collaborations, business planning and raising capital. We have not generated any revenues from the sale of any products to date. We have financed our operations primarily through the public and private offerings of our securities, collaborations with other biopharmaceutical companies, and government grants and contracts. Although it is difficult to predict our funding requirements, we anticipate that our cash, cash equivalents and marketable securities as of December 31, 2020, combined with anticipated and potential collaboration payments and product revenues, should enable us to fund our operations into 2023, assuming our programs and collaborations advance as currently contemplated.

Through December 31, 2020, we had an accumulated deficit of $771.8 million. We expect that over the next several years this deficit will increase as we increase our expenditures in research and development in connection with our ongoing activities with several clinical trials.

COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of a novel strain of coronavirus (COVID-19) as a pandemic, which continues to spread throughout the world. Developments have been occurring rapidly with respect to the spread of COVID-19 and its impact on human health and businesses. To date, the COVID-19 pandemic has negatively impacted the global economy, created significant financial market volatility, disrupted global supply chains, and resulted in a significant number of infections and deaths worldwide. In addition, several national, state and local governments have placed restrictions on people from gathering in groups or interacting within a certain physical distance and in certain cases, have ordered businesses to close, limit operations or mandate that people stay at home.

To date, although there has been some negative impact on our business and operations, including, for example, slowed clinical trial enrollment, we have been able to mitigate against more severe impacts of the COVID-19 pandemic on our business and operations. However, the COVID-19 pandemic could have a more significant negative impact on our business in the future depending on the depth of the effects and the duration of the crisis. In response to the COVID-19 pandemic, we have been focused on keeping our employees safe, continuing patients on trials, and maintaining our manufacturing capabilities and research efforts. The COVID-19 pandemic is an evolving situation and we continue to monitor our business very closely to try and mitigate any potential impacts. We expect the pandemic to continue to have some near-term impact on the initiation of new studies and on clinical trial enrollment. For example, in consideration of the current COVID-19 pandemic, we delayed our planned Phase 2 study of enoblituzumab, an investigational, Fc-engineered, anti-B7-H3 monoclonal antibody, in combination with checkpoint blockade in patients with advanced head and neck cancer until the first quarter of 2021. In addition, we stopped

enrollment in a Phase 1/2 study combining flotetuzumab with retifanlimab in patients with relapsed or refractory acute myeloid leukemia being conducted outside of the U.S. Significant delays in the timing of our clinical trials and in regulatory reviews could adversely affect our ability to commercialize the product candidates in our pipeline.

Notwithstanding the foregoing, we cannot precisely predict the impact that the COVID-19 pandemic will have in the future due to numerous uncertainties, including the severity of the disease, the duration of the outbreak, actions that may be taken by governmental authorities, the impact to the business of potential variations or disruptions in our supply chain, and other factors identified in Part I, Item 1A. “Risk Factors” in this Form 10-K. Given these uncertainties, the COVID-19 pandemic could disrupt the business of certain of our collaborators and impact our business operations and our ability to execute on our associated business strategies and initiatives, and adversely impact our consolidated results of operations and/or our financial condition in the future. We will continue to closely monitor and evaluate the nature and extent of the impact of the COVID-19 pandemic to our business, consolidated results of operations, and financial condition.

Collaborations

We pursue a balanced approach between product candidates that we develop ourselves and those that we develop with our collaborators. Under our strategic collaborations to date, we have received significant non-dilutive funding and continue to have rights to additional funding upon completion of certain research, achievement of key product development milestones and royalties and other payments upon the commercial sale of products. Our current collaborations include the following:

- *Incyte.* In 2017, we entered into an exclusive global collaboration and license agreement with Incyte Corporation (Incyte) for retifanlimab (also known as INCMGA0012), an investigational monoclonal antibody that inhibits programmed cell death protein 1 (PD-1) (Incyte License Agreement). Incyte has obtained exclusive worldwide rights for the development and commercialization of retifanlimab in all indications, while we retain the right to develop our pipeline assets in combination with retifanlimab. Incyte paid us an upfront payment of $150.0 million under the terms of the agreement.

  Under the terms of the Incyte License Agreement, Incyte leads global development of retifanlimab. Assuming successful development and commercialization of retifanlimab by Incyte, we could receive total development and regulatory milestones of up to approximately $420.0 million and up to $330.0 million in commercial milestones. We received $55.0 million of the total development milestones through December 31, 2020 and an additional development milestone of $10.0 million was earned in February 2021. If retifanlimab is approved and commercialized, we would be eligible to receive tiered royalties of 15% to 24% on any global net sales and we have the option to co-promote retifanlimab with Incyte. We retain the right to develop our pipeline assets in combination with retifanlimab, with Incyte commercializing retifanlimab and us commercializing our asset(s), if any such potential combinations are approved. We also have an agreement with Incyte under which we are to perform development and manufacturing services for Incyte's clinical needs of retifanlimab (Incyte Clinical Supply Agreement) and another agreement under which we are entitled to manufacture a portion of Incyte’s global commercial supply of retifanlimab (Incyte Commercial Supply Agreement).

- *Zai Lab*. In 2018, we entered into a collaboration and license agreement with Zai Lab Limited (Zai Lab) under which Zai Lab obtained regional development and commercialization rights in mainland China, Hong Kong, Macau and Taiwan (Zai Lab’s territory) for (i) margetuximab, an immune-optimized anti-HER2 monoclonal antibody, (ii) tebotelimab (formerly known as MGD013), a bispecific DART molecule designed to provide coordinate blockade of PD-1 and LAG-3 for the potential treatment of a range of solid tumors and hematological malignancies, and (iii) an undisclosed multi-specific TRIDENT molecule in preclinical development. Zai Lab will lead clinical development in its territory.

  Under the terms of the agreement, Zai Lab paid us an upfront payment of $25.0 million less foreign withholding tax of $2.5 million. Assuming successful development and commercialization of margetuximab, tebotelimab and the TRIDENT molecule, we could receive up to $140.0 million in development and regulatory milestones, of which we have already received $4.0 million ($3.6 million net of foreign withholding tax). In addition, Zai Lab would pay us tiered royalties at percentage rates of mid-teens to 20% for net sales of margetuximab in Zai Lab’s territory, mid-teens for net sales of tebotelimab in Zai Lab’s territory and 10% for net sales of the TRIDENT molecule in Zai Lab’s territory, which may be subject to adjustment in specified circumstances.

- *I-Mab Biopharma.* In July 2019, we entered into a collaboration and license agreement with I-Mab Biopharma (I-Mab) to develop and commercialize enoblituzumab, an immune-optimized, anti-B7-H3 monoclonal antibody that incorporates our proprietary Fc Optimization technology platform. I-Mab obtained regional development and

commercialization rights in mainland China, Hong Kong, Macau and Taiwan (I-Mab's territory), will lead clinical development of enoblituzumab in its territories, and will participate in global studies conducted by us.

Under the terms of the agreement, I-Mab paid us an upfront payment of $15.0 million. Assuming successful development and commercialization of enoblituzumab, we could receive up to $135.0 million in development and regulatory milestones. In addition, I-Mab would pay us tiered royalties ranging from mid teens to 20% on annual net sales in its territories.

- *Janssen.* In December 2020, we entered into a research collaboration and global license agreement to develop a preclinical bispecific molecule with Janssen Biotech, Inc. (Janssen). The research collaboration will incorporate our proprietary DART platform to enable simultaneous targeting of two undisclosed targets in a therapeutic area outside oncology. Under the terms of the agreement, Janssen paid us an upfront payment of $20.0 million and will be responsible for funding all expenses. We will also be eligible to receive up to $312.0 million in potential milestone payments and tiered royalties of up to 10% on worldwide product sales.

Financial Operations Overview

Revenue

Our revenue consists primarily of collaboration revenue, including amounts recognized relating to upfront nonrefundable payments for licenses or options to obtain future licenses, amounts earned by performing development and manufacturing services, research and development funding and milestone payments earned under our collaboration and license agreements with our strategic collaborators. In addition, we have earned revenues through several grants and/or contracts with the U.S. government and other research institutions on behalf of the U.S. government, primarily with respect to research and development activities related to infectious disease product candidates.

Research and Development Expense

Research and development expense consists of expenses incurred in performing research and development activities. These expenses include conducting preclinical experiments and studies, clinical trials, manufacturing efforts and regulatory filings for all product candidates, and other indirect expenses in support of our research and development activities. We capture research and development expense on a program-by-program basis for our product candidates and recognize these expenses as they are incurred. The following are items we include in research and development expense:

- employee-related expenses, such as salaries and benefits;
- employee-related overhead expenses, such as facilities and other allocated items;
- stock-based compensation expense to employees engaged in research and development activities;
- depreciation of laboratory and manufacturing equipment, computers and leasehold improvements;
- fees paid to consultants, subcontractors, clinical research organizations (CROs) and other third party vendors for work performed under our preclinical and clinical trials including, but not limited to, investigator grants, laboratory work and analysis, database management, statistical analysis, and other items;
- amounts paid to vendors and suppliers for laboratory supplies;
- internal and third party costs related to manufacturing clinical trial materials, including vialing, packaging and testing;
- license fees and other third party vendor payments related to in-licensed product candidates and technology; and
- costs related to compliance with regulatory requirements.

It is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates, or if, when or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical trials and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors,

including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

General and Administrative Expenses

General and administrative expenses consist of salaries and related benefit costs for employees in our executive, finance, legal and intellectual property, business development, human resources, information technology and other support functions, travel expenses and other legal and professional fees.

Other Income (Expense)

Other income (expense) consists of realized and unrealized gains and losses on equity securities and interest income earned on our cash, cash equivalents and marketable securities, offset by other expenses.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial conditions and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the balance sheets and the reported amount of the revenue and expenses recorded during the reporting period. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable. We review and evaluate these estimates on an on-going basis. These assumptions and estimates form the basis for making judgments about the carrying values of assets and liabilities and amounts that have been recorded as revenues and expenses. Actual results and experiences may differ from these estimates. The results of any material revisions would be reflected in the consolidated financial statements prospectively from the date of the change in estimate.

While a summary of significant accounting policies is described fully in Note 2 in our consolidated financial statements, we believe that the following accounting policies are the most critical to assist you in fully understanding and evaluating our financial results and the effect of the estimates and judgments we used in preparing our consolidated financial statements.

Revenue Recognition

We expect to launch MARGENZA in March 2021, but have not generated any revenue from product sales to date.

We recognize revenue under Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customer*s and all related amendments (collectively ASC 606) when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, management performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

We enter into licensing agreements that are within the scope of ASC 606, under which we may license rights to research, develop, manufacture and commercialize our product candidates to third parties. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products. We may also enter into development and manufacturing service agreements with our collaborators.

For each arrangement that results in revenues, we identify all performance obligations, which may include a license to intellectual property and know-how, research and development activities, transition activities and/or manufacturing services. In order to determine the transaction price, in addition to any upfront payment, management estimates the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract. We constrain (reduce) the estimates of variable consideration such that it is probable that a significant reversal of previously recognized revenue will not occur. When determining if variable consideration should be constrained, management considers whether there are factors outside our control that could result in a significant reversal of revenue. In making these assessments, management considers the likelihood and magnitude of a potential reversal of revenue. These estimates are re-assessed each reporting period as required.

Once the estimated transaction price is established, amounts are allocated to the performance obligations that have been identified. The transaction price is generally allocated to each separate performance obligation on a relative standalone selling price basis. We must develop assumptions that require judgment to determine the standalone selling price in order to account for these agreements. To determine the standalone selling price, management's assumptions may include (i) the probability of obtaining marketing approval for the product candidate, (ii) estimates regarding the timing and the expected costs to develop and commercialize the product candidate, and (iii) estimates of future cash flows from potential product sales with respect to the product candidate. Standalone selling prices used to perform the initial allocation are not updated after contract inception. We do not include a financing component to its estimated transaction price at contract inception unless we estimate that certain performance obligations will not be satisfied within one year.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Licenses. When we grant a license to our intellectual property, we determine whether the nature of the intellectual property to which the customer will have rights is functional intellectual property (functional IP), which has significant standalone functionality, or symbolic intellectual property (symbolic IP) which does not have significant standalone functionality. Revenue from functional IP is recognized at the point in time when control of the distinct license is transferred to the customer. Revenue from symbolic IP is recognized over the access period to our intellectual property. If the license to our intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, we recognize revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and when (or as) the customer is able to use and benefit from the license. In assessing whether a promise or performance obligation is distinct from the other promises, we consider factors such as the research, development, manufacturing and commercialization capabilities of the licensee and the availability of the associated expertise in the general marketplace. In addition, we consider whether the licensee can benefit from a promise for its intended purpose without the receipt of the remaining promise, whether the value of the promise is dependent on the unsatisfied promise, whether there are other vendors that could provide the remaining promise, and whether it is separately identifiable from the remaining promise. For licenses that are combined with other promises, management utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue we record in future periods.

Research, Development and/or Manufacturing Services. The promises under our agreements may include research and development or manufacturing services to be performed by us on behalf of the counterparty. If these services are determined to be distinct from the other promises or performance obligations identified in the arrangement, we recognize the transaction price allocated to these services as revenue over time based on an appropriate measure of progress when the performance by us does not create an asset with an alternative use and we have an enforceable right to payment for the performance completed to date. If these services are determined not to be distinct from the other promises or performance obligations identified in the arrangement, we recognize the transaction price allocated to the combined performance obligation as the related performance obligations are satisfied.

Customer Options. If an arrangement contains customer options, we evaluate whether the options are material rights because they allow the customer to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. We allocate the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised. If the options are deemed not to be a material right, they are excluded as performance obligations at the outset of the arrangement.

Milestone Payments. At the inception of each arrangement that includes development milestone payments, management evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. We evaluate factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to

achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, management reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties. For arrangements that include sales-based royalties which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, we have not recognized any royalty revenue resulting from any of our licensing arrangements.

We analyze our collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties who are both active participants in the activities and are both exposed to significant risks and rewards dependent on the commercial success of such activities. Such arrangements generally are within the scope of ASC 808, *Collaborative Arrangements* (ASC 808). While ASC 808 defines collaborative arrangements and provides guidance on income statement presentation, classification, and disclosures related to such arrangements, it does not address recognition and measurement matters, such as (1) determining the appropriate unit of accounting or (2) when the recognition criteria are met. Therefore, the accounting for these arrangements is either based on an analogy to other accounting literature or an accounting policy election by management. We account for certain components of the collaboration agreement that are reflective of a vendor-customer relationship (e.g., licensing arrangement) based on an analogy to ASC 606. We account for other components based on a reasonable, rational and consistently applied accounting policy election. Reimbursements from the counter-party that are the result of a collaborative relationship with the counter-party, instead of a customer relationship, such as co-development activities, are recorded as a reduction to research and development expense as the services are performed.

Research and Development Expenses, Including Clinical Trial Accruals/Expenses

Research and development expenses consist of costs we incur for our own research and development activities and costs incurred by our collaborators under cost sharing arrangements. Research and development costs consist of salaries and benefits, including related stock-based compensation, laboratory supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities on our behalf, such as CROs and contract manufacturing organizations (CMOs). Research and development costs are expensed as incurred. We receive estimates from our collaborators when we are sharing development expenses, and use these estimates to record an increase or decrease in research and development expense, depending on how much we have each spent during the period.

Clinical trial expenses are a significant component of research and development expenses, and we outsource a significant portion of these costs to third parties. Third party clinical trial expenses include investigator fees, site and patient costs, CRO costs, costs for central laboratory testing, data management and CMO costs. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as a prepaid asset or accrued expenses. These third party agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred**.** Non-refundable advance clinical payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted costs. 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 estimates made. The historical clinical accrual estimates have not been materially different from the actual costs.

Income Taxes

Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized as income in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more-likely-than-not threshold of that position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as

the largest amount that is more than 50% likely to be realized upon ultimate settlement. Our policy is to record interest and penalties related to uncertain tax positions as a component of income tax expense.

Stock-Based Compensation

We account for stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation* (ASC 718). ASC 718 requires all share-based payments to employees, including grants of employee stock options, to be recognized in the consolidated statements of operations and comprehensive loss based on their grant date fair values. We estimate the grant date fair value of each option award using the Black-Scholes option pricing model. The resulting fair value is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the option. The use of a Black-Scholes model requires us to make assumptions with respect to the expected term of the option, the expected volatility of our common stock consistent with the expected term of the option, the risk-free interest rate consistent with the expected term of the option, the expected dividend yield of our common stock and the expected forfeiture rate.

Recent Accounting Pronouncements

See Note 2, Summary of Significant Accounting Policies, to the consolidated financial statements for information under the caption "Recently Issued Accounting Standards."

Results of Operations

Revenue

The following represents a comparison of our revenue for the years ended December 31, 2020 and 2019:

	Year Ended December 31,		Increase/(Decrease)	
	2020	2019		
	(dollars in millions)			
Revenue from collaborative and other agreements	$ 97.8	$ 62.0	$ 35.8	58 %
Revenue from government agreements	7.1	2.2	4.9	223 %
Total revenue	**$ 104.9**	**$ 64.2**	**$ 40.7**	**63 %**

The increase of $35.8 million in revenue from collaborative and other agreements for the year ended December 31, 2020 compared to the year ended December 31, 2019 was primarily due to:

- recognition of $40.0 million in development milestones from Incyte related to the further advancement of retifanlimab, including Incyte's initiation of a Phase 3 clinical trial;
- recognition of the $20.0 million upfront license fee under the Janssen Agreement;
- recognition of a $12.0 million payment from Boehringer Ingelheim International GmbH (BII) for retention of rights to two DART molecules during 2020;
- recognition of $3.6 million in milestones under the Zai Lab collaboration and license agreement (Zai Lab Agreement) during the year ended December 31, 2020; and
- $1.4 million recognized under the Incyte Commercial Supply Agreement which was executed in 2020.

These increases were partially offset by:

- a decrease of approximately $13.5 million in revenue recognized under the Incyte Clinical Supply Agreement due to decreased development activity;
- a decrease of approximately $11.1 million in revenue recognition of the deferred upfront payment under the Zai Lab Agreement during the year ended December 31, 2020 compared to the year ended December 31, 2019;
- decreased revenue recognition of approximately $10.6 million of the Les Laboratoires Servier and Institut de Recherches Servier (collectively, Servier) flotetuzumab license grant fee during the year ended December 31, 2020 due to Servier's notice of their intention to terminate the agreement effective January 15, 2020; and

- decreased revenue recognition of $6.0 million of the F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (Roche) upfront payment during the year ended December 31, 2020 due to Roche's termination of the agreement effective November 2019.

The increase of $4.9 million in revenue from government agreements for the year ended December 31, 2020 compared to the year ended December 31, 2019 was primarily due to increased clinical trial activity of MGD014 and development of the second DART molecule.

Research and Development Expenses

The following represents a comparison of our research and development expenses for the years ended December 31, 2020 and 2019:

	Year Ended December 31,		Increase/(Decrease)	
	2020	2019		
	(dollars in millions)			
Margetuximab	$ 49.5	$ 52.2	$ (2.7)	(5) %
Flotetuzumab (a)	26.6	15.1	11.5	76 %
Tebotelimab	23.5	22.5	1.0	4 %
Retifanlimab	22.7	19.7	3.0	15 %
Enoblituzumab	14.2	20.7	(6.5)	(31) %
MGC018	12.8	12.6	0.2	2 %
MGD019	8.6	7.0	1.6	23 %
DART molecules under HIV government contract	7.0	2.9	4.1	141 %
IMGC936	4.3	6.2	(1.9)	(31) %
MGD024	3.3	3.5	(0.2)	(6) %
Other programs (b)	20.7	32.9	(12.2)	(37) %
Total research and development expenses	**$ 193.2**	**$ 195.3**	**$ (2.1)**	**(1)%**

(a) 2019 expenses are shown net of reimbursements from collaboration partner.

(b) Includes research and discovery projects, as well as early preclinical and terminated molecules.

Research and development expenses for the year ended December 31, 2020 decreased by $2.1 million compared to the year ended December 31, 2019. This decrease was primarily attributable to:

- decreased clinical trial costs related to our enoblituzumab studies;
- decreased costs related to margetuximab postBiologics License Application submission; and
- decreased spend on certain preclinical programs as well as decreased clinical trial costs related to MGD007 and MGD009 as these programs have been discontinued;

These decreases were partially offset by:

- increased flotetuzumab development costs due to increased clinical trial enrollment and regulatory costs, and the end of cost sharing with Servier;
- increased development and manufacturing costs related to the second DART molecule under our contract with the National Institute of Allergy and Infectious Diseases (NIAID); and
- increased development and manufacturing costs related to retifanlimab due to timing of manufacturing activities for Incyte.

General and Administrative Expenses

The following represents a comparison of our general and administrative expenses for the years ended December 31, 2020 and 2019:

	Year Ended December 31,		Increase/(Decrease)	
	2020	2019		
	(dollars in millions)			
General and administrative expenses	$ 42.7	$ 46.1	$ (3.4)	(7)%

General and administrative expenses decreased for the year ended December 31, 2020 by $3.4 million compared to 2019 primarily due to decreased spend on external expenses, including consulting.

Other Income (Expense)

The decrease in other income of $24.1 million for the year ended December 31, 2020 compared to the year ended December 31, 2019 is primarily due to the revaluation at June 30, 2019 of the warrants received under the Provention License Agreement and Asset Purchase Agreement and decreased investment income. The warrants were exercised, and the acquired shares subsequently sold, during 2019, therefore no such revaluation is reflected in other income during the year ended December 31, 2020.

Liquidity and Capital Resources

Our multiple product candidates currently under development will require significant additional research and development efforts that include extensive preclinical studies and clinical testing, and regulatory approval prior to commercial use.

As a biotechnology company, we have primarily funded our operations with proceeds from the sale of our common stock in equity offerings, revenue from our multiple collaboration agreements, and contracts and grants from NIAID. Management regularly reviews our available liquidity relative to our operating budget and forecast to monitor the sufficiency of our working capital, and anticipates continuing to draw upon available sources of capital, including equity and debt instruments, to support our product development activities. There can be no assurances that new sources of capital will be available to us on commercially acceptable terms, if at all. Also, any future collaborations, strategic alliances and marketing, distribution or licensing arrangements may require us to give up some or all rights to a product or technology at less than its full potential value. If we are unable to enter into new arrangements or to perform under current or future agreements or obtain additional capital, we will assess our capital resources and may be required to delay, reduce the scope of, or eliminate one or more of our product research and development programs or clinical studies, and/or downsize our organization. Although it is difficult to predict our funding requirements, we anticipate that our cash, cash equivalents and marketable securities as of December 31, 2020, anticipated and potential collaboration payments, and product revenues should enable us to fund our operations into 2023, assuming our programs and collaborations advance as currently contemplated.

Similar to the other risk factors pertinent to our business, the COVID-19 outbreak might unfavorably impact our ability to generate such additional funding. Given the uncertainty in the rapidly changing market and economic conditions related to the COVID-19 pandemic, we will continue to evaluate the nature and extent of the impact of the outbreak on our business and financial position.

Cash Flows

The following table represents a summary of our cash flows for the years ended December 31, 2020 and 2019:

	Year Ended December 31,		Increase/(Decrease)	
	2020	2019		
	(dollars in millions)			
Net cash provided by (used in):				
Operating activities	$ (111.9)	$ (134.3)	$ 22.4	17 %
Investing activities	(7.8)	(79.4)	71.6	90 %
Financing activities	174.3	120.0	54.3	45 %
Net increase (decrease) in cash and cash equivalents	**$ 54.6**	**$ (93.7)**	**$ 148.3**	**158 %**

Operating Activities

Net cash provided by or used in operating activities reflects, among other things, the amounts used to advance our clinical trials and preclinical activities. The principal use of cash in operating activities for all periods presented was primarily the result of our net loss, adjusted for non-cash items, with the year ended December 31, 2020 benefiting from the $40.0 million in milestone payments received from Incyte, the $20.0 million upfront payment from Janssen, and the $12.0 million received from BII. The year ended December 31, 2019 benefited from the $22.5 million net upfront payment from Zai Lab and the $15.0 million upfront payment from I-Mab.

Investing Activities

Net cash used in investing activities during the years ended December 31, 2020 and 2019 is primarily due to purchases of marketable securities, partially offset by maturities of marketable securities.

Financing Activities

Net cash provided by financing activities for the years ended December 31, 2020 and 2019 reflects net cash proceeds from our securities offerings of approximately $170.5 million and $118.7 million, respectively, and cash from stock option exercises and the purchase of shares under our employee stock purchase plan.

Contractual Obligations and Contingent Liabilities

Our current obligations and contingent liabilities are limited to the operating leases at our facilities in Maryland and California. The following table represents future minimum operating lease payments under non-cancelable operating leases as of December 31, 2020:

	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
			(in millions)		
Operating Leases	$ 39.1	$ 6.7	$ 13.7	$ 10.9	$ 7.8

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined under the rules and regulations of the Securities and Exchange Commission.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary objective when considering our investment activities is to preserve capital in order to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Our current investment policy is to invest principally in deposits and securities issued by the U.S. government and its agencies, Government Sponsored Enterprise agency debt obligations, corporate debt obligations and money market instruments. As of December 31, 2020, we had cash, cash equivalents and marketable securities of $272.5 million. Our primary exposure to market risk is related to changes in interest rates. Due to the short-term maturities of our cash equivalents and marketable securities and the low risk profile of our marketable securities, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities. We have the ability to hold our marketable securities until maturity, and we therefore do not expect a change in market interest rates to affect our operating results or cash flows to any significant degree.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is set forth beginning on page F-1 in this Annual Report on Form 10-K.

ITEM 9. CHANGES AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, including our principal executive and principal financial officers, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed in this Annual Report on Form 10-K has been appropriately recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, to allow timely decisions regarding required disclosure. Based on that evaluation, our principal executive and principal financial officers have concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

Changes in Internal Control

Our management, including our principal executive and principal financial officers, has evaluated any changes in our internal control over financial reporting that occurred during the quarterly period ended December 31, 2020, and has concluded that there was no change that occurred during the quarterly period ended December 31, 2020 that have materially affected, or are reasonably likely to materially effect, the Company's internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel, 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 and includes those policies and procedures that:

- pertain to the management of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2020. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (COSO) in Internal Control-Integrated Framework. Based on our assessment, management believes that, as of December 31, 2020, the Company's internal control over financial reporting is effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2020 has been audited by Ernst & Young, LLP, an independent registered public accounting firm, as stated in their report which is included herein on the following page.

ITEM 9B. OTHER INFORMATION

None.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of MacroGenics, Inc.

Opinion on Internal Control over Financial Reporting

We have audited MacroGenics, Inc.'s internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, MacroGenics, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and our report dated February 25, 2021, expressed an unqualified opinion thereon.

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

Baltimore, Maryland
February 25, 2021

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

We incorporate herein by reference the relevant information concerning directors, executive officers and corporate governance to be included in our definitive proxy statement for the 2021 annual meeting of stockholders (the 2021 Proxy Statement).

ITEM 11. EXECUTIVE COMPENSATION

We incorporate herein by reference the relevant information concerning executive compensation to be included in the 2021 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

We incorporate herein by reference the relevant information concerning security ownership of certain beneficial owners and management to be included in the 2021 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

We incorporate herein by reference the relevant information concerning certain other relationships and related transactions to be included in the 2021 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

We incorporate herein by reference the relevant information concerning principal accountant fees and services to be included in the 2021 Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Consolidated Financial Statements:

2. Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

3. Exhibits

The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately following our consolidated financial statements. The Exhibit Index is incorporated herein by reference.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized:

MacroGenics, Inc.

By: /s/ Scott Koenig
Scott Koenig, M.D., Ph.D.
President and CEO and Director

Pursuant to the requirements of the Securities Act of 1934, as amended, this Report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Scott Koenig Scott Koenig, M.D., Ph.D.	President and CEO and Director (Principal Executive Officer)	February 25, 2021
/s/ James Karrels James Karrels	Senior Vice President, Chief Financial Officer and Secretary (Principal Financial Officer)	February 25, 2021
/s/ Lynn Cilinski Lynn Cilinski	Vice President, Controller and Treasurer (Principal Accounting Officer)	February 25, 2021
/s/ Paulo Costa Paulo Costa	Director	February 25, 2021
/s/ Karen Ferrante, M.D. Karen Ferrante, M.D.	Director	February 25, 2021
/s/ Kenneth Galbraith Kenneth Galbraith	Director	February 25, 2021
/s/ Edward Hurwitz Edward Hurwitz	Director	February 25, 2021
/s/ Scott Jackson Scott Jackson	Director	February 25, 2021
/s/ Federica O'Brien Federica O'Brien	Director	February 25, 2021
/s/ Jay Siegel, M.D. Jay Siegel, M.D.	Director	February 25, 2021
/s/ David Stump, M.D. David Stump, M.D.	Director	February 25, 2021

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of MacroGenics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of MacroGenics, Inc. (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 25, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

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

We conducted our 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 financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Clinical Trial Accruals

Description of the Matter

As disclosed in Note 2 to the consolidated financial statements, the Company expenses research and development expenditures as incurred, which include costs relating to clinical trial activities. The Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the clinical research organizations (CROs), investigators, professional service providers, and other vendors providing development services (collectively, the "service providers"). The Company's clinical trial accrual balance at December 31, 2020 is included in accrued expenses and other current liabilities of $34.2 million on the consolidated balance sheet, and the Company's related 2020 clinical trial expenses are included in research and development costs and expenses of $193.2 million on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2020.

Auditing the Company's accruals for clinical trial costs involved complex and subjective auditor judgment due to the significant estimation required by management in determining the progress to completion of services that have been performed by the service providers and the associated costs that will be invoiced by the service providers subsequent to the date that the consolidated financial statements are issued.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls addressing the identified risks related to the Company's process for estimating accrued clinical trial costs. For example, we tested controls over management's review of the clinical trial expense calculations, the significant assumptions about the status of research and development services incurred, and the completeness and accuracy of the data used to calculate the estimates.

To test the clinical trial accruals, our audit procedures included, among others, reviewing a sample of agreements with the service providers to corroborate key financial and contractual terms, and testing the accuracy and completeness of the underlying data used in the accrual computations. We also evaluated management's estimates of the progress of a sample of clinical trials by making direct inquiries of the Company's operations personnel that oversee the clinical trials and obtaining information directly from certain service providers about the service providers' estimate of costs that had been incurred through December 31, 2020. To evaluate the completeness of the accruals, we also examined subsequent invoices from the service providers and cash disbursements to the service providers, to the extent such invoices were received, or payments were made prior to the date that the consolidated financial statements were issued.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2006.

Baltimore, Maryland
February 25, 2021

MACROGENICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 181,131	$ 126,472
Marketable securities	91,400	89,284
Accounts receivable	23,081	12,744
Prepaid expenses and other current assets	16,982	11,285
Total current assets	312,594	239,785
Property, equipment and software, net	42,225	48,211
Other assets	23,924	24,505
Total assets	$ 378,743	$ 312,501
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 8,031	$ 4,308
Accrued expenses and other current liabilities	34,198	27,139
Deferred revenue	4,456	10,700
Lease liabilities	3,988	3,020
Total current liabilities	50,673	45,167
Deferred revenue, net of current portion	6,926	9,153
Lease liabilities, net of current portion	25,260	27,553
Total liabilities	82,859	81,873
Stockholders' equity:		
Common stock, $0.01 par value -- 125,000,000 shares authorized, 56,244,771 and 48,958,763 shares outstanding at December 31, 2020 and December 31, 2019, respectively	562	490
Additional paid-in capital	1,067,150	872,204
Accumulated other comprehensive income (loss)	(7)	16
Accumulated deficit	(771,821)	(642,082)
Total stockholders' equity	295,884	230,628
Total liabilities and stockholders' equity	$ 378,743	$ 312,501

See accompanying notes.

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Year Ended December 31,		
	2020	**2019**	**2018**
Revenues:			
Revenue from collaborative and other agreements	$ 97,764	$ 62,024	$ 58,644
Revenue from government agreements	7,119	2,164	1,477
Total revenues	104,883	64,188	60,121
Costs and expenses:			
Research and development	193,201	195,309	190,827
General and administrative	42,742	46,064	40,500
Total costs and expenses	235,943	241,373	231,327
Loss from operations	(131,060)	(177,185)	(171,206)
Other income (expense)	1,321	25,374	(247)
Net loss	(129,739)	(151,811)	(171,453)
Other comprehensive loss:			
Unrealized gain (loss) on investments	(23)	19	58
Comprehensive loss	$ (129,762)	$ (151,792)	$ (171,395)
Basic and diluted net loss per common share	$ (2.47)	$ (3.16)	$ (4.19)
Basic and diluted weighted average number of common shares	52,442,389	48,082,728	40,925,318

See accompanying notes.

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance, December 31, 2017	36,859,077	$ 369	—	$ —	$ 611,270	$ (312,340)	$ (61)	$ 299,238
Cumulative effect of adoption of accounting standards	—	—	—	—	—	(6,478)	—	(6,478)
Share-based compensation	—	—	—	—	16,520	—	—	16,520
Issuance of common stock, net of offering costs	5,175,000	52	—	—	103,207	—	—	103,259
Stock plan related activity	319,224	3	11,070	(260)	1,990	—	—	1,733
Retirement of treasury stock	—	—	(11,070)	260	(260)	—	—	—
Unrealized gain on investments	—	—	—	—	—	—	58	58
Net loss	—	—	—	—	—	(171,453)	—	(171,453)
Balance, December 31, 2018	42,353,301	424	—	—	732,727	(490,271)	(3)	242,877
Share-based compensation	—	—	—	—	19,571	—	—	19,571
Issuance of common stock, net of offering costs	6,325,000	63	—	—	118,594	—	—	118,657
Stock plan related activity	280,462	3	—	—	1,312	—	—	1,315
Unrealized gain on investments	—	—	—	—	—	—	19	19
Net loss	—	—	—	—	—	(151,811)	—	(151,811)
Balance, December 31, 2019	48,958,763	490	—	—	872,204	(642,082)	16	230,628
Share-based compensation	—	—	—	—	20,676	—	—	20,676
Issuance of common stock, net of offering costs	6,612,815	66	—	—	170,390	—	—	170,456
Stock plan related activity	673,193	6	74,632	(2,012)	5,892	—	—	3,886
Retirement of treasury stock	—	—	(74,632)	2,012	(2,012)	—	—	—
Unrealized loss on investments	—	—	—	—	—	—	(23)	(23)
Net loss	—	—	—	—	—	(129,739)	—	(129,739)
Balance, December 31, 2020	56,244,771	$ 562	—	$ —	$1,067,150	$ (771,821)	$ (7)	$ 295,884

See accompanying notes.

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2020	**2019**	**2018**
Operating activities			
Net loss	$ (129,739)	$ (151,811)	$ (171,453)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	11,957	12,306	9,160
Amortization of premiums and discounts on marketable securities	(260)	(1,461)	(881)
Share-based compensation	20,676	19,571	16,520
Changes in operating assets and liabilities:			
Accounts receivable	(10,337)	16,839	(15,941)
Prepaid expenses	(5,697)	(4,878)	(3,255)
Other assets	581	(1,578)	(4,580)
Accounts payable	3,723	787	1,554
Accrued expenses and other current liabilities	6,994	(6,057)	3,208
Lease liabilities	(1,324)	2,881	—
Deferred revenue	(8,472)	(20,869)	13,405
Deferred rent	—	—	(971)
Net cash provided by (used in) operating activities	(111,898)	(134,270)	(153,234)
Cash flows from investing activities			
Purchases of marketable securities	(223,745)	(264,399)	(132,750)
Proceeds from sales and maturities of marketable securities	221,866	189,330	214,348
Purchases of property, equipment and software	(5,906)	(4,289)	(24,954)
Net cash used in investing activities	(7,785)	(79,358)	56,644
Cash flows from financing activities			
Proceeds from issuance of common stock, net of offering costs	170,456	118,657	103,259
Proceeds from stock option exercises and ESPP purchases	5,898	1,315	1,992
Purchase of treasury stock	(2,012)	—	(260)
Net cash provided by financing activities	174,342	119,972	104,991
Net change in cash and cash equivalents	54,659	(93,656)	8,401
Cash and cash equivalents at beginning of period	126,472	220,128	211,727
Cash and cash equivalents at end of period	$ 181,131	$ 126,472	$ 220,128
Non-cash operating and investing activities:			
Right-of-use assets modified in exchange for operating lease obligation	$ —	$ 6,408	$ —
Fair value of warrants received	$ —	$ —	$ 6,130

See accompanying notes.

1. Organization and Nature of Operations

MacroGenics, Inc. (the Company) is incorporated in the state of Delaware. The Company is a biopharmaceutical company focused on developing and commercializing innovative antibody-based therapeutics designed to modulate the human immune response for the treatment of cancer. In December 2020, the U.S. Food and Drug Administration (FDA) approved MARGENZA (margetuximab-cmkb). In addition, the Company has a pipeline of product candidates in human clinical testing that have been created primarily using its proprietary, antibody-based technology platforms. The Company believes its product candidates have the potential to have a meaningful effect on treating patients' unmet medical needs as monotherapy or, in some cases, in combination with other therapeutic agents.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, MacroGenics UK Limited and MacroGenics Limited. All intercompany accounts and transactions have been eliminated in consolidation. The Company currently operates in one operating segment. Operating segments are defined as components of an enterprise about which separate discrete information is available for the chief operating decision maker, or decision making group, in deciding how to allocate resources and assessing performance. The Company views its operations and manages its business in one segment, which is developing and commercializing monoclonal antibody-based therapeutics.

Use of Estimates

The preparation of the financial statements in accordance with generally accepted accounting principles (GAAP) requires the Company to make estimates and judgments in certain circumstances that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. In preparing these consolidated financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. On an ongoing basis, the Company evaluates its estimates, including those related to revenue recognition, fair values of assets, stock-based compensation, income taxes, preclinical study and clinical trial accruals and other contingencies. Management bases its estimates on historical experience or on various other assumptions that it believes to be reasonable under the circumstances. Actual results could differ from these estimates.

Cash, Cash Equivalents and Marketable Securities

The Company considers all investments in highly liquid financial instruments with a maturity of 90 days or less at the date of purchase to be cash equivalents. Cash and cash equivalents includes investments in money market funds with commercial banks and financial institutions, securities issued by the U.S. government and its agencies, Government Sponsored Enterprise agency debt obligations and corporate debt obligations. Cash equivalents are stated at amortized cost, plus accrued interest, which approximates fair value.

The Company carries marketable securities classified as available-for-sale at fair value as determined by prices for identical or similar securities at the balance sheet date. Marketable securities consist of Level 2 financial instruments in the fair-value hierarchy. The Company records unrealized gains and losses as a component of other comprehensive loss within the statements of operations and comprehensive loss and as a separate component of stockholders' equity. Realized gains or losses on available-for-sale securities are determined using the specific identification method and the Company includes net realized gains and losses in other income (expense).

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-13, *Financial Instruments – Credit Losses (Topic 326)* (ASU 2016-13), which modifies the measurement of expected credit losses on certain financial instruments. In addition, for available-for-sale debt securities, the standard eliminates the concept of other-than-temporary impairment and requires the recognition of an allowance for credit losses rather than reductions in the amortized cost of the securities. The Company adopted ASU 2016-13 and all related ASU amendments on January 1, 2020, using a modified retrospective transition method, which requires a cumulative-effect adjustment, if any, to the opening balance of retained earnings to be recognized on the date of adoption with prior periods not restated. The Company evaluated its available-for-sale debt securities at January 1, 2020 and determined that no cumulative-effect adjustment was required. Adoption of the new standard did not have a material impact on the Company's consolidated financial statements.

Under the new guidance, at each reporting date, entities must evaluate their individual available-for-sale debt securities that are in an unrealized loss position and determine whether the decline in fair value below the amortized cost basis results

from a credit loss or other factors. The Company evaluates various quantitative factors including, but not limited to, the nature of the investments, changes in credit ratings, interest rate fluctuations, industry analyst reports, and the severity of the impairment. The amount of the decline related to credit losses is recorded as a credit loss expense in earnings with a corresponding allowance for credit losses and the amount of the decline not related to credit losses is recorded through other comprehensive income. See Note 3, Marketable Securities, for additional information.

Accounts Receivable

Accounts receivable that management has the intent and ability to collect are reported in the consolidated balance sheets at outstanding amounts, less an allowance for doubtful accounts. The Company writes off uncollectible receivables when the likelihood of collection is remote.

The Company evaluates the collectability of accounts receivable on a regular basis. The allowance, if any, is based upon various factors including the financial condition and payment history of customers, an overall review of collections experience on other accounts and economic factors or events expected to affect future collections experience. No allowance was recorded as of December 31, 2020 or 2019, as the Company has a history of collecting on all outstanding accounts.

Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, accounts receivable, accounts payable and accrued expenses. The carrying amount of accounts receivable, accounts payable and accrued expenses are generally considered to be representative of their respective fair values because of their short-term nature. The Company accounts for recurring and non-recurring fair value measurements in accordance with FASB Accounting Standards Codification (ASC) 820, *Fair Value Measurements and Disclosures* (ASC 820). ASC 820 defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value, and requires expanded disclosures about fair value measurements. The ASC 820 hierarchy ranks the quality of reliability of inputs, or assumptions, used in the determination of fair value and requires assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

- Level 1 – Fair value is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities.
- Level 2 – Fair value is determined by using inputs other than Level 1 quoted prices that are directly or indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models, such as interest rates and yield curves that can be corroborated by observable market data.
- Level 3 – Fair value is determined by inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant and subjective judgments to be made by a reporting entity – e.g., determining an appropriate adjustment to a discount factor for illiquidity associated with a given security.

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the ASC 820 hierarchy.

Financial assets measured at fair value on a recurring basis were as follows (in thousands):

	Fair Value Measurement at December 31, 2020			
	Total	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3
Assets:				
Money market funds	$ 49,004	$ 49,004	$ —	$ —
U.S Treasury securities	60,623	—	60,623	—
Corporate debt securities	33,776	—	33,776	—
Total assets measured at fair value [(a)]	$ 143,403	$ 49,004	$ 94,399	$ —

	Fair Value Measurement at December 31, 2019			
	Total	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3
Assets:				
Money market funds	$ 46,149	$ 46,149	$ —	$ —
Government-sponsored enterprises	13,222	—	13,222	—
Corporate debt securities	103,135	—	103,135	—
Total assets measured at fair value [(b)]	$ 162,506	$ 46,149	$ 116,357	$ —

(a) Total assets measured at fair value at December 31, 2020 includes approximately $52.0 million reported in cash and cash equivalents on the balance sheet.

(b) Total assets measured at fair value at December 31, 2019 includes approximately $73.2 million reported in cash and cash equivalents on the balance sheet.

The fair value of Level 2 securities is determined from market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data. The fair value of Level 3 securities is determined using the Black-Scholes option-pricing model. There were no transfers between levels during the periods presented.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, marketable securities and accounts receivable. The Company maintains its cash and money market funds with financial institutions that are federally insured. While balances deposited in these institutions often exceed Federal Deposit Insurance Corporation limits, the Company has not experienced any losses on related accounts to date. The Company's investment policy limits investments to certain types of debt securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The counterparties are various corporations, financial institutions and government agencies of high credit standing.

The Company's revenue relates to agreements with various collaborators and contracts and research grants received from U.S. government agencies. The following table includes those collaborators that represent more than 10% of total revenue earned in the periods indicated:

	Year Ended December 31,		
	2020	2019	2018
Incyte Corporation (Incyte)	47%	35%	68%
Janssen Biotech, Inc. (Janssen)	19%	*	*
Zai Lab Limited (Zai Lab)	11%	29%	*
Les Laboratoires Servier and Institut de Recherches Servier (Servier)	*	18%	*

* Balance is less than 10%

The following table includes those counterparties that represent more than 10% of accounts receivable at the date indicated:

	December 31,	
	2020	2019
Janssen	87%	*
Incyte	*	62%
Zai Lab	*	23%

Property, Equipment and Software

Property, equipment and software are stated at cost. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation or amortization are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred. Depreciation and amortization are computed using the straight-line method over the following estimated useful lives:

Computer equipment	3 years
Software	3 years
Furniture	10 years
Laboratory and office equipment	5 years
Leasehold improvements	Shorter of lease term or useful life

Impairment of Long-Lived Assets

The Company assesses the recoverability of its long-lived assets in accordance with the provisions of ASC 360, *Property, Plant and Equipment* (ASC 360). ASC 360 requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset or asset group. If carrying value exceeds the sum of undiscounted cash flows, the Company then determines the fair value of the underlying asset group. Any impairment to be recognized is measured by the amount by which the carrying amount of the asset group exceeds the estimated fair value of the asset group. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less costs to sell. For the years ended December 31, 2020, 2019 and 2018, the Company determined that there were no impaired assets.

Income Taxes

Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized as income in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more-likely-than-not threshold of that position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as the largest amount that is more likely than not to be realized upon ultimate settlement. The Company's policy is to record interest and penalties related to uncertain tax positions as a component of income tax expense.

Revenues

The Company recognizes revenue under ASU No. 2014-09, *Revenue from Contracts with Customer*s and all related amendments (collectively ASC 606) when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into licensing agreements that are within the scope of ASC 606, under which it may license rights to research, develop, manufacture and commercialize its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products. The Company may also enter into development and manufacturing service agreements with its collaborators.

For each arrangement that results in revenues, the Company identifies all performance obligations, which may include a license to intellectual property and know-how, research and development activities, transition activities and/or manufacturing services. In order to determine the transaction price, in addition to any upfront payment, the Company estimates the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract. The Company constrains (reduces) the estimates of variable

consideration such that it is probable that a significant reversal of previously recognized revenue will not occur. When determining if variable consideration should be constrained, management considers whether there are factors outside the Company's control that could result in a significant reversal of revenue. In making these assessments, the Company considers the likelihood and magnitude of a potential reversal of revenue. These estimates are re-assessed each reporting period as required.

Once the estimated transaction price is established, amounts are allocated to the performance obligations that have been identified. The transaction price is generally allocated to each separate performance obligation on a relative standalone selling price basis. The Company must develop assumptions that require judgment to determine the standalone selling price in order to account for these agreements. To determine the standalone selling price, the Company's assumptions may include (i) the probability of obtaining marketing approval for the product candidate, (ii) estimates regarding the timing and the expected costs to develop and commercialize the product candidate, and (iii) estimates of future cash flows from potential product sales with respect to the product candidate. Standalone selling prices used to perform the initial allocation are not updated after contract inception. The Company does not include a financing component to its estimated transaction price at contract inception unless it estimates that certain performance obligations will not be satisfied within one year.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Licenses. When the Company grants a license to its intellectual property, it determines whether the nature of the intellectual property to which the customer will have rights is functional intellectual property (functional IP), which has significant standalone functionality, or symbolic intellectual property (symbolic IP) which does not have significant standalone functionality. Revenue from functional IP is recognized at the point in time when control of the distinct license is transferred to the customer. Revenue from symbolic IP is recognized over the access period to the Company's intellectual property. If the license to the Company's intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and when (or as) the customer is able to use and benefit from the license. In assessing whether a promise or performance obligation is distinct from the other promises, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the licensee and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the licensee can benefit from a promise for its intended purpose without the receipt of the remaining promise, whether the value of the promise is dependent on the unsatisfied promise, whether there are other vendors that could provide the remaining promise, and whether it is separately identifiable from the remaining promise. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Research, Development and/or Manufacturing Services. The promises under the Company's agreements may include research and development or manufacturing services to be performed by the Company on behalf of the counterparty. If these services are determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to these services as revenue over time based on an appropriate measure of progress when the performance by the Company does not create an asset with an alternative use and the Company has an enforceable right to payment for the performance completed to date. If these services are determined not to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to the combined performance obligation as the related performance obligations are satisfied.

Customer Options. If an arrangement contains customer options, the Company evaluates whether the options are material rights because they allow the customer to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised. If the options are deemed not to be a material right, they are excluded as performance obligations at the outset of the arrangement.

Milestone Payments. At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties. For arrangements that include sales-based royalties which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties who are both active participants in the activities and are both exposed to significant risks and rewards dependent on the commercial success of such activities. Such arrangements generally are within the scope of ASC 808, *Collaborative Arrangements* (ASC 808). While ASC 808 defines collaborative arrangements and provides guidance on income statement presentation, classification, and disclosures related to such arrangements, it does not address recognition and measurement matters, such as (1) determining the appropriate unit of accounting or (2) when the recognition criteria are met. Therefore, the accounting for these arrangements is either based on an analogy to other accounting literature or an accounting policy election by the Company. The Company accounts for certain components of the collaboration agreement that are reflective of a vendor-customer relationship (e.g., licensing arrangement) based on an analogy to ASC 606. The Company accounts for other components based on a reasonable, rational and consistently applied accounting policy election. Reimbursements from the counter-party that are the result of a collaborative relationship with the counter-party, instead of a customer relationship, such as co-development activities, are recorded as a reduction to research and development expense as the services are performed.

For a complete discussion of accounting for revenue from collaborative and other agreements, see Note 9, Collaboration and Other Agreements.

Research and Development Costs, Including Clinical Trial Accruals/Expenses

Research and development expenditures are expensed as incurred. Research and development costs primarily consist of employee related expenses, including salaries and benefits, expenses incurred under agreements with contract research organizations (CROs), investigative sites and consultants that conduct the Company's clinical trials, the cost of acquiring and manufacturing clinical trial materials, including costs incurred under agreements with contract manufacturing organizations (CMOs), and other allocated expenses, license fees for and milestone payments related to in-licensed products and technologies, stock-based compensation expense, and costs associated with non-clinical activities and regulatory approvals.

Right-to-develop agreements may contain cost-sharing provisions whereby the Company and the collaborator share the cost of research and development activities. Reimbursement of research and development expenses received in connection with these agreements is recorded as a reduction of such expenses.

Clinical trial expenses are a significant component of research and development expenses, and the Company outsources a significant portion of these costs to third parties. Third party clinical trial expenses include investigator fees, site and patient costs, CRO costs, costs for central laboratory testing, data management and CMO costs. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as a prepaid asset or accrued expenses. These third party agreements are generally cancellable, and related costs are recorded as research and development expenses as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, management analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. 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 estimates made. The historical clinical accrual estimates have not been materially different from the actual costs.

Stock-based Compensation

Stock-based payments are accounted for in accordance with the provisions of ASC 718, *Compensation – Stock Compensation*. The fair value of stock-based payments is estimated, on the date of grant, using the Black-Scholes model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option.

For all time-vesting awards granted, expense is amortized using the straight-line attribution method. For awards that contain a performance condition, expense is amortized using the accelerated attribution method. Recognition of stock-based compensation expense is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period.

The Company utilizes the Black-Scholes model for estimating fair value of its stock options granted. Option valuation models, including the Black-Scholes model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

Comprehensive Loss

Comprehensive loss represents net loss adjusted for the change during the periods attributed to unrealized gains and losses on available-for-sale debt securities.

Net Loss Per Share

Basic and diluted loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. All stock options and restricted stock units (RSUs) are excluded from the per share calculations as such securities were anti-dilutive for all periods presented. The following table presents the number of stock options and RSUs that were excluded from the calculation of net loss per share:

	Year Ended December 31,		
	2020	**2019**	**2018**
Stock options and RSUs	7,467,603	7,159,494	5,273,964

Recently Adopted Accounting Standards

In February 2016, the FASB issued ASU 2016-02, which requires lessees to recognize a right-of-use (ROU) asset and a lease liability for all leases with terms greater than 12 months and also requires disclosures by lessees and lessors about the amount, timing and uncertainty of cash flows arising from leases. Subsequent to the issuance of ASU 2016-02, the FASB clarified the guidance through several ASUs, with the resulting guidance collectively referred to as ASC 842. The Company adopted ASC 842 effective January 1, 2019, using the optional transition method provided under ASU 2018-11, which did not require adjustments to comparative periods nor require modified disclosures in those comparative periods. The Company has elected not to recognize leases with terms of one year or less on the balance sheet.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances. For leases where the Company is the lessee, ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term of the lease for which the rate is estimated. Certain adjustments to the ROU asset may be required for items such as initial direct costs paid or incentives received. The lease terms used to calculate the ROU asset and related lease liabilities include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for operating leases is recognized on a straight-line basis over the lease term as an operating expense while the expense for finance leases is recognized as depreciation expense and interest expense using the accelerated interest method of recognition. The Company has lease agreements which require payments for lease and non-lease components and has elected the practical expedient not to separate non-lease components from lease components for all classes of underlying assets.

As a result of the cumulative impact of adopting ASC 842, the Company recorded operating lease ROU assets of $16.4 million and operating lease liabilities of $27.7 million as of January 1, 2019, primarily related to real estate leases, based on the present value of the future lease payments on the date of adoption. The ROU asset is included in Other assets on the consolidated balance sheets. Refer to Note 5, Leases, for additional disclosures required by ASC 842.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles - Goodwill and Other - Internal-Use Software* (ASU 2018-15). This new standard requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in ASC 350-40, *Accounting for Internal-Use Software*, to determine which implementation costs to capitalize as assets and amortize over the term of the hosting arrangement or expense as incurred. The Company adopted ASU 2018-15 effective January 1, 2020 and elected to apply this standard prospectively to all implementation costs incurred after the date of adoption. The adoption of ASU 2018-15 did not have a material impact on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808)—Clarifying the interaction between Topic 808 and Topic 606* (ASU 2018-18). The amendments provide guidance on whether certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606. It also specifically (i) addresses when the participant should be considered a customer in the context of a unit of account, (ii) adds unit-of-account guidance in ASC 808 to align with guidance in ASC 606, and (iii) precludes presenting revenue from a collaborative arrangement together with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer. The Company adopted ASU 2018-18 effective January 1, 2020, and the adoption of this standard did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Standards

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* (ASU 2019-12). ASU 2019-12 is part of the FASB's overall simplification initiative and seeks to simplify the accounting for income taxes by updating certain guidance and removing certain exceptions. The updated guidance is effective for fiscal years beginning after December 15, 2020 and interim periods within those fiscal years. Early adoption is permitted. The Company does not anticipate the adoption of this standard will have a material impact on its consolidated financial statements and related disclosures.

The Company has evaluated all other ASUs issued through the date the consolidated financials were issued and believes that the adoption of these will not have a material impact on the Company's consolidated financial statements.

3. Marketable Securities

Available-for-sale marketable securities as of December 31, 2020 and 2019 were as follows (in thousands):

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 60,630	$ 1	$ (7)	$ 60,624
Corporate debt securities	30,777	2	(3)	30,776
Total	$ 91,407	$ 3	$ (10)	$ 91,400

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises	$ 13,216	$ 6	$ —	$ 13,222
Corporate debt securities	76,052	20	(10)	76,062
Total	$ 89,268	$ 26	$ (10)	$ 89,284

All of the Company's available-for-sale securities held at December 31, 2020 and 2019 had contractual maturities of less than one year. All of the Company's available-for-sale marketable debt securities in an unrealized loss position as of December 31, 2020 and 2019 were in a loss position for less than twelve months. Unrealized losses on available-for-sale debt securities as of December 31, 2020 were not significant and were primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. Accordingly, no allowance for credit losses related to the Company's available-for-sale debt securities was recorded for the year ended December 31, 2020. The Company does not intend to sell these investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity. No losses related to other-than-temporary impairments of the Company's available-for-sale debt securities were recorded in Accumulated other comprehensive income during the year ended December 31, 2019. The Company recorded interest income of $0.8 million, $3.4 million and $2.3 million during the years ended December 31, 2020, 2019 and 2018, respectively, which is included in Other income (expense) on the consolidated statements of operations and comprehensive loss.

4. Property, Equipment and Software

Property, equipment and software consists of the following (in thousands):

	December 31,	
	2020	2019
Computer equipment	$ 2,663	$ 2,430
Software	8,242	7,513
Furniture and office equipment	713	713
Motor vehicles	50	50
Lab equipment	41,202	38,368
Leasehold improvements	48,884	48,675
Construction in progress	2,022	187
Property, equipment and software	103,776	97,936
Less accumulated depreciation and amortization	(61,551)	(49,725)
Property, equipment and software, net	$ 42,225	$ 48,211

Depreciation and amortization expense related to property, equipment and software for the years ended December 31, 2020, 2019 and 2018 was $12.0 million, $12.3 million and $9.2 million, respectively.

5. Leases

As described in Note 2. Summary of Significant Accounting Policies, the Company adopted *Topic 842* as of January 1, 2019. Prior period amounts have not been adjusted and continue to be reported in accordance with historic accounting under *Topic 840*.

The Company has non-cancelable operating leases for manufacturing, laboratory, office and warehouse space in Maryland and a non-cancelable operating lease for laboratory and office space in California. A portion of the space under one of these leases is subleased to a third party. All of these leases include one or more options to renew, with those renewal periods ranging from five to fourteen years.

The table below presents supplemental balance sheet information related to operating leases:

	December 31,	
	2020	**2019**
Weighted-average remaining lease term (in years)	5.9	5.6
Weighted-average discount rate	9.7 %	9.9 %

Upon adoption of ASC 842 on January 1, 2019, it was not reasonably certain that the Company would extend any of its operating leases, therefore the options to extend the lease terms were not recognized as part of the ROU assets or lease liabilities. During the year ended December 31, 2019, the Company exercised the options to extend two leases for an additional five years each, therefore the Company remeasured the lease liability and adjusted the carrying amount of the ROU asset related to these leases. During the years ended December 31, 2020 and 2019, the Company made cash payments for operating leases of $5.9 million and $6.4 million, respectively. As of December 31, 2020 and 2019, the Company's ROU assets were valued at $19.3 million and $20.2 million, respectively, and are included in Other assets on the consolidated balance sheet.

The components of lease cost for the years ended December 31, 2020 and 2019 were as follows (in thousands):

	December 31,	
	2020	**2019**
Operating lease cost	$ 5,410	$ 5,463
Variable lease cost	1,083	1,366
Sublease income	(770)	(942)
Net lease cost	$ 5,723	$ 5,887

As of December 31, 2020, the maturities of the Company's operating lease liabilities were as follows (in thousands):

2021	$ 6,726
2022	6,940
2023	6,796
2024	5,856
2025	5,084
Thereafter	7,764
Total lease payments	39,166
Present value adjustment	(9,918)
Lease liabilities	$ 29,248

6. Stockholders' Equity

The Company's amended and restated certificate of incorporation authorizes 125,000,000 shares of common stock, and 5,000,000 shares of undesignated preferred stock, both with a par value of $.01 per share. There were no shares of undesignated preferred stock issued or outstanding as of December 31, 2020 or 2019.

In April 2018, the Company completed a firm-commitment underwritten public offering, in which the Company sold 4,500,000 shares of its common stock at a price of $21.25 per share. Additionally, the underwriters of the offering exercised the full amount of their over-allotment option resulting in the sale of an additional 675,000 shares of the Company's common stock at a price of $21.25 per share. Upon closing, the Company received net proceeds of approximately $103.3 million from this offering, net of underwriting discounts and commissions and other offering expenses.

In February 2019, the Company completed a firm-commitment underwritten public offering, in which the Company sold 5,500,000 shares of its common stock at a price of $20.00 per share. Additionally, the underwriters of the offering exercised the full amount of their over-allotment option resulting in the sale of an additional 825,000 shares of the Company's common stock at a price of $20.00 per share. The Company received net proceeds of approximately $118.7 million from this offering, net of underwriting discounts and commissions and other offering expenses.

In December 2019, the Company entered into a sales agreement with an agent to sell, from time to time, shares of its common stock in amounts of up to $50.0 million through an "at the market offering" (ATM Offering) as defined in Rule 415 under the Securities Act of 1933, as amended. This agreement was amended in June 2020 to increase the maximum amount of the offering to $175.0 million. The shares that may be sold under the sales agreement would be issued and sold pursuant to the Company's shelf registration statement on Form S-3 that was filed with the Securities and Exchange Commission on December 23, 2019. During the year ended December 31, 2020, the Company sold 6,612,815 shares of common stock at a weighted average price per share of $26.46, resulting in net proceeds of approximately $170.5 million, net of underwriting discounts and commissions and other offering expenses.

7. Stock-based Compensation

Employee Stock Purchase Plan

In May 2017, the Company's stockholders approved the 2016 Employee Stock Purchase Plan (the 2016 ESPP). The 2016 ESPP is structured as a qualified employee stock purchase plan under Section 423 of the Internal Revenue Code of 1986, as amended, and is not subject to the provisions of the Employee Retirement Income Security Act of 1974. The Company reserved 800,000 shares of common stock for issuance under the 2016 ESPP. The 2016 ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 10% of their eligible compensation, subject to any plan limitations. The 2016 ESPP provides for six-month offering periods ending on May 31 and November 30 of each year. At the end of each offering period, employees are able to purchase shares at 85% of the fair market value of the Company's common stock on the last day of the offering period. During the year ended December 31, 2020, employees purchased 32,430 shares of common stock under the 2016 ESPP for net proceeds to the Company of approximately $0.6 million.

Employee Stock Incentive Plans

Effective February 2003, the Company implemented the 2003 Equity Incentive Plan (2003 Plan), and it was amended and approved by the Company's stockholders in 2005. Stock options granted under the 2003 Plan may be either incentive stock options as defined by the Internal Revenue Code (IRC), or non-qualified stock options. In 2013, the 2003 Plan was terminated, and no further awards may be issued under the plan. Any shares of common stock subject to awards under the 2003 Plan that expire, terminate, or are otherwise surrendered, canceled, forfeited or repurchased without having been fully exercised, or resulting in any common stock being issued, will become available for issuance under the 2013 Stock Incentive Plan (2013 Plan), up to a specified number of shares. As of December 31, 2020, under the 2003 Plan, there were options to purchase an aggregate of 249,959 shares of common stock outstanding at a weighted average exercise price of $2.79 per share.

In October 2013, the Company implemented the 2013 Plan. The 2013 Plan provides for the grant of stock options and other stock-based awards, as well as cash-based performance awards. The aggregate number of shares of common stock initially available for issuance pursuant to awards under the 2013 Plan was 1,960,168 shares. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each year from January 1, 2014 through and including January 1, 2023, by the lesser of (a) 1,960,168 shares, (b) 4.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or (c) the number of shares of common stock determined by the Board of Directors. During the year ended December 31, 2020, the maximum number of shares of common stock authorized to be issued by the Company under the 2013 Plan was increased to 11,896,613. If an option expires or terminates for any reason without having been fully exercised, if any shares of restricted stock are forfeited, or if any award terminates, expires or is settled

without all or a portion of the shares of common stock covered by the award being issued, such shares are available for the grant of additional awards. However, any shares that are withheld (or delivered) to pay withholding taxes or to pay the exercise price of an option are not available for the grant of additional awards. As of December 31, 2020, under the 2013 Plan, there were options to purchase an aggregate of 7,008,394 shares of common stock outstanding at a weighted average exercise price of $22.14 per share.

The following stock-based compensation amounts were recognized for the periods indicated (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Research and development	$ 10,833	$ 10,023	$ 7,919
General and administrative	9,843	9,548	8,601
Total stock-based compensation expense	$ 20,676	$ 19,571	$ 16,520

Employee Stock Options

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model using the assumptions in the following table:

	Year Ended December 31,		
	2020	2019	2018
Expected dividend yield	0%	0%	0%
Expected volatility	67% - 109%	74% - 76%	68% - 72%
Risk-free interest rate	0.4% - 1.8%	1.4% - 2.6%	2.4% - 3.1%
Expected term	6.25 years	6.25 years	6.25 years

Expected Dividend Yield – The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

Expected Volatility – Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. For periods through December 31, 2019, the computation of expected volatility is based on the historical volatility of several public entities of similar size, complexity and stage of development, as the Company did not have sufficient history of its own volatility. As of December 31, 2019, the Company had sufficient company-specific historical and implied volatility information. As such, beginning the first quarter of 2020, the computation of expected volatility is based only on the historical volatility of the Company's common stock.

Risk-Free Interest Rate – This is the U.S. Treasury rate for the week of each option grant during the year, having a term that most closely resembles the expected life of the option.

Expected Term – This is the period of time that the options granted are expected to remain unexercised. Options granted have a maximum term of ten years. The Company uses a simplified method to calculate the average expected term.

In addition to the assumptions above, the Company estimates the forfeiture rate based on turnover data with further consideration given to the class of the employees to whom the options were granted. The forfeiture rate is the estimated percentage of options granted that is expected to be forfeited or canceled on an annual basis before becoming fully vested.

The following table summarizes stock option activity for 2020:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2019	6,706,994	$ 22.33	6.9	
Granted	1,851,327	15.11		
Exercised	(504,445)	10.56		
Forfeited or expired	(795,523)	20.72		
Outstanding, December 31, 2020	7,258,353	21.48	6.8	$ 27,409
December 31, 2020:				
Exercisable	4,660,921	22.92	5.8	13,906
Vested and expected to vest	6,973,272	21.57	6.7	26,011

During 2020, 2019 and 2018 the Company issued 504,445, 219,045 and 274,362 net shares of common stock, respectively, in conjunction with stock option exercises. The Company received cash proceeds from the exercise of stock options of approximately $5.3 million, $0.7 million and $0.9 million during 2020, 2019 and 2018, respectively.

The weighted-average grant-date fair value of options granted during 2020, 2019 and 2018 was $10.68, $13.98 and $17.90 per share, respectively. The total intrinsic value of options exercised during 2020, 2019 and 2018 was approximately $4.3 million, $2.9 million and $5.2 million, respectively. The total fair value of stock options which vested during 2020, 2019 and 2018 was $16.7 million, $17.7 million and $16.4 million, respectively. As of December 31, 2020, the total unrecognized compensation expense related to non-vested stock options, net of related forfeiture estimates, was $27.5 million, which the Company expects to recognize over a weighted-average period of approximately 2.4 years.

Restricted Stock Units

During 2019, the Company awarded RSUs under the 2013 Plan to all employees except executive officers and employees with less than six months of service as of the grant date. Each RSU entitles the holder to receive one share of the Company's common stock when the RSU vests. The RSUs vest in two equal installments on the first and second anniversary of the grant date. Compensation expense is recognized on a straight-line basis.

The following table summarizes RSU activity for 2020:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding, December 31, 2019	452,500	$ 15.32
Granted	15,000	23.68
Exercised	(210,950)	15.32
Forfeited or expired	(47,300)	15.32
Outstanding, December 31, 2020	209,250	15.92

At December 31, 2020, there was $2.0 million of total unrecognized compensation cost related to unvested RSUs, which the Company expects to recognize over a remaining weighted-average period of eight months.

8. Income Taxes

For the years ended December 31, 2020, 2019 and 2018 there was no provision for income taxes due to taxable losses generated, fully offset by a valuation allowance.

The significant components of the Company's deferred income tax assets (liabilities) were as follows (in thousands):

	December 31,	
	2020	2019
Deferred income tax assets:		
Federal U.S. net operating loss carryforward	$ 136,086	$ 116,436
State net operating loss carryforward	37,465	31,110
Research and development credit, net	50,271	35,580
Orphan drug credit, net	23,409	22,881
Operating lease liabilities	8,048	8,413
Deferred revenue	3,132	367
Other	14,285	9,123
Gross deferred income tax assets	272,696	223,910
Valuation allowance	(263,403)	(214,893)
Net deferred income tax assets	9,293	9,017
Deferred income tax liabilities:		
Depreciation	(2,123)	(438)
Operating lease ROU assets	(5,316)	(5,547)
Prepaid expenditures	(1,854)	(3,032)
Gross deferred income tax liabilities	(9,293)	(9,017)
Net deferred income tax asset/(liability)	$ —	$ —

The Company recognizes valuation allowances to reduce deferred tax assets to the amount that is more likely than not to be realized. In assessing the likelihood of realization, management considers (i) future reversals of existing taxable temporary differences; (ii) future taxable income exclusive of reversing temporary difference and carryforwards; (iii) taxable income in prior carryback years if carryback is permitted under applicable tax law; and (iv) tax planning strategies. The Company's net deferred income tax asset is not more likely than not to be utilized due to the lack of sufficient sources of future taxable income and cumulative book losses which have resulted over the years.

As of December 31, 2020, the Company has U.S. federal and state net operating loss (NOL) carryforwards of approximately $648.0 million. Of these NOLs, $237.7 million will expire in various years beginning in 2025 through 2037. $410.3 million of NOLs were generated post December 31, 2017 and carryforward indefinitely. In addition, the Company has U.S. federal tax credits of $69.6 million which will expire in various years beginning in 2022 through 2039.

The use of the Company's U.S. federal NOL and tax credit carryforwards in future years are restricted due to changes in the Company's ownership and tax attributes acquired through the Company's acquisitions. As of December 31, 2020, $13.5 million of the Company's U.S. Federal NOLs are limited for use over the years 2021 – 2028 in which a range of such amounts could be utilized on an annual basis of $0.2 million to $1.4 million. The remaining $634.5 million of NOLs is not limited and can be offset against future taxable income, subject to certain limitations for newly enacted tax legislation.

The reconciliation of the reported estimated income tax benefit to the amount that would result by applying the U.S. federal statutory tax rate to the net income is as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
United States federal tax at statutory rate	$ (27,245)	$ (31,880)	$ (36,005)
State taxes (net of federal benefit)	(8,100)	(9,524)	(11,133)
Deferred income tax adjustments	344	2,004	(4,435)
Research credit, net	(14,691)	(5,830)	(8,466)
Orphan drug credit, net	(528)	(301)	(872)
Other permanent items	1,156	1,206	148
Equity-based compensation	554	1,889	758
Change in valuation allowance	48,510	42,436	60,005
Income tax expense/(benefit)	$ —	$ —	$ —

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Beginning balance	$ 4,950	$ 4,318	$ 3,395
Increases for current year tax positions	839	637	642
Increases/(decreases) for prior year tax positions	337	(5)	281
Ending balance	$ 6,126	$ 4,950	$ 4,318

As of December 31, 2020 and 2019, of the total gross unrecognized tax benefits, approximately $6.1 million and $4.9 million would favorably impact the Company's effective income tax rate, respectively. Although, due to the Company's determination that the deferred income tax asset would not more likely than not be realized, a valuation allowance would be recorded, therefore, zero net impact would result within the Company's effective income tax rate. The Company's uncertain income tax position liability has been recorded to deferred income taxes to offset the tax attribute carryforward amounts.

For the years ended December 31, 2020, 2019 and 2018, the Company has not recognized any interest or penalties related to the uncertain income tax positions due to the fact such position is related to tax attribute carryforwards which have not yet been utilized. The Company does not expect its unrecognized income tax position to significantly decrease within the next twelve months.

The Company's U.S. Federal and state income tax returns from 2001 forward remain open to examination due to the carryover of unused income tax credits, and from 2004 forward due to the carryover of unused net operating losses.

9. Collaboration and Other Agreements

Incyte

In 2017, the Company entered into an exclusive global collaboration and license agreement with Incyte for retifanlimab (formerly known as MGA012 and INCMGA0012), an investigational monoclonal antibody that inhibits programmed cell death protein 1 (PD-1) (Incyte License Agreement). Incyte has obtained exclusive worldwide rights for the development and commercialization of retifanlimab in all indications, while the Company retains the right to develop its pipeline assets in combination with retifanlimab. Under the terms of the Incyte License Agreement, Incyte paid the Company an upfront payment of $150.0 million in 2017.

Under the terms of the Incyte License Agreement, Incyte will lead global development of retifanlimab. Assuming successful development and commercialization by Incyte, the Company could receive up to approximately $420.0 million in development and regulatory milestones, and up to $330.0 million in commercial milestones. From its inception through December 31, 2020, the Company has recognized $55.0 million in development milestones under this agreement, and another $10.0 million milestone was achieved related to development progress of retifanlimab outside the U.S. subsequent to December 31, 2020. If retifanlimab is approved and commercialized, the Company would be eligible to receive tiered royalties of 15% to 24% on any global net sales. The Company retains the right to develop its pipeline assets in combination with retifanlimab, with

Incyte commercializing retifanlimab and the Company commercializing its asset(s), if any such potential combinations are approved. In addition, the Company retains the right to manufacture a portion of both companies' global commercial supply needs of retifanlimab, subject to the separate commercial supply agreement. Finally, Incyte funded the Company's activities related to the ongoing monotherapy clinical study.

The Company evaluated the Incyte License Agreement under the provisions of ASC 606 and identified the following two performance obligations under the agreement: (i) the license of retifanlimab and (ii) the performance of certain clinical activities through a brief technology transfer period. The Company determined that the license and clinical activities are separate performance obligations because they are capable of being distinct, and are distinct in the context of the contract. The license has standalone functionality as it is sublicensable, Incyte has significant capabilities in performing clinical trials, and Incyte is capable of performing these activities without the Company's involvement; the Company performed the activities during the transfer period as a matter of convenience. The Company determined that the transaction price of the Incyte Agreement at inception was $154.0 million, consisting of the consideration to which the Company was entitled in exchange for the license and an estimate of the consideration for clinical activities to be performed. The transaction price was allocated to each performance obligation based on their relative standalone selling price. The standalone selling price of the license was determined using the adjusted market assessment approach considering similar collaboration and license agreements. The standalone selling price for agreed-upon clinical activities to be performed was determined using the expected cost approach based on similar arrangements the Company has with other parties. The potential development and regulatory milestone payments are fully constrained until the Company concludes that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price. Any consideration related to sales-based milestones and royalties will be recognized when the related sales occur, as they were determined to relate predominantly to the license granted to Incyte and, therefore, have also been excluded from the transaction price. The Company re-assesses the transaction price in each reporting period and when events whose outcomes are resolved or other changes in circumstances occur. During the year ended December 31, 2018, it became probable that a significant reversal of cumulative revenue would not occur for three development milestones totaling $15.0 million related to retifanlimab meeting certain clinical proof-of-concept criteria. Therefore the associated consideration was added to the estimated transaction price and was recognized as revenue. During the year ended December 31, 2020, it became probable that a significant reversal of cumulative revenue would not occur for two development milestones totaling $40.0 million related to clinical and regulatory activities related to the further advancement of retifanlimab, including Incyte’s initiation of a Phase 3 clinical trial. Therefore the associated consideration was added to the estimated transaction price and was recognized as revenue.

The Company recognized the $150.0 million allocated to the license when it satisfied its performance obligation and transferred the license to Incyte in 2017. The $4.0 million allocated to the clinical activities was recognized ratably as services were performed over a period spanning 2017 and 2018. The Company recognized revenue of $40.0 million, $0.1 million and $18.8 million under the Incyte Agreement during the years ended December 31, 2020, 2019 and 2018, respectively. The revenue recognized during the year ended December 31, 2020 reflected milestone revenue of $40.0 million, and the revenue recognized during the year ended December 31, 2018 included milestone revenue of $15.0 million.

The Company also has an agreement with Incyte, which was entered into in 2018, under which the Company is to perform development and manufacturing services for Incyte’s clinical needs of retifanlimab (Incyte Clinical Supply Agreement). The Company evaluated this agreement under ASC 606 and identified one performance obligation under the agreement: to perform services related to the development and manufacturing of the clinical supply of retifanlimab. The transaction price is based on the costs incurred to develop and manufacture drug product and drug substance, and is recognized over time as the services are provided, as the performance by the Company does not create an asset with an alternative use and the Company has an enforceable right to payment for the performance completed to date. The transaction price will be recognized using the input method reflecting the costs incurred (including resources consumed and labor hours expended) related to the manufacturing services. During the years ended December 31, 2020, 2019 and 2018, the Company recognized revenue of $8.6 million, $22.1 million and $22.2 million, respectively, for services performed under this agreement.

In October 2020, the Company entered into an agreement with Incyte pursuant to which the Company is entitled to manufacture a portion of the global commercial supply needs for retifanlimab (Incyte Commercial Supply Agreement). Unless terminated earlier, the term of the Incyte Commercial Supply Agreement will expire upon the expiration of Incyte’s obligation to pay royalties under the Incyte License Agreement. The Company evaluated this agreement under ASC 606 and identified one performance obligation under the agreement: to perform services related to manufacturing the commercial supply of retifanlimab. The transaction price is based on a fixed price per batch of bulk drug substance to be manufactured and is recognized over time as the services are provided, as the performance by the Company does not create an asset with an alternative use and the Company has an enforceable right to payment for the performance completed to date. The transaction price will be recognized using the input method reflecting the costs incurred (including resources consumed and labor hours

expended) related to the manufacturing services. During the year ended December 31, 2020, the Company recognized revenue of $1.4 million for services performed under this agreement.

Zai Lab

In 2018, the Company entered into a collaboration and license agreement with Zai Lab (Zai Lab Agreement) under which Zai Lab obtained regional development and commercialization rights in mainland China, Hong Kong, Macau and Taiwan (Zai Lab's territory) for (i) margetuximab, an immune-optimized anti-HER2 monoclonal antibody, (ii) tebotelimab (formerly known as MGD013), a bispecific DART molecule designed to provide coordinate blockade of PD-1 and LAG-3 for the potential treatment of a range of solid tumors and hematological malignancies, and (iii) an undisclosed multi-specific TRIDENT molecule in preclinical development. Zai Lab will lead clinical development of these molecules in its territory.

Under the terms of the Zai Lab Agreement, Zai Lab paid the Company an upfront payment of $25.0 million ($22.5 million after netting value-added tax withholdings of $2.5 million). Assuming successful development and commercialization of margetuximab, tebotelimab and the TRIDENT molecule, the Company could receive up to $140.0 million in development and regulatory milestones, $4.0 million of which ($3.6 million after netting value-added tax withholdings of $0.4 million) was earned during the year ended December 31, 2020. In addition, Zai Lab would pay the Company tiered royalties at percentage rates of mid-teens to 20% for net sales of margetuximab in Zai Lab's territory, mid-teens for net sales of tebotelimab in Zai Lab's territory and 10% for net sales of the TRIDENT molecule in Zai Lab's territory, which may be subject to adjustment in specified circumstances.

The Company evaluated the Zai Lab Agreement under the provisions of ASC 606 and identified the following material promises under the arrangement for each of the two product candidates, margetuximab and tebotelimab: (i) an exclusive license to develop and commercialize the product candidate in Zai Lab's territory and (ii) certain research and development activities. The Company determined that each license and the related research and development activities were not distinct from one another, as the license has limited value without the performance of the research and development activities. As such, the Company determined that these promises should be combined into a single performance obligation for each product candidate. Activities related to margetuximab and tebotelimab are separate performance obligations from each other because they are capable of being distinct, and are distinct in the context of the contract. The Company evaluated the promises related to the TRIDENT molecule and determined they were immaterial in context of the contract, therefore there is no performance obligation related to that molecule. The Company determined that the net $22.5 million upfront payment from Zai Lab constituted the entirety of the consideration to be included in the transaction price as of the outset of the arrangement, and the transaction price was allocated to the two performance obligations based on their relative standalone selling price. The standalone selling price of the performance obligations was determined using the adjusted market assessment approach considering similar collaboration and license agreements. The potential development and regulatory milestone payments are fully constrained until the Company concludes that achievement of the milestone is probable, and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price. Any consideration related to royalties will be recognized if and when the related sales occur, as they were determined to relate predominantly to the license granted to Zai Lab and, therefore, have also been excluded from the transaction price. The Company re-assesses the transaction price in each reporting period and when events whose outcomes are resolved or other changes in circumstances occur.

Due to the short-term nature of the recognition period, the revenue associated with the tebotelimab performance obligation was recognized on a straight-line basis as the Company performed research and development activities under the agreement. The fixed consideration related to the margetuximab performance obligation was also recognized on a straight-line basis as the Company performed research and development activities under the agreement due to the short-term nature of the recognition period. Straight-line recognition is materially consistent with the pattern of performance of the research and development activities of each product candidate. The variable consideration related to the margetuximab performance obligation was recognized upon certain regulatory achievements during 2020. During the years ended December 31, 2020, 2019 and 2018, the Company recognized revenue of $8.6 million, $16.1 million and $1.3 million, respectively, related to the Zai Lab Agreement. Revenue recognized during 2020 included net milestone revenue of $3.6 million, whereas revenue during 2019 and 2018 reflected the recognition of the deferred upfront payment. At December 31, 2019, $5.0 million of revenue was deferred under this agreement, all of which was current and recognized in 2020.

During 2019, the Company entered into two agreements under which the Company is to perform manufacturing services for Zai Lab's clinical needs of margetuximab and tebotelimab (Zai Lab Clinical Supply Agreements). The Company evaluated the agreements under ASC 606 and determined that they should be accounted for as a single contract and identified two performance obligations within the contract: to perform services related to manufacturing the clinical supply of each of margetuximab and tebotelimab. The transaction price is based on the costs incurred to manufacture drug product and drug substance, and is recognized over time as the services are provided, as the performance by the Company does not create an asset

with an alternative use and the Company has an enforceable right to payment for the performance completed to date. During the years ended December 31, 2020 and 2019, the Company recognized revenue of $2.7 million and $2.2 million, respectively, related to the Zai Lab Clinical Supply Agreements.

Janssen

In December 2020, the Company entered into a research collaboration and license agreement with Janssen to develop a novel DART molecule (Janssen Agreement). The research collaboration will incorporate the Company's proprietary DART platform to enable simultaneous targeting of two undisclosed targets in a therapeutic area outside oncology. Under the terms of the Janssen Agreement, Janssen paid the Company an upfront payment of $20.0 million and will be responsible for funding all research and development expenses. The Company will also be eligible to receive up to $312.0 million in potential milestone payments and tiered royalties of up to 10% on worldwide product sales.

Subject to the terms of this agreement, the Company granted Janssen an exclusive, royalty-bearing license to develop, manufacture and commercialize the preclinical bispecific molecule and the Company will perform certain research and development activities during a specified research term. The Company evaluated the Janssen Agreement under the provisions of ASC 606 and identified the following material promises under the arrangement: (i) a license to develop the preclinical bispecific molecule and (ii) performing certain research and development activities during the research term. The Company determined that the license and research and development activities are separate performance obligations because they are capable of being distinct, and are distinct in the context of the contract. The license has standalone functionality as Janssen could benefit from the license on its own without the Company's involvement during the research term. The Company determined that the transaction price of the Janssen Agreement at inception was $22.2 million, consisting of the consideration to which the Company was entitled in exchange for the license and an estimate of the consideration for research and development activities to be performed. The transaction price was allocated to each performance obligation based on their relative standalone selling price. The standalone selling price of the license was determined using the adjusted market assessment approach considering similar collaboration and license agreements as well as current market conditions. The standalone selling price for agreed-upon research and development activities to be performed was determined using the expected cost approach based on similar arrangements the Company has with other parties. This variable consideration is fully constrained until the Company begins its work under the performance obligation. The potential milestone payments are fully constrained until the Company concludes that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price. Any consideration related to sales-based milestones and royalties will be recognized when the related sales occur, as they were determined to relate predominantly to the license granted to Janssen and, therefore, have also been excluded from the transaction price. The Company re-assesses the transaction price in each reporting period and when events whose outcomes are resolved or other changes in circumstances occur.

The Company recognized the $20.0 million allocated to the license when it satisfied its performance obligation and transferred the license to Janssen in December 2020. The $2.2 million allocated to the research and development activities will be recognized over the Company's involvement in the research term, which is estimated to be less than two years.

I-Mab Biopharma

In 2019, the Company entered into a collaboration and license agreement with I-Mab Biopharma (I-Mab) to develop and commercialize enoblituzumab, an immune-optimized, anti-B7-H3 monoclonal antibody that incorporates the Company's proprietary Fc Optimization technology platform (I-Mab Agreement). I-Mab obtained regional development and commercialization rights in mainland China, Hong Kong, Macau and Taiwan (I-Mab's territory), will lead clinical development of enoblituzumab in its territories, and will participate in global studies conducted by the Company.

Under the terms of the I-Mab Agreement, I-Mab paid the Company an upfront payment of $15.0 million. Assuming successful development and commercialization of enoblituzumab, the Company could receive up to $135.0 million in development and regulatory milestones. In addition, I-Mab would pay the Company tiered royalties ranging from mid-teens to 20% on annual net sales in I-Mab's territory.

The Company evaluated the I-Mab Agreement under the provisions of ASC 606 and identified the following material promises under the arrangement: (i) an exclusive license to develop and commercialize enoblituzumab in I-Mab's territories, (ii) perform certain research and development activities and (iii) conduct a chronic toxicology study. The Company determined that the license and the related research and development activities were not distinct from one another, as the license has limited value without the performance of the research and development activities. As such, the Company determined that the license and related research and development activities should be combined into a single performance obligation. The Company determined that the $15.0 million upfront payment from I-Mab constituted the entirety of the consideration to be included in the transaction price as of the outset of the arrangement for the license and related research and development activities. The

Company has also determined that the chronic toxicology study is distinct from the other promises and has estimated the variable consideration of that performance obligation to be approximately $1.0 million. I-Mab paid the Company for the cost of this study as the costs were incurred during 2019 and 2020, and I-Mab will be entitled to a one-time credit of eighty percent of the total amount of such costs against a future milestone, at which point the Company will reassess the transaction price for that milestone. The potential development and regulatory milestone payments are fully constrained until the Company concludes that achievement of the milestone is probable, and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price. Any consideration related to royalties will be recognized if and when the related sales occur, as they were determined to relate predominantly to the license granted to I-Mab and, therefore, have also been excluded from the transaction price. The Company re-assesses the transaction price in each reporting period and when events whose outcomes are resolved or other changes in circumstances occur.

Revenue under the I-Mab Agreement is being recognized using a cost-based input method according to costs incurred to date compared to estimated total costs. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligations. During the years ended December 31, 2020 and 2019, the Company recognized revenue of $2.1 million and $2.3 million, respectively, related to the I-Mab Agreement. At December 31, 2020, $11.4 million in revenue was deferred under the I-Mab Agreement, $4.5 million of which was current and $6.9 million of which was non-current. At December 31, 2019, $13.5 million in revenue was deferred under the I-Mab Agreement, $4.4 million of which was current and $9.1 million of which was non-current.

Provention Bio, Inc.

In 2018, the Company entered into a license agreement with Provention Bio, Inc. (Provention) pursuant to which the Company granted Provention exclusive global rights for the purpose of developing and commercializing MGD010 (renamed PRV-3279), a CD32B x CD79B DART molecule being developed for the treatment of autoimmune indications (Provention License Agreement). As partial consideration for the Provention License Agreement, Provention granted the Company a warrant to purchase shares of Provention's common stock at an exercise price of $2.50 per share. If Provention successfully develops, obtains regulatory approval for, and commercializes PRV-3279, the Company will be eligible to receive up to $65.0 million in development and regulatory milestones and up to $225.0 million in commercial milestones. As of December 31, 2020, the Company has not recognized any milestone revenue under this agreement. If commercialized, the Company would be eligible to receive single-digit royalties on net sales of the product. The license agreement may be terminated by either party upon a material breach or bankruptcy of the other party, by Provention without cause upon prior notice to the Company, and by the Company in the event that Provention challenges the validity of any licensed patent under the agreement, but only with respect to the challenged patent.

Also in 2018, the Company entered into an asset purchase agreement with Provention pursuant to which Provention acquired the Company's interest in teplizumab (renamed PRV-031), a monoclonal antibody being developed for the treatment of type 1 diabetes (Asset Purchase Agreement). As partial consideration for the Asset Purchase Agreement, Provention granted the Company a warrant to purchase shares of Provention's common stock at an exercise price of $2.50 per share. If Provention successfully develops, obtains regulatory approval for, and commercializes PRV-031, the Company will be eligible to receive up to $170.0 million in regulatory milestones and up to $225.0 million in commercial milestones. As of December 31, 2020, the Company has not recognized any milestone revenue under this agreement. If commercialized, the Company would be eligible to receive single-digit royalties on net sales of the product. Provention has also agreed to pay third-party obligations, including low single-digit royalties, a portion of which is creditable against royalties payable to the Company, aggregate milestone payments of up to approximately $1.3 million and other consideration, for certain third-party intellectual property under agreements Provention is assuming pursuant to the Asset Purchase Agreement. Further, Provention is required to pay the Company a low double-digit percentage of certain consideration to the extent it is received in connection with a future grant of rights to PRV-031 by Provention to a third party.

The Company evaluated the Provention License Agreement and Asset Purchase Agreement under the provisions of ASC 606 and determined that they should be accounted for as a single contract and identified two performance obligations within that contract: (i) the license of MGD010 and (ii) the title to teplizumab. The Company determined that the transaction price of the Provention agreements was $6.1 million, based on the Black-Scholes valuation of the warrants to purchase a total of 2,432,688 shares of Provention's common stock. The transaction price was allocated to each performance obligation based on the number of shares of common stock the Company is entitled to purchase under each warrant. The potential development and regulatory milestone payments are fully constrained until the Company concludes that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price. Any consideration related to sales-based milestones and royalties will be recognized when the related sales occur, therefore they have also been excluded from the transaction price. The

Company re-assesses the transaction price in each reporting period and when events whose outcomes are resolved or other changes in circumstances occur.

The Company recognized revenue of $6.1 million when it satisfied its performance obligations under the agreements and transferred the MGD010 license and teplizumab assets to Provention in 2018. The warrants were revalued at each reporting period based on the current Black-Scholes parameters until the warrants were exercised in July 2019. The resulting increase or decrease in the value of the warrants is reflected in Other income (expense) on the 2019 consolidated statement of operations and comprehensive loss. In July 2019, the Company exercised the warrants on a cashless basis, and subsequently sold all the shares of Provention common stock acquired through the exercise. No shares of Provention stock were held subsequent to the sale of stock in 2019.

Servier

In 2012, the Company entered into a collaboration agreement with Servier and granted it exclusive options to obtain three separate exclusive licenses to develop and commercialize DART molecules, consisting of those designated by the Company as flotetuzumab (also known as MGD006 or S80880) and MGD007, as well as a third DART molecule, in all countries other than the United States, Canada, Mexico, Japan, South Korea and India (Servier Agreement). In 2014, Servier exercised its exclusive option to develop and commercialize flotetuzumab. During the term of the agreement, Servier did not exercise its options for either MGD007 or the third DART molecule. In July 2019, Servier informed the Company of its intention to terminate the Servier Agreement and the agreement was terminated effective January 15, 2020. As a result of this termination, the Company will regain full exclusive, worldwide commercialization rights to develop and market flotetuzumab.

Upon execution of the agreement, Servier made a nonrefundable payment of $20.0 million to the Company. The Company evaluated the Servier Agreement under the provisions of ASC 606 and concluded that Servier is a customer prior to the exercise of any of the three options. The Company identified the following material promises under the arrangement for each of the three molecules: (i) a limited evaluation license to conduct activities under the research plan and (ii) research and development services concluding with an option trigger data package. The Servier Agreement also provided exclusive options for an exclusive license to research, develop, manufacture and commercialize each subject molecule. The Company evaluated these options and concluded that the options were not issued at a significant and incremental discount, and therefore do not provide material rights. As such, they are excluded as performance obligations at the outset of the arrangement. The Company determined that each license and the related research and development services were not distinct from one another, as the license has limited value without the performance of the research and development activities. As such, the Company determined that these promises should be combined into a single performance obligation for each molecule, resulting in a total of three performance obligations; one for flotetuzumab, one for MGD007, and one for the third DART molecule.

The Company determined that the $20.0 million upfront payment from Servier constituted the entirety of the consideration to be included in the transaction price as of the outset of the arrangement, and the transaction price was allocated to the three performance obligations based on their relative standalone selling price. The milestone payments that the Company was eligible to receive prior to the exercise of the options were excluded from the transaction price, as all milestone amounts were fully constrained based on the probability of achievement. Two milestones were achieved in 2014 when the Investigational New Drug (IND) applications for flotetuzumab and MGD007 were cleared by the FDA. Upon achievement of each milestone, the constraint related to the $5.0 million milestone payment was removed and the transaction price was re-assessed. This variable consideration was allocated to each specific performance obligation in accordance with ASC 606.

Revenue associated with each performance obligation was recognized as the research and development services were provided using a cost-based input method according to research and development costs incurred to date compared to estimated total research and development costs. The transfer of control occurred over this time period and, in management’s judgment, was the best measure of progress towards satisfying the performance obligation. No revenue was recognized related to the MGD007 option during the years ended December 31, 2020 and 2019. During the year ended December 31, 2018 the Company recognized revenue of $1.9 million related to the MGD007 option.

As discussed above, in 2014, Servier exercised its option to obtain a license to develop and commercialize flotetuzumab in its territories and paid the Company a $15.0 million license grant fee. Upon exercise, the Company's contractual obligations include (i) granting Servier an exclusive license to its intellectual property, (ii) technical, scientific and intellectual property support to the research plan and (iii) participation on an executive committee and a research and development committee. Under the terms of the Servier Agreement, the Company and Servier will share costs incurred to develop flotetuzumab during the license term. Due to the fact that both parties share costs and are exposed to significant risks and rewards dependent on the commercial success of the product, the Company determined that the arrangement is a collaborative arrangement within the scope of ASC 808. The arrangement consists of two components; the license of flotetuzumab and the research and development activities, including committee participation, to support the research plan.

Under the provisions of ASC 808, the Company has determined that it will use ASC 606 by analogy to recognize the revenue related to the license. The Company evaluated its performance obligation to provide Servier with an exclusive license to develop and commercialize flotetuzumab and determined that its transaction price is equal to the license grant fee payment of $15.0 million and Servier consumes the benefits of the license over time as the research and development activities are performed. Therefore, the Company was recognizing the transaction price over the development period, using an input method according to research and development costs incurred to date compared to estimated total research and development costs. As noted above, in July 2019, Servier informed the Company of its intention to terminate the Servier Agreement and the agreement was terminated effective January 15, 2020. Therefore, the Company reassessed the end date of its performance obligations under the contract to be January 15, 2020.

During the years ended December 31, 2020, 2019 and 2018 the Company recognized revenue of $1.0 million, $11.6 million, and $1.2 million, respectively, related to the flotetuzumab license grant fee. At December 31, 2019, $1.0 million of revenue related to the flotetuzumab license grant fee was deferred, all of which was current and recognized in 2020.

The research and development activities component of the arrangement is not analogous to ASC 606, therefore the Company follows its policy to record expense incurred as research and development expense and record reimbursements received from Servier as an offset to research and development expense on the consolidated statement of operations and comprehensive loss during the development period. During the years ended December 31, 2019 and 2018, the Company recorded approximately $3.6 million and $6.0 million, respectively, as an offset to research and development expense under this collaborative arrangement. No offset to research and development expense under this collaborative arrangement was recorded during the year ended December 31, 2020.

Roche

In 2017, the Company entered into a research collaboration and license agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (Roche) to jointly discover and develop novel bispecific molecules to undisclosed targets (Roche Agreement). During the research term, both companies would leverage their respective platforms, including the Company's DART platform and Roche's CrossMAb and DutaFab technologies to select a bispecific format and lead product candidate. Roche would then further develop and commercialize any such product candidate. Each company would be responsible for their own expenses during the research period. In 2019, Roche informed the Company of its intention to terminate the Roche Agreement, and the agreement was terminated effective November 21, 2019.

Under the terms of the Roche Agreement, Roche received rights to use certain of the Company’s intellectual property rights to exploit collaboration compounds and products, and paid the Company an upfront payment of $10.0 million. The Company would also be eligible to receive up to $370.0 million in potential milestone payments and royalties on future sales. As of December 31, 2020, the Company has not recognized any milestone revenue under this agreement.

The Company evaluated the Roche Agreement under the provisions of ASC 606 and identified the following promises under the agreement: (i) the non-exclusive, non-transferable, non-sublicensable license to the Company's intellectual property and (ii) the performance of certain activities during the research period. The Company determined that the license was capable of being distinct, but was not distinct in the context of the contract because it had limited value to Roche without the research activities required to be performed by the Company. Therefore, the Company concluded that there was one performance obligation under the agreement. The Company determined that the transaction price of the Roche Agreement was $10.0 million. The potential milestone payments were fully constrained and were excluded from the transaction price. Any consideration related to sales-based royalties would be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Roche and therefore were also excluded from the transaction price.

The $10.0 million transaction price was being recognized over the expected research period, which was originally 30 months, using a cost-based input method to measure performance. Upon notice of Roche's intent to terminate the agreement in August 2019, the recognition period was adjusted to end in November 2019. There was no revenue recognized under this agreement during the year ended at December 31, 2020. The Company recognized revenue under this agreement of $6.0 million and $4.0 million, respectively, during the years ended December 31, 2019 and 2018.

Boehringer Ingelheim International GmbH

In 2010, the Company entered into a collaboration and license agreement with Boehringer Ingelheim International GmbH (BII) to discover, develop and commercialize multiple DART molecules that were to be evaluated during a five-year period that ended in 2015 (Boehringer Agreement). Under the terms of the agreement, the Company granted BII an exclusive, worldwide, royalty-bearing, license under its intellectual property to research, develop, and market DART molecules generated under the agreement. During the evaluation period, BII selected two product candidates to develop (BII DARTs). Under the terms of the Boehringer Agreement, BII paid the Company an upfront payment of $15.0 million which was fully recognized

prior to December 31, 2015. The variable consideration under this agreement included potential future development and sales milestones and royalties on net sales in the event that the BII DARTs are commercialized.

In June 2020, BII agreed to a payment of $12.0 million in order to retain rights to develop the BII DARTs under the Boehringer Agreement. As a result, the Company received and recognized as revenue $12.0 million during the year ended December 31, 2020. The remaining potential development milestone payments are fully constrained until the Company concludes that achievement of the milestone is probable, and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price. Any consideration related to royalties will be recognized when the related sales occur and therefore, have also been excluded from the transaction price. The Company re-assesses the transaction price in each reporting period and when events whose outcomes are resolved or other changes in circumstances occur.

NIAID Contract

The Company entered into a contract with the National Institute of Allergy and Infectious Diseases (NIAID), effective as of September 15, 2015, to perform product development and to advance up to two DART molecules, including MGD014. Under this contract, the Company will develop these product candidates for Phase 1/2 clinical trials as therapeutic agents, in combination with latency reversing treatments, to deplete cells infected with human immunodeficiency virus (HIV) infection. NIAID does not receive goods or services from the Company under this contract, therefore the Company does not consider NIAID to be a customer and concluded this contract is outside the scope of ASC 606.

This contract includes a base period of $7.5 million to support development of MGD014 through IND application submission with the FDA, as well as up to $17.0 million in additional development funding via NIAID options. Should NIAID fully exercise such options, the Company could receive total payments of up to $24.5 million. The total potential period of performance under the award is from September 15, 2015 through December 31, 2024. In 2017, NIAID exercised the first option in the amount of up to $10.8 million to fund the commencement of the MGD014 clinical trial and development of the second DART molecule. The Company recognized revenue of $7.1 million, $2.2 million and $1.3 million under the NIAID contract during the years ended December 31, 2020, 2019 and 2018, respectively.

10. Commitments and Contingencies

On September 13, 2019, a securities class action complaint was filed in the U.S. District Court for the District of Maryland by Todd Hill naming the Company, its Chief Executive Officer, Dr. Koenig, and its Chief Financial Officer, Mr. Karrels, as defendants for allegedly making false and materially misleading statements regarding the Company’s SOPHIA trial. On August 17, 2020, the Employees’ Retirement System of the City of Baton Rouge and Parish of East Baton Rouge was appointed as Lead Plaintiff, and on October 16, 2020, the Lead Plaintiff filed an amended complaint. The amended complaint asserts a putative class period stemming from February 6, 2019 to June 4, 2019. The Company filed a Motion to Dismiss on November 30, 2020. Plaintiff filed an Opposition brief on January 29, 2021, to which the Company plans to file a timely reply. The Company intends to vigorously defend against this action. However, the outcome of this legal proceeding is uncertain at this time and the Company cannot reasonably estimate a range of loss, if any. Accordingly, the Company has not accrued any liability associated with this action.

11. Employee Benefit Plan

In 2002, the Company established the MacroGenics 401(k) Plan (the Plan) for its employees under Section 401(k) of the IRC. Under this Plan, all employees at least 21 years of age are eligible to participate in the Plan, starting on the first day of each month. Employees may contribute up to 100% of their salary, subject to government maximums.

Employees are 100% vested in their contributions to the Plan. The Company's contribution to the Plan, as determined by the Board of Directors, is discretionary. The Company's contributions to the Plan totaled $1.4 million in each of the years ended December 31, 2020 and 2019, and $1.3 million for the year ended December 31, 2018.

EXHIBIT INDEX

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of the Company and Certificate of Correction to the Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibits 3.1 and 3.3, respectively, to the Company's Current Report on Form 8-K filed on October 18, 2013)
3.2	Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.4 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
4.1	Specimen Stock Certificate (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 9, 2013)
4.2	Description of Common Stock
4.3†	Investor Agreement by and between Johnson and Johnson Innovation-JJDC, Inc. and the Company, dated December 19, 2014 (incorporated by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K filed on March 3, 2015)
10.1	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
10.2†	Global Collaboration and License Agreement by and between the Company and Incyte Corporation, dated October 24, 2017 (incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K filed on February 27, 2018)
10.3+	Company 2003 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
10.4+	Form of Incentive Stock Option Agreement under 2003 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
10.5+	Company 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
10.6+	Form of Incentive Stock Option Agreement under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
10.7+	Form of Nonstatutory Stock Option Agreement under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
10.8+	Form of Restricted Stock Units Grant Notice under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 6, 2015)
10.9+	2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-8 (File No. 333-214386) filed by the Company on November 2, 2016)
10.10+	Employment Agreement between the Company and Scott Koenig, M.D., Ph.D. (incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K filed by the Company on February 29, 2016)
10.11+	Employment Agreement between the Company and James Karrels (incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K filed by the Company on February 29, 2016)
10.12+	Employment Agreement between the Company and Ezio Bonvini, M.D. (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on May 4, 2016)
10.13+	Employment Agreement between the Company and Eric Risser (incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K filed on February 28, 2017)
10.14†	Amendment No, 1 to the Global Collaboration and License Agreement by and between the Company and Incyte Corporation, dated March 15, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 7, 2017)
10.15#	Commercial Supply Agreement by and between AGC Biologics (f/k/a CMC ICOS Biologics, Inc.) and the Company, dated December 11, 2017
10.16#	Commercial Supply Agreement by and between Incyte Corporation and the Company, dated October 13, 2020

10.17#	Product Commercialization Agreement by and between the Company and Eversana Life Science Services, LLC, dated November 13, 2020
23.1	Consent of Ernst & Young, LLP, Independent Registered Public Accounting Firm
31.1	Rule 13a-14(a) Certification of Principal Executive Officer
31.2	Rule 13a-14(a) Certification of Principal Financial Officer
32.1	Section 1350 Certification of Principal Executive Officer
32.2	Section 1350 Certification of Principal Financial Officer
101.INS	XBRL Instance Document
101.SCH	XBRL Schema Document
101.CAL	XBRL Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Labels Linkbase Document
101.PRE	XBRL Presentation Linkbase Document
104	Cover Page Interactive Data (formatted as Inline XBRL and contained in Exhibit 101 filed herewith)

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment granted by the SEC.
# Portions of this document (indicated by "[***]" have been omitted because they are not material and would likely cause competitive harm to the Company if disclosed.
+ Indicates management contract or compensatory plan.

Exhibit 4.2

DESCRIPTION OF SECURITIES
REGISTERED UNDER SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2020, MacroGenics, Inc. ("we", "our" and "us"), has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: common stock, par value of $0.01 per share (Common Stock).

The following description of our Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Amended and Restated Certificate of Incorporation, as amended (our Certificate of Incorporation), our Certificate of Correction of our Certificate of Incorporation (our Certificate of Correction), our Amended and Restated By-laws (our By-laws) and applicable provisions of the Delaware General Corporation Law (DGCL). Our Certificate of Incorporation, Certificate of Correction and By-laws are included as exhibits to the Annual Report on Form 10-K of which this Exhibit 4.2 forms a part. We encourage you to carefully read our Certificate of Incorporation, Certificate of Correction and By-laws and the applicable provisions of the DGCL for additional information.

General

Under our Certificate of Incorporation, we have the authority to issue 125,000,000 shares of our Common Stock.

Our Common Stock is listed on the Nasdaq Global Select Market under the symbol "MGNX." 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 we may issue in the future.

Common Stock Outstanding

The outstanding shares of our Common Stock are duly authorized, validly issued, fully paid and non-assessable.

Voting Rights

Holders of our Common Stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter.

Dividend Rights

Holders of our Common Stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any outstanding preferred stock.

Liquidation Rights

In the event of our liquidation or dissolution, the holders of our Common Stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

Other Rights

Holders of our Common Stock have no preemptive, subscription, redemption or conversion rights. 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.

Transfer Agent and Registrar

Computershare Trust Company, Inc. is the transfer agent and registrar for our Common Stock.

Provisions of our Certificate of Incorporation and By-laws and Delaware Law that may have Anti-Takeover Effects

Delaware law contains, and our Certificate of Incorporation and our By-laws contain, provisions that 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 coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors.

Authorized but Unissued Shares. The authorized but unissued shares of our Common Stock will be available for future issuance without obtaining stockholder approval and the authorized but unissued shares of our preferred stock are available for future issuance. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions, and employee benefit plans. The existence of authorized but unissued shares of our Common Stock and preferred stock could render more difficult or discourage an attempt to obtain control over us by means of a proxy contest, tender offer, merger or otherwise

Removal of Directors. A director may be removed only for cause and only by the affirmative vote of the holders of at least 75% of the votes that all of our stockholders would be entitled to cast in an annual election of directors. Any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Staggered Board of Directors. Our Certificate of Incorporation provides for a staggered board of directors consisting of three classes of directors. Directors of each class are chosen for three-year terms upon the expiration of their current terms and each year one class of our directors will be elected by our stockholders. Additionally, there is no cumulative voting in the election of directors. This classified board provision could have the effect of making the replacement of incumbent directors more time consuming and difficult. At least two annual meetings of stockholders, instead of one, will generally be required to effect a change in a majority of our board of directors. Thus, the classified board provision could increase the likelihood that incumbent directors will retain their positions. The staggered terms of directors may delay, defer or prevent a tender offer or an attempt to change control of us, even though a tender offer or change in control might be believed by our stockholders to be in their best interest.

Stockholder Action by Written Consent; Special Meetings. Our Certificate of Incorporation provides that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of such holders and may not be effected by any consent in writing by such holders. Our Certificate of Incorporation and By-laws also provide that, except as otherwise required by law, special meetings of our stockholders can only be called by our chairman of the board, our chief executive officer or our board of directors.

Advance Notice Requirements for Stockholder Proposals. Our by-laws have established an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of persons for election to our board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder’s intention to bring such business before the meeting. These provisions could have the effect of delaying until the next

stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities.

Amendment of Our Certificate of Incorporation and By-laws. The DGCL provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless a corporation's restated certificate of incorporation or by-laws, as the case may be, requires a greater percentage. Our By-laws may be amended or repealed by a majority vote of our board of directors or by the affirmative vote of the holders of at least 75% of the votes that all of our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes that all of our stockholders would be entitled to cast in any annual election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our Certificate of Incorporation described above under "Removal of Directors" and "Stockholder Action by Written Consent; Special Meetings."

Delaware Business Combination Statute. We are subject to Section 203 of the DGCL. Subject to specified exceptions, Section 203 of the DGCL restricts some types of transactions and business combinations between a corporation and a 15% stockholder. A 15% stockholder is generally considered by Section 203 to be a person owning 15% or more of the corporation's outstanding voting stock. Section 203 refers to a 15% stockholder as an "interested stockholder." Section 203 restricts these transactions for a period of three years from the date the stockholder acquires 15% or more of our outstanding voting stock. With some exceptions, unless the transaction is approved by the board of directors and the holders of at least two-thirds of the outstanding voting stock of the corporation, Section 203 prohibits significant business transactions such as:

- a merger with, disposition of significant assets to or receipt of disproportionate financial benefits by the interested stockholder; and
- any other transaction that would increase the interested stockholder's proportionate ownership of any class or series of our capital stock.

The shares held by the interested stockholder are not counted as outstanding when calculating the two-thirds of the outstanding voting stock needed for approval.

The prohibition against these transactions does not apply if:

- prior to the time that any stockholder became an interested stockholder, the board of directors approved either the business combination or the transaction in which such stockholder acquired 15% or more of our outstanding voting stock; or
- the interested stockholder owns at least 85% of our outstanding voting stock as a result of a transaction in which such stockholder acquired 15% or more of our outstanding voting stock. Shares held by persons who are both directors and officers or by some types of employee stock plans are not counted as outstanding when making this calculation.

Exhibit 10.15

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT BOTH (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED. SUCH EXCLUDED INFORMATION HAS BEEN MARKED WITH "[***]".

CONFIDENTIAL

EXECUTION COPY

COMMERCIAL SUPPLY AGREEMENT

BETWEEN

CMC ICOS BIOLOGICS, INC.

and

MACROGENICS, INC.

244238347 v3

CONTENTS

APPENDIX THREE__56

THIS COMMERCIAL SUPPLY AGREEMENT is made as of December 11, 2017 (the "**Effective Date**").

BETWEEN

(1) CMC ICOS BIOLOGICS, INC., duly incorporated under the laws of the state of Washington and having its principal place of business at 22021 20th Ave SE, Bothell, Washington, USA (hereinafter referred to as "**CMC**"); and,

(2) MACROGENICS, INC., duly incorporated under the laws of the state of Delaware and having its principal place of business at 9704 Medical Center Drive, Rockville, MD 20850 (hereinafter referred to as "**Customer**").

CMC and Customer may each be referred to herein as a "**Party***"* and collectively as the "**Parties**."

RECITALS

(A) Customer is engaged in the research, development, manufacture and sale of pharmaceuticals and biologics, including the product designated by Customer as margetuximab ("**MGAH22**");

(B) CMC and Customer have previously entered into a Master Services Agreement for the development and manufacture (for clinical evaluation) of MGAH22;

(C) In addition to development and scale-up activities, CMC also provides commercial manufacturing activities for biological products to pharmaceutical and biotechnology companies; and

(D) Customer wishes to contract with CMC for the provision of the commercial supply of Product (as defined below) as more clearly defined by the Services (as defined below); and

(E) CMC is willing to provide the Services to the Customer on the terms and conditions set out in this Agreement in exchange for the Batch Price.

NOW THEREFORE, THE PARTIES AGREE as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 For the purposes of this Agreement, the terms defined in this clause shall have the respective meanings set forth below.

"**Affiliate**"	any company, partnership or other entity which directly or indirectly through one or more intermediaries controls or is controlled by, or is under common control with a Party. For the purpose of this definition control means the direct or indirect beneficial ownership of more than fifty percent (50%) of the voting share capital in such company, partnership or entity or the legal power to control the general management and policies of such company, partnership or entity;
"**Agreement**"	this Agreement including all Appendices and any amendments to the foregoing made in accordance with this Agreement;
"**Appendix**" or "**Appendices**"	one or more of the Appendices to this Agreement;
“Applicable Laws”	all applicable ordinances, rules, regulations, laws, guidelines, requirements and court orders of any kind whatsoever of any national (e.g., the FDA, EPA, etc,), supra-national (e.g., the European Commission, the Council of the European Union, or the European Medicines Agency), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity of the US or EU applicable to the Services;
“Authority Submission”	has the meaning set out in **Clause 8.3**;
"**Batch**"	BDS that is intended to be of uniform character and quality, within specific limits, and is produced in one cell culture run using the Cell Line at a specified bioreactor scale, and such purification, analytical and further processing steps as described in a Work Statement applicable to the BDS harvested from that run resulting in one lot of BDS;
“Batch Price”	the price payable for each Batch as initially described in the Appendix Two and as may be amended by agreement between the Parties or by operation of **Clause** 7**;**
“Binding Batch”	has the meaning set out in **Clause 5.8**;
“BLA”	a Biologics License Application and any amendments or supplements thereto filed with the FDA pursuant to 21 C.F.R. Part 601 or any other application required for the purpose of marketing and selling a biological product filed with a Regulatory Authority outside the United States, including with respect to the EU a Marketing Authorization Application;

“Bulk Drug Substance or BDS”	means the Product in bulk, as expressed by the Cell Line and harvested and purified in bulk from a cell culture run pursuant to the applicable Process;
"Business Day"	any day which is not a Saturday, a Sunday or a U.S. public holiday;
“Calendar Day” “Calendar Quarter”	any day; a 3-month period beginning on January 1, April 1, July 1, or October 1 of each year;
“Calendar Year”	a period of time commencing on January 1 and ending on the following December 31; provided that the first Calendar Year of the Term shall begin on the Effective Date and end on the first December 31 thereafter, and the last Calendar Year during the Term shall end upon the expiration of the Term;
“Campaign”	a series of Batches manufactured consecutively in accordance with the Process;
“Cancellation Fee”	has the meaning set out in **Clause 5.10**;
"**Cell Line**"	the mammalian cell line [***] and any progeny clone of the foregoing cell line(s);
"**Certificate of Analysis**"	CMC’s standard form certificate of analysis confirming that Product to which the certificate relates meets the Specification and such other criteria as identified on the certificate;
“**Certificate of Compliance”**	means a document, signed by an authorized representative of CMC, attesting that a particular Batch was manufactured in accordance with cGMP and other Applicable Laws;
"**cGMP**"	Current Good Manufacturing Practices as promulgated under each of the following as in effect on the Effective Date and as amended or revised after the Effective Date: (a) the U.S. Food, Drug & Cosmetics Act (21 U.S.C. § 301 *et seq.*) and related U.S. regulations, including 21 Code of Federal Regulations (Chapters 210, 211, 600 and 610) and other FDA regulations, policies, or guidelines in effect at a particular time for the manufacture, testing and quality control of investigational drugs; (b) EudraLex Volume 4; (c) the ICH guide Q7 “ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients;” and (d) any other laws, regulations and statutes set forth by a Government Authority applicable to the manufacture of compounds and products by CMC under this Agreement;

“**Change in Control**”	in relation to a body corporate, the occurrence of an event or circumstance where a person who is not presently able to do any of the following things becomes able to do one of the following things (whether directly or indirectly or through one or more intervening persons, companies or trusts): (a) control the composition of more than one half of the body's board of directors; (b) be in a position to cast, or control the casting of, more than one half of the maximum number of votes that might be cast at a general meeting of the members of the body; or (c) hold or have a beneficial interest in more than onehalf of the issued share capital of the body;
"**CMC Facility**"	CMC’s manufacturing facility in Bothell, Washington or another facility agreed on by the Parties in writing;
“CMC Failure”	has the meaning set out in **Clause 13.3**;

"**CMC Intellectual Property Rights**"	Intellectual Property rights and CMC Know-How owned by CMC and used in the Services;
"**CMC Know-How**"	all information, techniques, trade secrets, data and technical information known to CMC which is not of general public knowledge, other than provided to CMC by Customer, or developed during the Services;
"**Commencement Date**"	in respect of a cGMP Batch the date on which (i) [***], or (ii) [***]; whichever is the earlier;
"**Commercial Quality Agreement" (QAg)"**	the agreement between the Parties defining the quality responsibilities, including cGMP standards, regarding the performance of the Services;
"**Commercially Reasonable Efforts**"	with respect to CMC, such level of efforts and resources required to carry out an obligation under this Agreement in a sustained manner consistent with the efforts normally used by companies that provide manufacturing and related services in the biopharmaceutical industry, as applicable, of comparable size and resources to CMC, for a similar activity with respect to the scope of Services to be provided under this Agreement;
"Committee Member"	has the meaning set out in **Clause 4.9**;
"**Confidential Information**"	means all information disclosed by, or on behalf of, the Disclosing Party to Recipient Party relating to this Agreement and includes: (I) information disclosed in writing, orally or by any other means; (II) information disclosed before, after or on the date of this Agreement; and (iii) information relating to the Disclosing Party's operations, processes, plans, intentions, production information, know how, data, formulae, expertise, methodology, drawings, specifications, design rights, trade secrets, market opportunities

	and business affairs, and any new and novel combinations thereof;
"**Customer Intellectual Property Rights**"	Intellectual Property rights and Customer Know-How owned by Customer or licensed to Customer by a Third Party covering any aspect of the Services, Cell Line, BDS or materials, techniques or processes used in the Services;
"**Customer Know- How**"	all information, techniques, trade secrets, data and technical information known to Customer in connection with the Cell Line, Customer Materials, Process and Product which are (i) not known to CMC prior to being provided to CMC by or on behalf of Customer; or (ii) not of general public knowledge;
"**Customer Materials**"	the Cell Line, vectors, plasmids and all other materials and equipment supplied by Customer, its Affiliate or agent to CMC or made available to CMC by or on behalf of Customer or purchased by CMC on behalf of Customer;
"Defect"	has the meaning in **Clause 6.4**;
"Defect Notice"	has the meaning in **Clause 6.4**;
"**Deliverables**"	the data, results and materials generated from the performance of the Services including Drug History Record and Product;
"**Delivery**" or "**Delivered**"	has the meaning in **Clause 6.2**;
“Delivery Date”	means, as applicable, the date a Batch is to be delivered or is actually Delivered;
“Disputed Deliverable”	has the meaning in **Clause 6.9**;
“Drug History Record”	all lot disposition documentation relevant to a cGMP Batch to be provided to Customer with the Product from that cGMP Batch, including but not limited to manufacturing batch records, Certificates of Compliance and Certificates of Analysis;

"**Effective Date**"	the date set forth on page 3 as the effective date of this Agreement;
“EMA”	European Medicines Agency or any successor agency;
"Exceptional Batches"	has the meaning in **Clause 5.7**;
“Existing Agreement”	the Master Services Agreement between the Parties dated June 4, 2014;
“Facility Modification”	has the meaning set out in **Clause 4.8**;
“Facility Modification Notice”	has the meaning set out in **Clause 4.8**;
"FDA”	means the United States Food and Drug Administration, or its successor agency;
“Firm Order”	has the meaning set out in **Clause 5.3.1;**
"Forecast"	has the meaning set out in **Clause 5.1;**
“Fundamental Change”	means a Change of Control, merger, acquisition or change of management of CMC or Affiliates;
"**Group**"	in respect of the relevant Party, its Affiliates and holding companies and the Affiliates of those holding companies;
"**Intellectual Property**"	all intellectual property rights, including, without limitation, patents, supplementary protection certificates, petty patents, utility models, trademarks, database rights, rights in designs, copyrights (whether or not any of these are registered or capable of being registered) and including all applications and the right to apply for registered protection of the foregoing and all inventions, trade secrets, know- how, techniques and confidential information and other proprietary knowledge and information, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world, in each case for their full term and together with any renewals or extensions;

"Joint Steering Committee"	has the meaning set out in **Clause 4.9**;
"Minimum Volumes"	the minimum number of Batches that must be ordered per Calendar Year by Customer as stipulated in **Clause 5.3.4**;
"Non-Fault Delays"	has the meaning set out in **Clause 4.1**;
"Order"	a Firm Order or a Semi-Firm Order;
"Other Customers"	has the meaning set out in Clause **5.12**;
"**Permitted Recipients**"	(a) the directors, officers, employees, Testing Laboratories or professional advisers who are required, on a strict need to know basis, in the course of their duties to receive and consider the Confidential Information of the other Party for the purpose of enabling the relevant Party to perform its obligations under this this Agreement; and (b) in communications with existing or prospective licensees, sublicensees or collaborators, and consultants and advisors of each Party in connection with transactions or prospective transactions or pursuant to the conduct of such Party's business; provided that in the case of (a) and (b), such Persons are under obligations of confidence no less onerous than those set out in **Clause 10** imposed on the recipient Party;
"Person(s)"	any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein;
"**PPQ-Batches"**	the process performance qualification batches required for registration of the Product.
"**Process**"	the method for manufacture, harvesting and purification of the Product as defined in Customer approved manufacturing batch records;
"**Product**"	Customer's biologic known as margetuximab manufactured in Batch form as Bulk Drug Substance;
"**Project Manager"**	has the meaning set out in **Clause 4.9**;

"**Project Team**"	has the meaning set out in **Clause 4.10**;
“Purchase Order”	has the meaning set out in **Clause 5.6.1**;
“Quality Release(d)”	certification by CMC’s Quality Department that a Batch of BDS complies with its Specifications as confirmed by release testing;
"**Raw Materials**"	media, resins, chemicals, solvents, filters, membranes, disposable analytical test kits, disposable bags, and other items consumed for the manufacture of Products in accordance with this Agreement as well as any subcontracted analytical testing performed by Testing Laboratories during the performance of the Services;
“Recall”	any action to withdraw from supply or distribution or to recover title to or possession of quantities of Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Product from the market or correction) or the detention or destruction of any Product by any Regulatory Authorities;
“Regulatory Approval”	the approval, license or authorization of the applicable Regulatory Authority necessary for commercialization of the Product, including approval of a Biologics License Application or Market Authorization Application for the Product;
“Regulatory Approval Submission”	the earlier of the first submission of a Biologics License Application or Market Authorization Application for the Product;
“Regulatory Obligations"	those mandatory regulatory requirements applicable in Europe and the United States of America and Canada to the manufacture of cGMP Product for human use;
“Regulatory Authority”	the FDA in the United States or any health regulatory authority in another country in Europe and Canada that is a counterpart to the FDA and holds responsibility for allowing development of the Product and/or granting Regulatory Approval for a Product, including the EMA, and any successor(s) thereto;
“Release For Further Processing”	has the meaning set out in **Clause 6.11**;

“Representative(s)	has the meaning set out in **Clause 4.10**;
"Semi-Firm Order"	has the meaning set out in **Clauses 5.3.2** and **5.3.3**;
"**Services**"	manufacturing of the Product by CMC and all activities to be conducted by CMC related to the manufacturing of the Product under this Agreement;
“Shipping Company”	a shipping company or other agent designated by Customer to receive a Delivery on behalf of Customer;
"**Shipping Guidelines**"	the storage and transport guidelines for the Product that are determined by mutual written agreement of the Parties;
“**Slot**”	in respect of CMC’s cGMP manufacturing suite the period of time the suite is reserved in preparation for and the performance of a Batch;
"**Specification**"	the specification for the Product as defined in Appendix 1 or as may otherwise be agreed between the Parties or modified in accordance with **Clause 4.5** which includes (i) specifications for BDS and Raw Materials, (ii) manufacturing, testing and packaging instructions and specifications for Product in accordance with the Process, (iii) storage and shipping requirements, and (iv) any other technical information necessary to manufacture a Batch;
"**Standard Operating Procedures**" or "**SOPs**"	the standard operating procedures of CMC which define CMC's methods of performing activities applicable to the Services;
“**Storage Cost**”	has the meaning set out in **Clause 7.8**;
“Supply Failure”	has the meaning set out in **Clause 5.17**;
“Term”	the Initial Term (as defined in **Clause 14.1**) and all Additional Terms (as defined in **Clause 14.1**);
"**Testing Laboratories**"	the Third Parties listed in the Quality Agreement which shall conduct testing or provide other services to support Quality Release;
“**Timelines**”	collectively and individually the dates to manufacture Product and render other Services to Deliver Product according to the Forecast and/or each accepted Commencement Date and Delivery Date;
“Third Party(ies)”	any person, company, organization or entity other than CMC, Customer or their Affiliates;
“Work Statement”	the Work Statement #1 effective between the Parties, dated [***], and all amendments thereto and the subsequent agreement between the Parties, effective [***].

1.2 Additional Definitions. Each of the following definitions is set forth in the clause of this Agreement indicated below:

Definition:	**Clause:**
Binding Batches	5.8
Reserve Payment Producer	7.1
Price Index	7.3

1.3 In this Agreement (except where the context otherwise requires):

1.3.1 any reference to a recital, clause or appendix is to the relevant recital, clause or appendix of or to this Agreement and any reference to a sub-clause or paragraph is to the relevant sub-clause or paragraph of the clause or appendix in which it appears;

1.3.2 the table of contents and clause headings are included for convenience only and shall not affect the interpretation of this Agreement;

1.3.3 use of the singular includes the plural and vice versa and use of any gender includes the other genders;

1.3.4 a reference to a "Party" is a reference to a party to this Agreement and a reference to a "Party" includes a reference to that Party's successors in title, permitted assignees and transferees (if any);

1.3.5 a reference to “records”, “data”, “documents” and “information” refers to such items in tangible, and electronic and visual mediums unless specified to the contrary; and

1.3.6 any phrase introduced by the terms "including", "include", "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

1.4 The Appendices form an integral part of this Agreement shall have effect as if set out in full in the body of this Agreement and any reference to this Agreement includes the Appendices.

1.5 Where there is any inconsistency between the Appendices and the main body of this Agreement, the conflicting terms of the main body of this Agreement shall, unless expressly specified to the contrary, prevail.

2. MANUFACTURING SUPPLY AND APPLICABLE STANDARDS

2.1 During the Term CMC shall use Commercially Reasonable Efforts to manufacture Product:

(a) according to the Process; (b) that meets Specifications; (c) in compliance with Applicable Laws and Regulatory Obligations; and (d) in accordance with the terms of this Agreement and the Commercial Quality Agreement.

2.2 During the Term, CMC shall use Commercially Reasonable Efforts to manufacture Product in the quantity of Batches that are the subject of each Firm Order and Semi-Firm Order pursuant to the forecast mechanism set out in **Clause 5** and in accordance with the terms and requirements set out in this Agreement. Customer shall purchase from CMC and CMC shall supply to Customer the Product in the quantity of Batches in accordance with the terms of this Agreement.

2.3 CMC will comply with quality standards as agreed to in the Commercial Quality Agreement.

2.4 CMC shall maintain a completed Drug History Record and such other records as specified in the Commercial Quality Agreement for the period of time specified in the Commercial Quality Agreement. CMC shall retain and store samples of all Quality Released Product for such period as may be required by Applicable Laws and Regulatory Obligations and the Commercial Quality Agreement, which in the absence of a definitive time period shall be [***] from the date of release or Delivery. If the Parties agree, CMC shall retain such samples for a longer period at the Customer's cost.

Third Party Subcontractors

2.5 CMC may subcontract:

2.5.1 to its Affiliates, any part of the Services (provided that the Affiliates may not further subcontract those parts of the Services), with the prior written consent of Customer (such consent not to be unreasonably withheld, delayed or conditioned);

2.5.2 to Testing Laboratories; and;

2.5.3 to any other reputable qualified Third Party, any part(s) of the Services (provided CMC identifies the specific Services to be performed) with the prior written consent of Customer (such consent not to be unreasonably withheld, delayed or conditioned).

CMC shall remain responsible for the Services to be rendered by Third Parties to whom it subcontracts and shall ensure such Third Parties perform such subcontracted Services in compliance with the terms and conditions of this Agreement.

3. RAW MATERIALS, CUSTOMER MATERIALS, AND EQUIPMENT

3.1 CMC shall be responsible for obtaining Raw Materials required for the manufacture of Product in reasonable quantities consistent with the Forecast and Purchase Orders.

CMC shall ensure that all Raw Materials (i) conform to their respective Specifications; and (ii) are stored and handled in accordance with cGMP, Applicable Laws and Regulatory Obligations and the Commercial Quality Agreement.

3.2 [***]

3.3 CMC will be responsible for risk of loss of Customer Materials while in CMC's control.

3.4 All equipment acquired by CMC to perform Services for which the entire purchase cost is paid for or charged to Customer, shall be owned by Customer. Customer shall be responsible for all delivery, installation, maintenance (except as provided in the immediately following sentence) and storage costs associated with such equipment. CMC shall use such equipment solely to render the Services and in accordance with Customer's instructions CMC shall maintain such equipment and be responsible for any damage to (excluding normal wear and tear), or loss or theft of, the equipment while in its possession and shall insure it accordingly, except to the extent such damage, loss or theft is caused by the negligence or wilful misconduct of Customer. Upon termination or expiration of this

Agreement, CMC shall transfer such equipment to Customer at Customer's cost unless otherwise agreed.

4. TIMELINE, SPECIFICATION AND PROJECT MANAGEMENT

Timeline

4.1 CMC shall use Commercially Reasonable Efforts to maintain the Timeline. Notwithstanding that obligation, the Parties acknowledge and agree that the Timeline may be varied as agreed by CMC and the Customer in writing in order to accommodate delays or changes caused by or contributed to by (i) actions or omissions of the Customer (or its agents); and/or
(ii) additional activities added to the Services; and/or (iii) Force Majeure Situations or other circumstances beyond CMC's reasonable control ("**Non-Fault Delays**"). Non-Fault Delays shall exclude delays caused by (i) [***]; (ii) [***]; and/or (iii) [***] (collectively, "**Fault-Based Failures**").

4.2 In the event of any Non-Fault Delays, CMC shall update the Timeline as agreed with the Customer and, shall endeavour to keep the revised Timeline as close as possible to the Timeline in its form as it existed immediately prior to the Non-Fault Delays.

4.3 The Timeline may be amended by agreement between CMC and Customer provided that the revised Timeline is set out in writing and agreed by the Project Team.

4.4 Where the Timeline has been amended in accordance with this **Clause 4,** it shall be automatically binding upon the Parties. CMC shall keep Customer updated as to the current Timeline on a reasonable frequency. Customer may at any time on a

reasonable basis request an update on the progress of the Services compared to the current Timeline.

Specification, Process & Quantities

4.5 The Specifications shall be amended only as agreed upon in writing by the Parties and signed by an authorized representative of each Party; provided, however, that the Parties agree to cooperate to amend or supplement the Specifications to the extent reasonably necessary to comply with changes in Applicable Laws or as Customer may reasonably request from time to time (provided such request is made in good faith). CMC shall follow the change control procedures set forth in the Commercial Quality Agreement for any proposed changes in the Specifications. For the avoidance of doubt, where the Parties cannot agree to modify, amend or update the Specification, the previous Specification as agreed to by the Parties shall apply.

4.6 For clarity the Parties acknowledge that all quantities of Product derived from a Batch are [***], except to the extent caused by a breach of this Agreement or CMC's negligence or wilful misconduct.

4.7 CMC shall not make any change to the Process, except by prior written approval of Customer for such change. The Parties agree to cooperate to amend or supplement the Process to the extent reasonably necessary to comply with changes in Applicable Laws and/or Regulatory Obligations. CMC shall follow the change control procedures set forth in the Commercial Quality Agreement for any proposed changes in the Process.

4.8 In the event that CMC intends to change or modify the CMC Facility in a manner that is likely to have an impact on the Process or Product or require submissions to or approvals from any Regulatory Authority related to the Process or Product ("**Facility Modification**"), CMC [***] and shall work with Customer through the JSC to ensure disruptions to the Timeline and Product Delivery are minimized and impact to the validated state of the Product and Process are evaluated and minimized.

Project Manager, Joint Steering Committee and Project Team

4.9 Each Party shall, [***], appoint an individual as a project leader ("**Project Manager**") who shall be responsible for leading and co-ordinating the day to day operation of the Services. In addition, [***], each Party shall select two of their senior technical staff (each a "**Committee Member**"), one of whom (for each Party) may be a Project Manager, to form the steering committee who shall have responsibility for providing leadership and strategic oversight of the Services governed by this Agreement ("**Joint Steering Committee**" or "**JSC**").

4.10 Separate from the Joint Steering Committee, the Parties shall each name and notify the other of representatives ("**Representatives**") who shall form the project team and will be responsible for the day to day performance of the Services including planning, executing and discussing issues regarding the Forecast, Timeline, the Services and

communicating between the Parties ("**Project Team**"). Any disputes or issues that cannot be readily resolved by the Project Team shall be referred to the Joint Steering Committee for resolution.

4.11 Each Party's Project Manager shall, subject to the oversight of the Joint Steering Committee, (i) manage the relationship between the Parties, (ii) oversee the performance of the Services and the activities of the Project Team, (iii) undertake actions delegated to them by the Joint Steering Committee and (iv) be the principal point of contact for the Services. The Project Managers shallmeet upon reasonable request either in person or by telephone or video-conference and each Party shall bear its own costs for attending such meetings.

4.12 The Joint Steering Committee shall be responsible for (i) making decisions regarding issues outside the scope of the Project Team or Project Managers, (ii) reviewing the decisions of the Project Team and/or Project Managers, (iii) providing a forum for the Parties to exchange information and coordinate their respective activities regarding the Services, (iv) providing a forum to discuss any technical difficulties or changes to Services or Batch Price triggered by a change to the Services or in accordance with **Clause 7.4** as well as resolving

any disputes or disagreements before escalation to the dispute resolution provided for in **Clause 17,** and (v) ensure that intent of this Agreement is maintained throughout the Term. The Joint Steering Committee shall meet on a reasonably regular basis during the Term.

4.13 At regular intervals the Representatives shall schedule Project Team meetings for the purpose of overcoming any issues with Forecasts, delivery of Product or the performance of all other aspects of the Services and providing an initial forum for discussing and resolving any difficulties or hurdles encountered in the performance of the Services. Such meetings shall be conducted by telephone conference or, if necessary, by face-to-face meetings at an agreed frequency unless particular difficulties arise which dictate the need for more frequent meetings. Each Party shall be responsible for their own costs in attending and conducting the Project Team meetings.

4.14 Any decision by the Project Team, the Project Managers or Joint Steering Committee which has the effect of amending the Services in any way must, before it becomes binding, be recorded in writing and signed by both Parties in accordance with **Clause 18.4** and **18.5.**

5. FORECASTS, ORDERS, MANUFACTURING CAPACITY AND FAILURE TO SUPPLY

Forecasts

5.1 Commencing on the Effective Date, and thereafter [***], Customer shall, subject to the provisions of this clause, deliver to CMC a [***] forecast of Customer's requirements for CMC to manufacture Product [***] ("**Forecast**").

5.2 Each Forecast shall set out the number of Batches of Product to be manufactured for Customer [***] covered by the Forecast together with the requested Commencement Date and Delivery Date for each Batch covered by the Forecast. In preparing a Forecast Customer shall attempt to aggregate the number of Batches required throughout the period covered by the Forecast into contiguous Campaigns.

5.3 In respect of each Forecast:

5.3.1 [***] by the Forecast shall be a definitive and binding order on Customer (a "**Firm Order**");

5.3.2 [***] by the Forecast shall be [***] binding on Customer (a **"Semi-Firm Order")**;

5.3.3 [***] by the Forecast shall be [***] binding on Customer (the order referred to in this **Clause 5.3.3**, also a "**Semi-Firm Order**");

5.3.4 (i) [***], the Minimum Volumes shall [***], (ii) [***], the Minimum Volumes shall be [***], and (iii) subject to **Clause 5.3.5**, during [***], without the prior written consent of CMC, the Minimum Volume shall be [***];

CMC shall reserve the Slots for the Minimum Volumes as described in Clause 5.3.4 and manufacture the Batches ordered for such Minimum Volumes. Customer shall be entitled to reserve additional slots that CMC may have available or [***].

5.3.5 Customer shall have [***] option [***]. Customer may exercise this option [***] ("**Option**"); provided that [***]**.** Provided that Customer has [***] in accordance with the preceding sentence, Customer shall have the right to exercise the Option [***]. If Customer exercises the Option, [***].

Customer shall also have the option [***]. The [***] to the Minimum Volume.

5.4 The Forecasts are prepared for and intended to provide CMC with clarity as to the Customer's requirements for Product. Forecasts shall be provided by Customer on [***] as provided above and each subsequent Forecast shall reflect the previous relevant Forecasts provided by Customer such that:

5.4.1 the quantity of Product set out in [***] shall, respectively, in the next Forecast, [***] (other than with CMC's prior written consent);

5.4.2 the quantity of Product set out in [***] shall, respectively, in the next Forecast, [***] in the next Forecast and [***]; and (ii) [***] and may [***];

5.4.3 the quantity of Product set out in [***] shall, respectively, in the next Forecast, [***] and may be [***]; and (ii) [***] and may be [***].

5.4.4 Customer shall provide a new projection for the [***] in accordance with the principles set out in **Clause 5.3.**

5.5 Should Customer [***] Forecast in accordance with the preceding provisions of this **Clause 5,** a Forecast [***] under this clause by Customer where:

5.5.1 [***]; and

5.5.2 [***]; and

5.5.3 the [***] of the [***] Forecast shall be the [***] of the [***].

Orders

5.6 Orders for Product shall be provided by Customer and accepted by CMC as follows:

5.6.1 Customer shall provide written or electronic purchase orders (each, a "**Purchase Order**") for each Firm Order in conformance with the relevant Forecast [***] Forecast submitted by Customer under **Clause 5.1**.

5.6.2 Each Purchase Order shall include: (a) a Commencement Date [***] for each Batch subject to such Purchase Order; and (b) a [***] subject to such Purchase Order, unless otherwise agreed by CMC.

5.6.3 CMC shall be deemed to accept each Purchase Order and its Commencement Date and Delivery Date, [***], CMC provides written notice to Customer with an alternative Commencement Date [***] Commencement Date and the corresponding

Delivery Date shall be [***] as the time difference between the [***]. Upon acceptance of each Purchase Order, CMC shall provide the confirmed Commencement Date of each Batch in the Purchase Order.

5.6.4 No terms contained in any Purchase Order, order acknowledgment or similar document shall be construed to amend or modify the terms of this Agreement and in the event of any conflict, this Agreement shall prevail and control, unless the Parties otherwise expressly agree in writing by making reference to both this Agreement and the alternative terms.

5.7 Notwithstanding the limits on ordering under a Forecast, CMC may, in response to Customer's written request, elect to manufacture additional Batches of Product in a [***] beyond the quantity submitted in a Firm Order for that same [***] ("**Exceptional Batches**"). CMC's obligation to manufacture Exceptional Batches shall only arise

upon CMC's written acceptance whereby the Exceptional Batches accepted by CMC shall be deemed part of the Firm Order(s) for the relevant [***].

5.8 All quantities of Batches that are the subject of a Firm Order or a Semi-Firm Order (i.e., the binding portion of a Semi-Firm Order) shall (i) be binding ("**Binding Batches**") upon Customer and CMC and (ii) may not be delayed or cancelled by Customer or CMC except as provided for in this Agreement. Partial Batches subject of a Firm or a Semi-Firm Order shall be rounded up to the nearest whole Batch.

5.9 Should Customer fail to order the Minimum Volume in any Calendar Year (as determined based on the Commencement Date of each Batch in any Calendar Year), then Customer shall pay to CMC a sum calculated as [***]. CMC shall be entitled to invoice in December of each Calendar Year, and Customer shall pay such invoice [***] in accordance with the provisions of **Clause 7.** Notwithstanding the foregoing, in the event that, in accordance with **Clause 5.6.3**, CMC provides an alternative Commencement Date and Delivery Date that [***], the Batches affected by such change shall [***] Commencement Date and Delivery Date [***].

5.10 Should Customer delay or cancel a Binding Batch in any Calendar Year, then Customer [***] (**"Cancellation Fee"**); provided that if Customer cancels any Batch(es), for the purpose of determining the Cancellation Fee, [***]. CMC shall be entitled to invoice the cancelled or delayed Batch [***], and Customer shall pay such invoice [***] in accordance with the provisions of **Clause** 7. For the purposes of determining the Minimum Volume, [***].

5.11 Notwithstanding the provisions of **Clause 5.10**, [***]. In the event the [***], Customer shall not owe CMC the Cancellation Fee for such cancelled Batch. [***] under **Clause 5.9**.

5.12 Notwithstanding the provisions of **Clause 5.10**, CMC shall [***] **Clause 5.9**.

5.13 In the case of cancelled Batches for which Raw Materials have been purchased by CMC and paid by Customer and which cannot be used to manufacture future Batches subject to the Forecast, Customer shall be entitled to elect to either [***].

5.14 CMC shall use the Forecasts to plan for and, as appropriate, reserve Slots in its cGMP manufacturing suite for those Batches to be manufactured under Firm Orders and Semi- Firm Orders according to the then current Timeline.

5.15 Where a Timeline is amended and such amendment affects the scheduled Slot(s) for those Batches which are the subject of a Firm Order, CMC shall update its manufacturing schedule and reserve a new Slot for each affected Batch which, subject to reserved slots under CMC's existing manufacturing schedule for the entire CMC Facility, shall be reserved as near in time to the existing vacated Slots as CMC's then current schedule will permit.

Supply Uncertainty and Supply Failure

5.16 Should CMC become aware or conclude that it will be unable to meet the Timeline for manufacture or Delivery of one or more Binding Batch(es) ("**Supply Uncertainty**"), then CMC shall as soon as reasonably practicable provide notification in writing to Customer of such circumstances, identify the Batches that may be affected bysuch Supply Uncertainty, identify what CMC believes will cause such Supply Uncertainty and explain what efforts CMC is taking to minimize such Supply Uncertainty (a "**Supply Uncertainty Notification**"). In the event that Customer receives a Supply Uncertainty Notification or a Supply Uncertainty occurs, CMC and Customer [***] in accordance with the current Forecast and any Purchase Orders accepted by CMC for Batches that may be or are affected by such Supply Uncertainty.

5.17 In the event the manufacture of the Product is [***] ("**Supply Failure**") or Customer receives a Supply Uncertainty Notification stating that the manufacture of the Product [***], Customer shall be entitled to engage an alternate supplier to manufacture the Batchesand CMC shall support transfer of the Process and test methods to such alternate supplier (including conducting a technology transfer consistent with the transfer of information described in **Clause 15**);

5.18 If the Supply Failure results primarily from any Fault-Based Failure or other cause within CMC's reasonable control (including any default or failure with respect to the Facility), the following shall apply until the Supply Failure is resolved:

5.18.1 The Forecast and Customer's obligations thereunder will be suspended such [***].

5.18.2 CMC will reserve capacity for the [***], CMC and Customer shall agree on allocation of the reserved Minimum Volume capacity across each remaining Calendar Year of the Term.

5.18.3 If Customer engages an alternate supplier, [***], up to the applicable number of Batches included in the Minimum Volume for the relevant Calendar Year.

5.18.4 [***]

5.18.5 [***]

5.18.6 At Customer's sole option, any [***] that cannot be manufactured due to a Supply Failure shall be credited against other payments owed by Customer to CMC under this Agreement.

5.19 If the cause of a Supply Failure results primarily from Customer's act or omission:

5.19.1 CMC shall use Commercially Reasonable Efforts to adjust the Timeline to allow for time to resolve the cause for the Supply Failure. Until the Supply

Failure is resolved Customer shall continue to be obligated to pay for Binding Batches.

5.19.2 The Minimum Volume obligation shall be unaffected during the Supply Failure and [***].

5.20 If the cause of a Supply Failure results primarily from a Force Majeure Situation:

5.20.1 CMC and Customer shall work collaboratively through the JSC to discuss and find ways for CMC to promptly minimize such Supply Failure and ensure supply of Product as soon as practicable in accordance with the current Forecast and any Purchase Orders currently in effect for Batches that are affected by such Supply Failure.

5.20.2 CMC shall use Commercially Reasonable Efforts to adjust the Timeline to allow for time to resolve the cause for the Supply Failure. Until the Supply Failure is resolved [***].

5.20.3 The Forecast and Customer's obligations thereunder will be suspended such [***] until CMC and Customer agree the Supply Failure has been resolved and manufacturing resumes.

5.20.4 [***]

5.20.5 [***]

5.21 If CMC is able to utilize uncommitted capacity of the CMC Facility to remedy any Supply Failure, but at the time when that capacity arises CMC is under an obligation to endeavour to remedy similar deficiencies for any other customer(s) of the CMC Facility, CMC shall liaise with all customers concerned to try to agree on an appropriate arrangement for using that (or that and other) available capacity for all concerned. In the event that no agreement can be reached, then the capacity shall be allocated taking into consideration each

customer's number of batches subject to firm orders, CMC's manufacturing schedule and availability of raw materials.

6. DELIVERY AND EXAMINATION

Delivery and Examination

6.1 CMC shall provide Customer with advance written notice of each anticipated Delivery Date and, in any event, [***].

6.2 Except as set out in **Clause 6.3** or in the Specifications, the Product that CMC manufactures pursuant to this Agreement shall be released to Customer [***] Customer that the Product is available for collection. The Deliverables will be deemed to have been delivered in accordance with the following: (a) with respect to Product,

delivery will be deemed to have occurred [***]; and (b) with respect to all other Deliverables, delivery will be deemed to have occurred [***] ("**Deliver**", "**Delivery**" or "**Delivered**"). Collection may be arranged at any time during normal business hours on Business Days or such other time as may be agreed by the Parties.

6.3 Upon Delivery of the relevant Batch, and no later than [***] after such Delivery, CMC shall provide the [***] shall be delivered by courier with registered delivery or by other electronic means agreed by Customer.

6.4 [***] examine and/or test the Deliverables for any defect or non-conformity, including in the case of Product non-conformity with the Specifications and cGMP standards which Deliverables are specified to meet (a "**Defect**" or "**Defective**). Where any alleged Defect is identified, Customer shall notify CMC by written notice ("**Defect Notice**") [***]; provided that with respect to any defect in the Deliverables that was not, and could not reasonably be expected to have been found upon Delivery by exercise of ordinary care in inspection and testing, Customer shall provide written notice [***].

6.5 A Defect Notice must identify (i) the Deliverable and, in the case of Product, the Batch from which the Product was derived, (ii) the date(s) of Delivery, (iii) reasonable detail, including, as applicable, test results, of the Defect, (iv) where applicable full disclosure of the methodology of all analytical tests performed on the Deliverables and the results of those tests, (v) confirmation that, after Delivery to Customer, the Deliverables have been stored

and transported in accordance with applicable Shipping Guidelines, and (vi) where the Customer asserts that the Defect is due to CMC, the reasons why the Customer makes that assertion. If a Defect in any Deliverable is not notified to CMC in accordance with the provisions and time limits stipulated in **Clause 6.4** the Deliverable shall be deemed accepted and free of Defect and Customer shall have no further remedy against CMC in respect of that Deliverable.

6.6 CMC shall store at the CMC Facility any such Deliverable [***] on behalf of Customer. Storage of a Deliverable at CMC's premises after Delivery shall be at Customer's sole risk and liability except that CMC shall be responsible for damage to such Deliverables to the extent any damage is caused during such storage solely by an act of CMC's negligence, wilful misconduct and/or illegal conduct. If Deliverables have not been collected by Customer or Customer's Shipping Company [***], CMC shall notify Customer of the outstanding collection. CMC shall be entitled [***] to continue to store it [***], unless the Parties have previously negotiated for longer term storage or Customer informs CMC in writing to dispose of such Deliverables.

Consequences of Defective Product

6.7 Upon receipt of the Defect Notice CMC shall promptly investigate whether or not the Defect is due to CMC's negligence or failure to comply with its obligations hereunder and shall report to Customer [***].

6.8 If a Defect is primarily due to CMC's fault, and not as a result of Customer action or inaction or any Third Party (other than an agent of CMC performing Services) then CMC shall replace the Defective Deliverables at no charge to Customer. CMC shall use Commercially Reasonable Efforts, having regard to its other obligations and commercial commitments to third parties and subject to availability of Raw Materials in the timing of such replacement, to replace such Defective Deliverables [***].

6.9 If there is a dispute regarding whether or not a Deliverable is Defective ("**Disputed Deliverable**"), then (a) analysts from both parties will directly communicate to determine the Parties' respective methods of analysis are the same and are being executed in the same manner, and to attempt to determine whether any non-compliance may have been caused during the shipment of the sample from the CMC Facility, and (b) carefully controlled and split samples as agreed should be sent from one site to another for testing in an attempt to reach agreement (which may involve Customer sending a representative and a sample of the Disputed Deliverable to CMC, and the Parties conducting jointly agreed upon tests on the Customer sample of the Disputed Deliverable and a sample of the Disputed Deliverable retained by CMC). The Parties will use good faith efforts [***] to resolve whether the Disputed Deliverable is Defective due to CMC's failure to manufacture in accordance with this Agreement.

6.10 In the event the Parties cannot resolve their dispute in the manner described, a mutually agreed-upon independent laboratory, acting as an expert and not as an arbitrator, shall be asked to test the Disputed Deliverable. The costs of such independent laboratory shall be borne by the Parties equally; provided, however, the Party that is determined to be incorrect in the dispute shall be responsible for all such reasonable costs and shall reimburse the correct Party for its share of such reasonable costs incurred. The decision of such independent laboratory shall be in writing and shall be binding on both CMC and Customer. During the further dispute resolution described above in this section, at Customer's request, CMC shall use Commercially Reasonable Efforts to supply Customer with replacement Product subject to availability of Raw Materials and capacity in CMC's Facility, which replacement Product Customer shall purchase on the same terms as Product that is the subject of the independent testing. With respect to all Product that Customer properly rejects, Customer shall destroy all remaining unused Product as soon as possible after CMC's request and at CMC's expense. In no event may Customer use any of the rejected Product for any human clinical testing or trials after it becomes aware of the basis for such rejection (and Customer shall indemnify CMC for all liabilities, costs and damages incurred by CMC resulting from Customer's breach of this limitation on use).

Release For Further Processing

6.11 Subject [***].

Title and Risk

6.12 Subject to **Clause 6.6**, title and risk in the Deliverables shall pass to Customer on Delivery.

Packaging, Storage and Transport

6.13 Unless otherwise agreed, all Product and Deliverables shall be packaged by CMC in accordance with its applicable packaging SOPs and Applicable Laws. Customer shall inform CMC in advance of any special packaging and labeling requirements and CMC shall accommodate reasonable customer specific packaging requests.

6.14 Customer shall, prior to the collection of the Deliverables, inform CMC of its Shipping Company. Customer shall coordinate with such Shipping Company for the shipment of the Product and CMC shall not be responsible for any shipping costs of the Shipping Company.

Upon collection, Customer shall be responsible for ensuring that the Deliverables are stored and transported in accordance with the Shipping Guidelines.

6.15 Except as otherwise agreed by the Parties, CMC shall not be responsible for or have an obligation to clear for export or import any Deliverables that CMC (or its subcontractors) generates or manufactures pursuant to this Agreement.

7. BATCH PRICE, PAYMENT TERMS AND MILESTONE PAYMENTS

Reserve Payment and Batch Price

7.1 Customer shall pay CMC: (a) [***], and (b) [***] under the Amended Agreement effective between the parties on or about the Effective Date (the foregoing payments [***], "**Reserve Payments**"). CMC shall invoice Customer for such amounts upon the occurrence of the above-referenced events and Customer shall [***].

7.2 Additional payment for Batches will be due as described in Appendix Two. The Batch Price in Appendix Two is stated in U.S. Dollars and is exclusive of all taxes, duties, or other fees of whatever nature imposed by or under the authority of any state, government or public authority (other than taxes on CMC's income), or any external costs, Raw Materials or shipping and associated costs that CMC incurs to provide the Services, which Customer agrees to pay in addition to the Batch Price.

7.3 The Batch Price stated in Appendix Two may be adjusted on an annual basis, commencing with the first anniversary of the Effective Date and thereafter on each anniversary of the Effective Date in an amount not to exceed [* * *] . For the avoidance of doubt, if the [***]. For example, the Batch Price stated in Appendix Two shall [***], the Batch Price shall be [***]. The [***] Batch Price shall be [***]. The Batch Price [***]. CMC shall give written notice to the Customer of the new Batch Price schedule [***]; provided however that CMC [***].

7.4 If there are any material and unforeseen changes in cGMP or manufacturing regulations promulgated pursuant to enabling legislation under a statute that:

7.4.1 are specific to the Product and not of general requirement for biologics contract manufacturing services; or

7.4.2 which result in the financial returns under this Agreement being substantially affected to CMC's detriment other than by the acts or omissions of CMC, then the Parties shall negotiate in good faith a way to continue the Services while overcoming such financial investment or detriment. For purposes of clarity, CMC [***].

Invoicing & Payment Terms

7.5 All invoices will be in U.S. Dollars and Customer agrees to pay all sums due hereunder in U.S. Dollars.

7.6 CMC will issue invoices in accordance with the provisions of Appendix Two.

7.7 All invoices shall be paid by wire transfer to the following account:
ACCOUNT DETAILS:

[***]

Unless expressly stated on an invoice to the contrary, all invoices are issued net and if not disputed in good faith in writing before the due date, will be paid in full without any deductions, deferment or set off by Customer [***]. If Customer disputes an invoice, Customer shall notify CMC in writing of the dispute, which notice must include a description of the dispute; provided that if Customer disputes an invoice and intends to withhold payment of such invoice, Customer shall notify CMC in writing of the dispute prior to the due date of such invoice. The Parties shall use commercially reasonable efforts to resolve the dispute as quickly as possible. If the dispute [***], the CEOs of the parties shall meet and resolve the dispute. Customer shall, subject

to the other terms and conditions of this Agreement, pay amounts due that are not in dispute.

7.8 Raw Materials costs for all Services will be invoiced to Customer as set forth in Appendix Two. If Customer requests CMC purchase Raw Materials in excess of what is needed to meet the Forecast ("**Excess Raw Materials**"), Customer shall pay to CMC, [***].

7.9 All shipping [***]

Late Payments

7.10 If the undisputed portion of an invoice is not settled by Customer in full in accordance with this Agreement and after providing the Customer [***], CMC may, at its discretion:

7.10.1 charge Customer, which Customer will pay, [***] and/or;

7.10.2 [***], suspend the performance of the Services. Where performance is suspended, CMC shall have no liability to Customer for such suspension or delay in the Timeline and the Batch Price for any Batches that are the subject of a Firm Order or a Semi- Firm Order which are delayed as a result of the suspension shall become due and payable by Customer.

Payments due to Customer

7.11 Where any payment, credit or refund is properly due to the Customer under this Agreement, the Customer can elect to:

7.11.1 have that amount refunded to it by CMC [***]; or

7.11.2 have that amount set-off against any further amount payable by the Customer under this Agreement or any future agreement the Parties enter into.

7.12 Where Customer elects to have an amount set-off against any further amount payable by the Customer under this Agreement and, subsequent to that credit, the Customer remains entitled to a payment, credit or refund, CMC shall refund that amount to the Customer [***].

8. CUSTOMER AUDITS, REGULATORY INSPECTIONS & MATTERS

Audits

8.1 Customer's audit rights are as set forth in the Commercial Quality Agreement.

Regulatory Inspections

8.2 Regulatory inspections are addressed in the Commercial Quality Agreement. CMC shall use Commercially Reasonable Efforts to make available the CMC Facility, subcontractor facilities, records, data, documents, information and/or personnel as are reasonably necessary or useful pursuant to and during regulatory inspections by government authorities as further set forth in the Commercial Quality Agreement. For the purposes of this **Clause 8.2** records, data, documents and information refers to copies in tangible, and electronic and visual mediums.

Regulatory Filings and Standards

8.3 During the preparation for filing with any Regulatory Authority of any documentation for the Product which is or is equivalent to the Regulatory Authority's Chemistry and Manufacturing Controls portion of an approval application, including any BLA ("**Authority Submission**"), Customer shall provide CMC with [***]. CMC shall provide Customer with its comments [***]. For clarity, CMC's [***] applies to [***] shall be provided by CMC to the Customer [***].

8.4 For clarity, the Parties agree that in reviewing the documents referred to in **Clause 8.3** above, CMC's role will be limited to [***]. As such, CMC shall not assume responsibility or liability for the accuracy of the filings with Regulatory Authorities other than for

information provided by CMC in writing and intended for inclusion in regulatory filings. The sole responsibility of the preparation and filing of all regulatory documents with the Regulatory Authorities with respect to the Product shall be borne by Customer.

8.5 Customer shall provide to CMC all documents relating to the Product and services performed hereunder by CMC that are reasonably requested by CMC and required to comply with any Regulatory Authority's pre-approval inspection of the CMC Facility, including but not limited to, development reports, Chemistry and Manufacturing Controls documentation and stability data, subject to Customer being able to legally provide such documents to CMC.

8.6 [***], Customer shall provide CMC with a copy of the documents incorporating such data so as to permit CMC to verify the accuracy and regulatory validity of such documents as it related to the CMC-generated data.

8.7 CMC will provide Customer with information and data regarding the manufacture of Product to the extent reasonably requested by Customer or necessary for Customer to prepare and

defend any inquiries from the FDA or other Regulatory Authorities to satisfy regulatory requirements with respect to Product. Without limiting the foregoing,

8.7.1 CMC shall provide regulatory support to Customer for a Regulatory Authority's pre-approval inspection of the CMC Facility and during review of any Authority Submission [***].

8.7.2 Customer will inform CMC of requests for information from Regulatory Authorities during review of an Authority Submission for which CMC support is needed. CMC will use diligent efforts to adhere with the turn-around times requested by Customer to support such regulatory responses.

8.8 If CMC is required by the FDA, EMA, or any other Regulatory Authority to modify the CMC Facility or validate or re-validate the Process that will impact the manufacturing of the Product, CMC shall notify Customer and consult with Customer regarding the required activities. Customer shall [***] and not generally for CMC's manufacturing activities for other customers, provided, however that CMC shall be responsible for the costs of any such validation or re-validation arising primarily from (a) CMC's breach of this Agreement or CMC's negligence or wilful misconduct or (b) a modification to the CMC Facility that is generally required for CMC's manufacturing activities.

Person in Plant

8.8 CMC shall permit [***] with reasonable advance notice [***] to observe manufacturing or packaging pursuant to this Agreement on-site at the CMC Facility during the Term.

Customer's representatives shall have access to CMC's production and quality control and storage areas related to the Product (including when in operation) and to Product related documentation. Customer agrees that Customer's representatives shall comply with CMC's reasonable rules, regulations and safety procedures (that are provided to Customer) and cGMP while on CMC's premises. In addition, CMC shall provide reasonable accommodations for Customer's representatives, including a desk and access to the internet, phones, copiers, fax machines and other miscellaneous office equipment as requested.

Validation

8.9 The Parties recognize [***].

8.10 Upon successful completion of [***] as specified in the Work Statement.

8.11 CMC is responsible to ensure that all equipment, facilities, utilities and computer systems used for the production of the GMP steps of the Product are qualified or validated in accordance with all applicable GMP regulations and guidance documents and are maintained in a validated state

9. WARRANTIES

Customer Warranties

9.1 Customer warrants and represents to CMC that:

9.1.1 to its knowledge, it has the right to supply and deliver to CMC the Customer Materials (including the Cell Line provided by or on behalf of Customer where applicable) and the Customer Intellectual Property Rights for use in the performance of the Services and the manufacture of Product pursuant to this Agreement;

9.1.2 to its knowledge, the Materials and Safety Data Sheet for the BDS is accurate and the Cell Line provided by or on behalf of Customer and any Customer Materials are free from all contaminants including, without limitation, virus, bacteria or other vectors and if handled and used in accordance with the recommendations and guidelines in the Materials and Safety Data Sheet supplied by Customer will not cause a health hazard or biohazard; and

9.1.3 to its knowledge the use of any of the Cell Line, Customer Materials, Customer Intellectual Property Rights, and the Process and the manufacture of the Product in accordance with this Agreement does not infringe any valid Intellectual Property rights of third parties, except that no warranty is given with respect to any CMC Intellectual Property Rights;

9.1.4 the license of Customer Intellectual Property Rights to CMC for the Services is lawfully granted; and

9.1.5 to its knowledge the Cell Line provided by or on behalf of the Customer and Customer Materials are viable, adequate and suitable for the effective performance of the Services and manufacture of the Product according to the Specification and the information regarding the Cell Line and the Process provided to CMC by or on behalf of the Customer is complete and accurate.

CMC Warranties

9.2 CMC warrants and represents to Customer that:

9.2.1 it has the necessary permits, facilities, Third Party contractors and skilled personnel necessary of a biologics contract manufacturer for the regular provision of manufacturing and development services of biologic material and required for performance of the Services in accordance with this Agreement;

9.2.2 all Deliverables shall be Delivered free of encumbrances or liens but for the avoidance of doubt no warranty is given in this **Clause 9.2.2 i**n respect (i) non- infringement of Third Party Intellectual Property Rights, or (ii) freedom to use;

9.2.3 to its knowledge, the CMC Intellectual Property Rights used in the Services and the performance of the Services do not infringe Third Party Intellectual Property rights, except that no warranty is given with respect to the Cell Line, Process, Customer Materials and Customer Intellectual Property Rights;

9.2.4 where the Services are to be performed according to cGMP, CMC shall apply the appropriate cGMP standards to the performance of such Services; and

9.2.5 Services and Manufacture of Product will be performed in accordance with applicable industry standards and all Applicable Laws;

9.2.6 the Product at the time of Delivery shall comply with the Specifications, cGMP and any other criteria specified in the Certificate of Analysis for such Product;

9.2.7 none of CMC or its Affiliates, or any officer of CMC or its Affiliates or any employee, consultant or other contractor engaged by CMC to perform activities under this Agreement, (a) have been debarred, or are subject to a pending debarment, or will use in any capacity in connection with this Agreement any person who has been debarred pursuant to section 306 of the FDCA, 21 U.S.C. § 335a, (c) has been listed by any federal and/or state agencies as excluded, debarred, suspended or otherwise been made ineligible to participate in federal or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f), (c) has been convicted of a criminal offense related to the provision of healthcare items or services, or (d) is subject to any such pending action or is the subject of a conviction or pending action described in such sections. CMC shall notify Customer in writing immediately if CMC, its

Affiliates or any of their respective officers or any person or entity used by CMC or its Affiliates to perform activities under this Agreement is subject to any of the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to the best of CMC's knowledge, is threatened.

Mutual Warranties

9.3 Each Party warrants and represents to the other that:

9.3.1 it has the right and corporate authority to enter into this Agreement and the execution, delivery and performance of this Agreement does not conflict with any agreement, instrument or understanding, oral or written, to which such Party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it;

9.3.2 it shall obtain and during the Term maintain in force all appropriate permits and regulatory licenses required in connection with such Party's handling, transport and storage of the Cell Line and Product;

9.3.3 neither Party shall perform any actions that are prohibited by local and other anti- corruption laws (including the U.S. Foreign Corrupt Practices Act, collectively "**Anti- Corruption Laws**") that may be applicable to one or both Parties. Without limiting the foregoing, neither Party shall make any payments, or offer or transfer anything of value, to any government official or government employee, to any political party official or candidate for political office or to any other third party related to the transaction in a manner that would violate Anti-Corruption Laws.

Exclusion of other express and implied warranties

9.4 Except as provided in this Agreement, to the maximum extent permitted by the applicable law of this Agreement, except for those express warranties set out above, the Parties neither make nor give any other express or implied (whether by statute, custom or otherwise) warranties in relation to each of their respective obligations, duties or activities owed or performed under this Agreement and hereby exclude any other such express or implied warranty in respect of that subject matter.

10. CONFIDENTIAL INFORMATION

10.1 In consideration of one Party (the "**Disclosing Party**") making available its Confidential Information to the other (the "**Recipient Party**"), the Recipient Party hereby undertakes that it shall, and shall procure that each of its Permitted Recipients, shall:

10.1.1 treat and safeguard as private and confidential all the Confidential Information of the Disclosing Party;

10.1.2 use the Confidential Information of the Disclosing Party only during the Term for those purposes reasonably necessary to perform its obligations or exercise its rights under this Agreement and without prejudice to the generality of the foregoing, not use any Confidential Information of the Disclosing Party to obtain any commercial advantage over the Disclosing Party;

10.1.3 ensure the proper and secure storage of all Confidential Information of the Disclosing Party applying standards of care reasonably expected and no less stringent than standards applied to protection of Recipient Party's own confidential information; and

10.1.4 not at any time without the Disclosing Party's prior written consent disclose or reveal, whether directly or indirectly, any of the Confidential Information of the Disclosing Party to any person whatsoever except its Permitted Recipients, and then only on a limited need to know basis, who shall be informed by it of the confidential nature of such Confidential Information and of the confidentiality terms

of this Agreement and for whom it hereby accepts full responsibility in the event that any such person shall breach the duty of confidence imposed upon them;

10.2 The obligations in this Agreement regarding Confidential Information do not apply to information:

10.2.1 which, at the time of its disclosure by the Disclosing Party, was wholly available to the public;

10.2.2 which becomes generally available to the public after such disclosure otherwise than by reason of a breach of any of the undertakings in this Agreement, including any breaches of confidence by the Recipient Party or its Permitted Recipients;

10.2.3 which is, at the time of such disclosure and as evidenced by the Recipient Party's written records, lawfully already within its possession; or

10.2.4 was independently discovered or developed by the Recipient Party without the use of or reference to the Disclosing Party's Confidential Information as evidenced by written records.

10.3 In addition, notwithstanding **Clause 10.1**, the Recipient Party may disclose Confidential Information to the extent the disclosure is required by Applicable Law or a valid order of a court or other governmental body having jurisdiction; *provided, however,* that the Recipient Party gives reasonable prior written notice to the

Disclosing Party of such required disclosure and makes a reasonable effort to assist the Disclosing Party in obtaining, a protective order preventing or limiting the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation requires, or for which the order was issued. Notwithstanding anything to the contrary herein, Customer may use and disclose Confidential Information of CMC (a) in preparing and submitting BLAs to Regulatory Authorities or marketing Products subject to Section 8.3, or

(b) in communications with existing or prospective investors, acquirers, merger partners, consultants, advisors, licensees or collaborators under obligations of confidentiality and non-use consistent with this **Clause 10.**

10.4 Other than the limited and restricted rights of use set out in this **Clause 10** nothing in this Agreement intends to or has the effect of granting any right, title, license or interest in or to the Recipient Party or Permitted Recipients in respect of the Disclosing Party's Confidential Information.

10.5 If the Recipient Party or any of its Permitted Recipients is/are compelled to disclose any Confidential Information in the circumstances described in **Clause 10.3** of this Agreement or a breach or threatened breach of this **Clause 10** occurs or becomes apparent, the Recipient Party shall inform the Disclosing Party in writing of such obligation or fact as soon as possible after it is informed, or becomes aware, of it and if possible, before any Confidential Information is disclosed, so that (if the Disclosing Party in its absolute discretion shall see fit) a protective order or other appropriate remedy may be sought. The Recipient

Party agrees to assist and co-operate (and shall procure that each of its Permitted Recipients shall, as appropriate, assist and co-operate) in any action which the Disclosing Party may decide to take.

10.6 Each Party shall be permitted to disclose the terms of this Agreement, in each case under appropriate confidentiality provisions substantially equivalent to those of this Agreement, to any actual or potential acquirers, merger partners, licensees, sublicensees, investors and professional advisors on a need to know basis and to its board of directors in connection with the corporate governance of such Party. Except as otherwise provided for in this Agreement (including this **Clause 10.6**) or otherwise required by law or administrative authorities, neither Customer nor CMC shall disclose any terms or conditions of the Agreement to any Third Party without the prior written consent of the other Party.

10.7 At the request of the Disclosing Party, the Recipient Party shall promptly destroy (on request) or return to the Disclosing Party any and all Confidential Information (including copies of documents, computer records and records on all other media) then in its possession or under its control except where such Confidential Information is covered under surviving license rights between the Parties. Notwithstanding the foregoing, the Parties may retain copies of any document containing the Disclosing

Party's Confidential Information solely for the purpose of determining the scope of the obligations under this Agreement or to comply with regulatory obligations. Further, the Recipient Party shall not be required to return or destroy any electronic back-up tapes or other electronic back-up files that have been created solely by their automatic or routine archiving and back-up procedures.

10.8 The Parties acknowledge that they have received Confidential Information under other agreements between each other. The Parties hereby agree that Confidential Information received under those earlier agreements may be used for the purposes of performing the Services under this Agreement or exercising rights under this Agreement.

10.9 The provisions of this **Clause 10** shall survive expiration or termination of the Agreement for a period of 10 years.

10.10 For the avoidance of doubt, the provisions of this **Clause 10** do not restrict the Customer's right to disclose or otherwise deal with the Deliverables after such Deliverables have been Delivered to the Customer.

11. INTELLECTUAL PROPERTY

Pre-Existing Intellectual Property

11.1 Any Intellectual Property owned by a Party or licensed by a Third Party to a Party as of the Effective Date or before the commencement of the Services ("**Pre-Existing IPR**") shall remain the sole and absolute property of the Party that owned or was licensed to use such Pre-Existing IPR. Nothing in this Agreement shall act as any assignment or transfer of the Pre-Existing IPR. The Pre-Existing IPR shall not be licensed to the other Party under this Agreement unless an express license is granted hereunder.

Customer's grant of Intellectual Property License for the Services

11.2 The Customer hereby grants to CMC for the Term a non-exclusive, royalty-free, non- sublicensable (except to CMC's Affiliates performing Services in accordance with this Agreement), limited license in respect of Customer Intellectual Property Rights and Customer Agreement IPR solely to the extent the same is required and necessary for the proper performance of the Services. This license:

11.2.1 does not prevent the Customer from granting a license to or making any use of its Pre-Existing IPR; and

11.2.2 terminates automatically upon the expiry or termination of this Agreement, whichever is the earlier.

Intellectual Property created in the course of the Services

11.3 Without affecting **Clauses 11.1** and **11.2**, all data, results, information, processes, materials, trade secrets, know-how and corresponding Intellectual Property newly generated by CMC exclusively in its performance of the Services and which [***] shall

be owned by Customer ("**Customer Agreement IPR**"). CMC shall cooperate with Customer and execute any appropriate documents to fully effect the foregoing.

11.4 All Intellectual Property other than Customer Agreement IPR generated by CMC under the Services shall be owned by CMC ("**CMC IPR**").

License to CMC IPR

11.5 CMC hereby grants to Customer a general, royalty free, sub-licensable, worldwide license to use CMC Intellectual Property Rights or CMC IPR to the extent that the same is necessary or useful for the exploitation (including to make, have made, use, sell, offer for sale, distribute or import) of the Product or use of the Cell Line or Process to manufacture Product. Except to Permitted Recipients or as otherwise provided in this Agreement, nothing in the foregoing shall permit Customer to make any disclosure of Confidential Information or CMC's Know-How to a Third Party without the express prior written consent of CMC. This license does not prevent CMC granting a license to or making any use of CMC Intellectual Property Rights or CMC Agreement IPR.

Right to file for protection

11.6 Each Party may file patent protection on any Intellectual Property it owns in accordance with this **Clause 11** above and the other Party shall promptly upon request co-operate at the requesting Party's reasonable expense, with any requests to assist or enable the Party's protection including but not limited to signing and delivering documents and other information necessary for the valid application and prosecution of any such patent.

Party's Names & Press Release

11.7 Except as otherwise provided for in this Agreement or required by Applicable Law, neither Party shall use the name of the other Party or of the other Party's Affiliates, directors, officers

or employees in any advertising, news release, publication or other without the prior consent of the other Party, which shall not be unreasonably withheld or delayed.

12. INDEMNITIES AND LIABILITY

CMC's Indemnity

12.1 Customer shall indemnify, defend and hold harmless CMC and each of its directors, officers, employees and Testing Laboratories (the "**CMC Parties**") against any and all losses, demands, liabilities, damages, costs and expenses (including but not limited to, court costs and reasonable documented attorney's fees and expenses together with any applicable taxes thereon) **("Losses"**) arising out of any Third Party claim, action of proceeding ("**Claims**") that the CMC Parties may or have suffered or incurred directly as a result of the following:

12.1.1 any infringement or alleged infringement (including direct, contributory, inducement and wilful infringement) or breach of any Third Party Intellectual Property rights by CMC's use of the Cell Line, Process, Customer Intellectual Property Rights, Customer Materials in the performance of the Services or manufacture of Product hereunder;

12.1.2 any claims resulting from the use, handling, distribution, marketing, safety or sale of the Product or BDS, including any derivative, conjugated form or formulation of the same, by or on behalf of Customer;

12.1.3 any use, handling, distribution, marketing, safety or sale by or on behalf of Customer of Product which was the subject of a [***] in accordance with **Clause 6.13**; or

12.1.4 any acts or omissions of an auditor of Customer while on CMC's premises.

In addition, Customer agrees to indemnify and hold harmless CMC from and against any Losses arising out of contamination or damage to the CMC Facility to the extent caused by the Customer Materials except to the extent such Losses are caused by the Customer Materials not being handled in accordance with the Materials and Safety Data Sheet. The foregoing indemnities shall not apply to the extent the Losses or Claims arose from CMC's or any of its representatives or contractors (including Testing Laboratories) negligence, gross negligence, breach of this Agreement, or wilful misconduct (other than wilful infringement covered by Section 12.1.1) or are covered by an indemnity under **Clause 12.2.**

Customer's Indemnity

12.2 CMC shall promptly indemnify, defend and hold harmless Customer and each of its directors and officers, employees, agents, contractors or representatives ("**Customer Parties**") against any and all Losses arising out of any Claim that the Customer Parties may or have suffered or incurred directly as a result of the following:

12.2.1 the negligence or wilful misconduct (other than wilful infringement covered by Section 12.1.1) of CMC or any CMC representative or CMC Parties or a breach of this Agreement by CMC;

12.2.2 a material inaccuracy in a Certificate of Analysis such that certified Product at the time of Delivery does not meet Specification when certified to meet Specification or CMC's failure to manufacture Product or BDS according to cGMP, the Process or the Specifications; or

12.2.3 the infringement or alleged infringement or breach of any Third Party rights, including Intellectual Property rights, by CMC to the extent such infringement is due to CMC's use of the CMC Intellectual Property Rights in the performance of the Services, but excluding claims where such use is caused

by the combination of the CMC Intellectual Property Rights with the Cell Line, Customer Materials, Process or Customer Intellectual Property Rights.

The foregoing indemnities shall not apply to the extent the Losses or Claims arose from the Customer or any of the Customer Parties' negligence, gross negligence, breach of this Agreement or wilful default or are covered by an indemnity under **Clause 12.1.**

Indemnification Procedure

12.3 The Party (the "**Indemnitee**") that intends to claim indemnification under this **Clause 12** shall:

12.3.1 promptly, [***], notify the other Party (the "**Indemnitor**") in writing in general terms of any Claim, threat or action which has or has the potential to give rise to the Indemnitee seeking to rely on and claim the benefit of the indemnification together with notification of the Indemnitee's intention to rely on such indemnity, provided that, failure to give such notice shall not relieve the Indemnitor of its indemnification obligations except and only to the extent such failure actually and materially prejudices the ability of the Indemnitor to defend against such Claims;

12.3.2 not prejudice any defence to any Claim or attempt to settle or compromise such claim;

12.3.3 shall comply with the procedure in **Clause 12.3.1** except that nothing shall prevent it from complying with the procedural requirement of any proceedings which have been commenced;

12.3.4 subject to its other rights and obligations and compliance with the procedures set out in this **Clause 12** permit the Indemnitor to have overall control of the conduct of the negotiations and the proceedings including any counterclaim;

12.3.5 cooperate as reasonably requested by the Indemnitor, at the Indemnitor's expense, in the conduct of such Claim (and any counterclaim); and

12.3.6 have the right (at the Indemnitor's expense) to instruct independent counsel and participate in all proceedings and negotiations whether named or not as a party in the Claim or proceedings.

12.4 Notwithstanding any other provision in this **Clause 12,** the Indemnitor shall not settle or consent to an adverse judgement in any such claim, demand, action or other proceeding that adversely affects the rights or interests of any Indemnitee or imposes additional obligations (financial or otherwise) on such Indemnitee, without the prior express written consent of such Indemnitee (such consent to be at the Indemnitee's sole discretion).

12.5 In the event of a claim under **Clause 12.1.1 or 12.2.3**, the Parties shall promptly and in good faith discuss ways, whether by modifications to the Services or Product, licensing or otherwise, to settle or overcome the Claim. In the event that legal proceedings are commenced by a Third Party, the Parties shall [***]. If the Parties are unable to agree to a solution to avoid the infringement [***], the Parties shall discuss and consider whether to suspend the infringing Services before [***].

12.6 In the event that Customer challenges its obligation to indemnify the CMC Parties for a Claim arising under Clause 12.1.1, Customer agrees to promptly pay CMC for all costs and expenses of the action or proceeding, including reasonable attorneys' fees and court costs and collection expenses.

Insurance

12.7 Customer shall procure from a reputable insurance carrier commercial general liability insurance including coverage for product liability [***]. Customer will maintain such insurance during the Term of this Agreement [***]. Upon reasonable request, Customer will deliver a certificate of insurance evidencing such coverage and an endorsement of additional insured in favour of CMC.

12.8 CMC shall maintain, at its expense comprehensive general liability insurance and workers compensation insurance, including product liability insurance, [***]. All insurance required under this Agreement shall be maintained during the Term, and CMC shall from time to time provide copies of certificates of such insurance to Customer upon reasonable request. Notwithstanding the preceding sentence, CMC shall be obligated to maintain product liability insurance obtained by it pursuant to this **Clause 12.8** during the Term and after expiration or termination of this Agreement [***].

12.9 Each Party will provide the other Party evidence of such coverage upon request. Each Party will provide the other Party [***] to non-renewal, termination or modification of their respective insurance coverage as described above.

Limitation of Liability

12.10 The Parties represent and acknowledge that they have negotiated the terms of this Agreement and have reached agreement on the terms based on their own assessment of their own risks, liabilities and rewards in connection with this Agreement and the Product in addition to having had the benefit of professional legal advice and accordingly the Parties agree that without prejudice to the terms of **Clauses 16, 12.10** and **12.12** CMC's aggregate liability to Customer for any loss or damage suffered by the Customer as a result of breach of this Agreement or of any other liability (including but not limited to negligence, misrepresentation or claim under the indemnities) in respect to any claim arising under this Agreement or in connection with the Services shall be limited, in the aggregate, to the [***].

12.11 Without prejudice to **Clause 12.12** neither CMC nor Customer shall be liable for any loss or damage howsoever caused (even if foreseeable or in the contemplation of CMC or Customer) in respect of:

12.11.1 [***]; and

12.11.2 [***].

12.12 Nothing in this Agreement shall purport or attempt or serve to exclude or restrict any liability [***].

13. PRODUCT RECALL

13.1 Subject to **Clause 13.3.1,** the costs and obligations with respect to any Recall of Product and handling enquiries and contacts from any Regulatory Authority relating to any Recall of Product shall be the responsibility of Customer. Customer shall notify all Regulatory Authorities having jurisdiction over Product (whether or not the issue arose in the jurisdiction controlled by the Regulatory Authority) of any Recall, and shall be responsible for coordinating all necessary activities regarding the action taken. CMC shall, [***], provide all reasonable assistance to Customer in connection with any

Recall. The Parties agree to keep each other advised of any Recall, the progress of undertaking any Recall, and to exchange copies of such documentation as may be reasonably required, to assure regulatory compliance with a Recall.

13.2 If either Party has reason to believe that any Product (whether the Product itself or particular Batch(es)) should be Recalled, such Party shall promptly inform the other in writing, to also include the reasons and explanations for the Recall, prior to taking any such action. In addition, Customer shall give CMC prompt written notice of any Recalls that Customer believes were caused by or may have been caused by CMC's failure to comply with its obligations under this Agreement.

13.3 If any Product is Recalled for safety reasons or due to a mandatory notification from a Regulatory Authority dictating the Recall and, in either case, such reasons are as a result of CMC's failure to manufacture Product in accordance with the terms of this Agreement or otherwise as a result of CMC's negligence or wilful misconduct ("**CMC Failure**"), then CMC shall, subject to **Clause 12,** reimburse Customer for all reasonable expenses incurred by Customer in undertaking the Recall of those specific Products which are the subject of a CMC Failure. Such payment shall be made [***]. If CMC disputes that the Recall is:

13.3.1 due to safety reasons or mandatory notification from a Regulatory Authority dictating the Recall then the Parties shall mutually select a regulatory expert to evaluate whether the Recall was appropriate to address the safety reason or comply with the Regulatory Authority's notice (as applicable); and/or

13.3.2 due to CMC's CMC Failure, then the Parties shall mutually select an independent laboratory to evaluate whether the Product is defective due to CMC's CMC Failure; and

the evaluation(s) by the regulatory expert and/or independent laboratory shall be binding on the Parties (other than where such decision is a manifest error). If such evaluation substantially supports CMC's basis(es) for the dispute, then CMC shall not be responsible for any costs of the Recall. Subject to Clauses 9 and 12, any payment by CMC under this Clause 13.3 shall be Customer's sole remedy for the costs of the Recall.

14. TERM AND TERMINATION

14.1 This Agreement shall commence on and have effect as of the Effective Date and will, subject to earlier termination in accordance with this **Clause 14** or otherwise, continue for an initial term of four (4) years (the "**Initial Term**") commencing on the Effective Date. The term of this Agreement may be extended by Customer beyond the then current term for further periods of up to two (2) years duration ("**Additional Term**") provided that (i) Customer is not in material breach of this Agreement and (ii) Customer provides CMC with

written notice to extend the current Term [***].

14.2 Upon Customer reaching a decision not to extend the Initial Term or extend the Term with an Additional Term (i) [***]; and (ii) Customer shall not be entitled to seek extension of the Term under the provisions of **Clause 14.1.**

Events of Termination

14.3 Either Party ("**Non-Defaulting Party**") may terminate this Agreement before expiry of the Term with immediate effect upon prior written notice to the other Party ("**Defaulting Party**") if:

14.3.1 the Defaulting Party fails to pay any undisputed sum payable under this Agreement [***]

14.3.2 the Defaulting Party commits a material breach of its obligations under this Agreement and if the breach is capable of remedy, [***];

14.3.3 the Defaulting Party is (i) generally unable to pay its debts as they become due; or

(ii) has an administrator appointed or administration order made against it or an order for winding-up or dissolution made (otherwise than in the course of a bona fide reorganisation previously approved in writing by the Non-Defaulting Party) [***];

14.3.4 any material permit or regulatory license is permanently revoked preventing the performance of the Services by the Defaulting Party.

14.4 Customer may terminate this Agreement before expiry of the Term with immediate effect upon prior written notice to CMC:

[***].

Effect of Termination

14.5 Upon termination of this Agreement, Customer shall pay to CMC:

14.5.1 Unless such termination was by CMC according to Customer being the Defaulting Party under **Clause 14.3**:

14.5.1.1 payments due by Customer to CMC in respect of Services performed in accordance with the terms and conditions of this Agreement up to and including the day of such termination, in full for all completed Services and for partially completed Services a sum calculated on a pro-rata basis having regard to the Price for the cancelled Services (fairly determined by the Project Team having regard to man hours, materials, profit element and irreversible commitments incurred by CMC);

14.5.2 If such termination was by CMC according to Customer being the Defaulting Party under **Clause 14.3**:

14.5.2.1 in respect of Firm Orders and Semi-Firm Orders in existence at the date of termination, a payment calculated as [***];

14.5.2.2 In the event that Customer failed to order the Minimum Volume in the Calendar Year of such termination, then Customer shall pay to CMC [***].

14.5.3 Subject to Section 14.6, CMC shall invoice Customer for all payments due at the time of termination pursuant to **Clauses 7.5 and 14** and/or **Appendix Two [***]** of termination and Customer shall pay all undisputed amounts [***];

14.6 In the event of the expiration or termination of this Agreement for any reason, all amounts for which Customer is entitled to a credit pursuant to this Agreement shall be credited to any amounts due to CMC under **Clause 14.5.** In the event of the termination of this Agreement by Customer under **Clause 14.4.1** or **14.4.2**, to the extent paid to CMC, [***] to any undisputed payments due to CMC under **Clause 14.5** with [***] and any other amounts for which Customer has paid for Services that were not rendered, returned to Customer [***].

14.7 [***] under **Clause 14.3** primarily due to CMC being the Defaulting Party or if this Agreement expires, CMC shall [***]. In the event of termination of this Agreement by CMC under **Clause 14.3** due to Customer being the Defaulting Party, [***] CMC under **Clause 14.5** with the remainder [***].

14.8 In the event of a termination of this Agreement under **Clause 14.4.3**, Customer [***].

Upon termination of this Agreement for any reason, provided the Customer has paid all undisputed sums outstanding and which are properly due under this Agreement, CMC [***], provide the Customer with all Deliverables then manufactured or generated and all transferable work in progress and all Product then manufactured. CMC shall not be obliged to transfer any materials pursuant to this Clause where the Customer has not paid CMC all undisputed invoiced sums due [***].

Survival

14.9 Termination or expiry of this Agreement for whatever reason shall not affect the accrued rights of either CMC or Customer arising under or out of this Agreement before the effective date of termination. The provisions of this Agreement which are expressed to survive this Agreement including **Clauses 1**, **2.4**, **3.4, 10**, **11, 12**, **13**, **14.5** through **14.8**, this Section **14.9**, **15, 17** and **18.4** through **18.13** shall survive termination or expiry of this Agreement to the degree necessary to permit their complete fulfilment or discharge.

15. TECHNOLOGY TRANSFER

15.1 Upon (i) termination or during the notice period regarding termination of this Agreement or the Services other than where termination is for material breach by Customer or (ii) on expiry of this Agreement; Customer may by written notice to CMC seek assistance from CMC with respect to the transfer to another manufacturer of the then-current Process and test methods solely for the purpose of manufacturing and testing the Product ("**Technology Transfer**"). Following CMC's receipt of such notice, the Parties will establish, in good faith, a schedule and plan for effecting such transfer and CMC will thereafter co-operate with Customer in implementing such plan as agreed by the Parties. As part of the Technology Transfer, CMC will make available for collection, subject to any Regulatory Obligations, all Customer Materials, Cell Line and one copy of all documentation (to the extent not previously delivered to Customer) generated pursuant to the Services up to the date of

termination or expiry including batch records, development and validation reports and production process documentation, test method SOPs and method development and validation reports.

15.2 The obligations on CMC in respect of the Technology Transfer shall only be exercisable by Customer [***]. Customer shall pay, CMC's costs providing the Technology Transfer [***]. The Customer will not, and CMC will not be obliged to,

transfer any CMC Know-How pursuant to this Technology Transfer until the contract manufacturer to whom the process is transferred enters into a limited royalty-free license and confidentiality agreement reasonably acceptable to and with CMC in order to protect CMC's Know-How and Confidential Information.

16. FORCE MAJEURE

16.1 Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement or the Services to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the other Party ("**Impeded Party**") including but not limited to fires, earthquakes, floods, embargoes, wars, acts of war (whether war is declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labour disturbances, other substantial similar acts of nature, omissions or delays in acting by any administrative authority, government agency or other Party (a "**Force Majeure Situation**").

(b) The Impeded Party shall notify the other Party in writing of any Force Majeure Situation which prevents the Impeded Party from complying with an obligation under this Agreement. If a Force Majeure Situation [***], and is adversely affecting the performance of this Agreement, the Party which is not the Impeded Party will have the right, on written notice to the other Party, to immediately terminate this Agreement. In the case of such termination, Customer will not have a right to reimbursement for any sums paid under this Agreement for which Services have been rendered or any claim for damages solely as a result of the termination of this Agreement or non-performance of the Services due to such Force Majeure Situation. Notwithstanding any other provision under this **Clause 16.2**, in the event this Agreement is terminated under this **Clause 16.2**, (a) CMC shall refund Customer for any and all amounts for which Customer has paid Services that were not rendered, [***] if the Customer's termination due to Force Majeure occurs [***] after notice of the Force Majeure Situation; and (b) Customer shall pay to CMC any sums due under this Agreement in respect of Services performed up to and including the date of termination in accordance with **Clause 14.5.1.1**.

This **Clause 16.2** shall not apply to excuse either Party's payment obligations under this Agreement which have accrued prior to termination.

17. APPLICABLE LAW, JURISDICTION AND DISPUTE RESOLUTION

Applicable Law

17.1 This Agreement shall be interpreted and governed, and all rights and obligations of the Parties shall be determined, in accordance with the laws of [***] (regardless of choice of law provisions). The Parties waive application of the provisions of the 1980 U.N. Convention on Contracts for the International Sale of Goods, as amended.

17.2 Before resorting to litigation, unless emergency relief is required by either Party when either Party shall be free to resort to litigation, the Parties shall use their reasonable efforts to negotiate in good faith and settle amicably any dispute that may arise out of or relate to this Agreement (or its construction, validity or termination) (a "Dispute"). If a Dispute cannot be settled through negotiations by appropriate representatives of each of the Parties, either Party may give to the other a notice in writing (a "Dispute Notice"). [***] shall each refer the Dispute to their respective Chief Executive Officers who shall meet in order to attempt to resolve the dispute. If [***] (i) the Dispute is not settled by agreement in writing between the Parties or (ii) the Parties have failed to discuss the Dispute or use good faith negotiations, the Dispute may be submitted to and finally be settled [***]. Nothing in this MSA shall prohibit (nor force) the Parties to submit to any other dispute resolution forums as they may between themselves subsequently agree to or discuss.

18. MISCELLANEOUS

Fundamental Change

18.1 The occurrence of a Fundamental Change shall not relieve CMC of its responsibility for performance of its obligations under this Agreement. CMC must promptly:

18.1.1 notify Customer as soon as CMC is aware that a Fundamental Change has occurred or is reasonably likely to occur;

18.1.2 upon request, provide to Customer such further information and written assurances, from CMC and its successors that there will be no adverse consequences to the supply of Product to Customer or the performance of CMC obligations under this Agreement resulting from the occurrence of the Fundamental Change. Without prejudice to the generality of this **Clause 18.1.2**, Customer may seek written assurances from CMC and its successors relating to CMC's ongoing corporate and management culture, capacity, capability and financial viability.

18.2 Neither CMC not its successor shall be entitled to terminate this Agreement as a result of a Fundamental Change.

18.3 For the avoidance of doubt, a breach of **Clause 18.1,** shall be deemed to be a material breach of this Agreement.

Binding Agreement

18.4 Each party agrees that this Agreement is legal and valid and the obligations binding upon such party are enforceable by their terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors; and other than as provided for elsewhere in this Agreement in respect of the Timeline, any modification, extension or variation of this Agreement (or any document entered into pursuant to or in connection with this Agreement) shall only be valid if it is in writing and signed by or on

behalf of each Party to this Agreement. No modification or variation of this Agreement shall be valid if made by e-mail.

Amendment

18.5 Unless expressly so agreed, no modification or variation of this Agreement shall constitute or be construed as a general waiver of any provisions of this Agreement, nor shall it affect any rights, obligations or liabilities under this Agreement which have already accrued up to the date of such modification or waiver, and the rights and obligations of the Parties under this Agreement shall remain in full force and effect, except and only to the extent that they are so modified or varied.

Assignment

18.6 This Agreement may not be assigned by either Party without the prior written consent of the other Party except that a Party may otherwise assign its respective rights and transfer its respective duties to any assignee of all or substantially all of its business (or that portion thereof to which this Agreement relates) or in the event of its merger or consolidation or similar transaction.

18.7 An assignment by either Party will not release that Party of any obligation to the other Party under the terms of this Agreement.

Entire Agreement

18.8 This Agreement, and the documents referred to in it, constitutes the entire Agreement and understanding of the Parties and supersedes any previous agreement between the Parties relating to the subject matter of this Agreement. If any term of this Agreement conflicts with any term of the Commercial Quality Agreement, the conflicting term of this Agreement shall prevail.

Waiver and amendment

18.9 In no event will any delay, failure or omission (in whole or in part) in enforcing, exercising or pursuing any right, power, privilege, claim or remedy conferred by or arising under this Agreement or by law, be deemed to be or construed as a waiver of that or any other right, power, privilege, claim or remedy in respect of the circumstances in question, or operate so as to bar the enforcement of that, or any other right, power, privilege, claim or remedy, in any other instance at any time or times subsequently.

Severability

18.10 If any provision of this Agreement shall be found by any court or administrative body of competent jurisdiction to be invalid or unenforceable, such invalidity or unenforceability shall not affect the other provisions of this Agreement which shall remain in full force and effect. The Parties agree, in the circumstances referred to in this clause to attempt to substitute for any invalid or unenforceable provision a valid or enforceable provision which achieves to the greatest extent possible the same effect as would have been

achieved by the invalid or unenforceable provision. The obligations of the Parties under any invalid or unenforceable provision of this Agreement shall be suspended while an attempt at such substitution is made.

Notices

18.11 Any notice or other communication given or made under this Agreement shall be in writing and in English and signed by or on behalf of the Party giving it and shall be served by (a) hand, (b) delivering it or sending it by prepaid recorded or special delivery post or prepaid international recorded airmail, or (c) facsimile or e-mail transmission provided the recipient provides a confirmation of receipt of such facsimile or e-mail transmission, to the address and for the attention of the relevant Party set out in this **Clause 18.11** (or as otherwise notified by that Party hereunder). Any such notice shall be deemed to have been received:

18.11.1 if hand delivered or sent by prepaid recorded or special delivery post or prepaid international recorded airmail, at the time of delivery;

18.11.2 if sent by post (other than by prepaid recorded or special delivery post), [***]; or

18.11.3 if sent by airmail (other than by prepaid international recorded airmail), [***];

Provided that if deemed receipt [***] the notice shall be deemed to have been received [***], and if deemed receipt [***], the notice shall be deemed to have been received [***].

The addresses of the Parties for the purposes of this **Clause 18.11** are: CMC ICOS Biologics, Inc.

22021 20th AVENUE SE, BOTHELL, WA, USA 98021

For the attention of: Legal Department

MacroGenics, Inc.
9704 Medical Center Drive Rockville, MD 20850
For the attention of:

[***]

With a copy to MacroGenics, Inc.

9704 Medical Center Drive Rockville, MD 20850
For the attention of: General Counsel

or such other address as may be notified in writing from time to time by the relevant Party to the other Party. Any such change to the place of service shall take effect [***].

Counterparts

18.12 This Agreement may be executed in any number of counterparts and by the Parties to it on separate counterparts, each of which shall be an original, but all of which together shall constitute one and the same instrument. This Agreement is not effective until each Party has executed at least one counterpart.

No partnership or agency

18.13 Nothing in this Agreement is intended to or shall operate to create a partnership or joint venture of any kind between the Parties or to authorise either Party to act as agent for the other, and no Party shall have authority to act in the name or on behalf of or otherwise to bind the other in any way (including but not limited to the making of any representation or warranty, the assumption of any obligation or liability and the exercise of any right or power). Each Party is entering into this Agreement as principal not agent, and may not enforce any of its rights under or in connection with this Agreement for the benefit of any other person.

THIS AGREEMENT has been executed by or on behalf of the Parties as of the Effective Date.

Signed on behalf of)
CMC ICOS BIOLOGICS, INC.)
By : */s/ Gustavo Mahler*)
)
Name : Gustavo Mahler, Ph.D. Position :)
)
CEO & President)
)
)

Signed on behalf of)
MACROGENICS, INC.)
by: */s/ Scott Koenig*)
)
)
Name : Scott Koenig, MD, Ph.D. Position :)
)
President & CEO)
)
)
)
)

APPENDIX ONE

[***]

APPENDIX TWO

[***]

APPENDIX THREE

[***]

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT BOTH (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED. SUCH EXCLUDED INFORMATION HAS BEEN MARKED WITH "[***]".

COMMERCIAL SUPPLY AGREEMENT

This Commercial Supply Agreement (the "**Agreement**") is entered into as of September 30, 2020 ("**Effective Date**"), by and between Incyte Corporation, with an address of 1801 Augustine Cut-off, Wilmington, DE 19803 ("**Incyte**"), and MacroGenics, Inc., with an address of 9704 Medical Center Drive, Rockville, MD 20850 ("**MacroGenics"**). Incyte and MacroGenics are sometimes referred to herein individually as a "**Party**" and collectively as **"Parties**.**"**

RECITALS

WHEREAS, MacroGenics discovered and was developing the Licensed Compound (defined below), coded by MacroGenics as "**MGA012**", for various human therapeutic uses;

WHEREAS, MacroGenics has granted certain licenses to Incyte, and Incyte has obtained certain licenses from MacroGenics, to develop, manufacture and commercialize the Licensed Compound and products and treatment regimens incorporating the Licensed Compound, pursuant to the Global Collaboration and License Agreement, dated as of October 24, 2017, between the Parties (the "**Collaboration Agreement**");

WHEREAS, the Parties entered into a Development Manufacturing & Clinical Supply Agreement dated August 31, 2018 pursuant to which MacroGenics manufactured and/or supplied to Incyte, and Incyte purchased from MacroGenics, the Licensed Compound Bulk Drug Substance and the Licensed Compound Drug Product (the "**Clinical Supply Agreement**"); and

WHEREAS, pursuant to the Collaboration Agreement, MacroGenics will Manufacture and supply to Incyte and Incyte will purchase from MacroGenics according to the terms of this Agreement, Licensed Compound Drug Substance for use under the Collaboration Agreement by Incyte and Incyte's and its Affiliates, Collaborators and licensee's;

WHEREAS, the Parties now also wish to set forth the terms by which MacroGenics will perform certain ongoing Manufacturing Development activities as set forth in an approved development plan as may be updated from time to time (the "**CMC Development Plan**" as hereafter further defined) and MacroGenics, as further set forth herein, will Manufacture and/or supply to Incyte the Licensed Compound Bulk Drug Substance which Incyte will purchase for Commercialization; and

NOW, THEREFORE, for valuable consideration and the mutual covenants, terms and conditions hereinafter expressed, the sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS

The defined terms are used throughout this Agreement:

"**Annual Global Commercial Supply Forecast**" means the total amount of Licensed Compound Bulk Drug Substance needed to fulfill the annual projected global commercial supply of Licensed Compound Drug Product.

“Applicable Law” means all applicable statutes, ordinances, regulations, directives, rules, or orders of any kind whatsoever of any Governmental Authority applicable to any activity hereunder, including the EU Data

Protection Directive and the regulations issued under the U.S. Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the U.S. Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.) ("FFDCA"), the Prescription Drug Marketing Act of 1987 (21 U.S.C. §§331, 333, 353, 381), the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335(a) et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), the Federal False Claims Act (31 U.S.C. §3729 et seq.), and the Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.), and the Foreign Corrupt Practices Act of 1977 (15 U.S.C. §§ 78dd-1, et seq.), all as amended from time to time, together with any rules, regulations, and guidance documents, and regulatory standards (including GCP, GLP, and GMP) promulgated relating to any of the foregoing, all as amended from time to time.

"**Batch**" means a specific quantity of Licensed Compound Bulk Drug Substance that is intended to be of uniform character and quality, within specific limits, and is produced during the same cycle of Manufacture as defined by the applicable Batch Record.

"**Batch Failure**" means the failure of a Batch to be Delivered because (i) it failed meet its Product Specifications; or (ii) Manufacturing of such Batch was discontinued prior to release testing, or (iii) a deviation from the Manufacturing Process results in rejection of the Batch.

"**Batch Record**" means the final executed batch production and quality control records, prepared in accordance with GMP, for each Batch of Licensed Compound Bulk Drug Substance, as applicable, Manufactured under this Agreement.

"**Certificate of Analysis**" means a document certifying that a Batch meets the applicable Product Specifications, as signed and dated by a duly authorized representative of MacroGenics' quality assurance department.

"**CMC Development Plan**" means for the purposes of this Agreement, the development plan attached to this Agreement as Exhibit D.

"Commercial Quality Agreement" means the written agreement entered into by the Parties on or within [***] after the Effective Date defining pharmaceutical and certain operational responsibilities of the Parties with respect to the quality that is applicable to the Manufacture and Supply of the Licensed Compound Bulk Drug Substance under GMP.

"Deliver(ed) means to deliver (or have delivered) a Batch EXW (as defined in Incoterms 2020), the MacroGenics Manufacturing Facility according to the date provided in written a notification to Incyte of such delivery. "**Delivery**" means delivery of a Batch by in such manner.

"**Force Majeure**" means any event beyond the reasonable control of the affected Party, which may include embargoes; war or acts of war, including terrorism; insurrections, riots, or civil unrest; labor strikes or lockouts; epidemics, fire, floods, earthquakes or other severe acts of nature; widespread unavailability of raw materials or reagents affecting manufacturers generally, actions by a Regulatory Authority affecting the manufacture of Monoclonal Antibodies generally, and the Licensed Compound Bulk Drug Substance specifically, federal, state and local governmental actions and orders that halt, curtail or impede commercial activity and omissions or delays in acting by any Governmental Authority, other than any such Governmental Authority omissions or delays resulting from the negligence or omission by the Party affected by Force Majeure.

"**FTE**" means [***] of work devoted to or in direct support of specified Manufacturing Development, Manufacturing Related Activities or other specified activities under this Agreement, conducted by one or more qualified employees, contractors, consultants or other personnel of a Party or its Affiliates. For clarity, any individual contributing [***] (or equivalent pro-rata portion thereof for the period beginning on the Effective Date and ending on the last day of the first Calendar Year) will be deemed a fraction of an FTE on a pro- rata basis.

"**FTE Cost**" means, with respect to any period and a Party or its Affiliate, the FTE Rate multiplied by the number of FTEs expended by such Party or its Affiliate during such period; provided that a Party will not be charged twice for any FTE Cost if such FTE Cost is already included as a component of the Price for Licensed Compound Bulk Drug Substance under this Agreement.

"**FTE Rate**" means a rate of [***] (pro-rated for the period beginning on [***] and ending on the [***]); provided, however, that such rate will be [***], by the applicable CPI Adjustment. The FTE Rate is "fully burdened" and covers employee salaries, benefits, travel and other such costs.

"**Good Manufacturing Practices**" or "**GMP**" means the then-current good manufacturing practices required by the (i) Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicine Products for human use as more specifically detailed in EUDRALEX Volume IV Part II and its Annexes, (ii) EU Guidelines on principles of Good Distribution Practices of active substances for medicinal Products for human use, (2015/C95/01) and (iii) 21 C.F.R. Parts 210 and 211, as promulgated by the FDA; (iv) the ICH (International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use) guidelines, including without limitation, ICH Q7 "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients" and (iv) comparable Applicable Law related to the manufacture and testing of pharmaceutical materials in such jurisdictions as the Parties may hereinafter agree.

"**Incyte Manufacturing Facility**" means Incyte's GMP Manufacturing plant located at Avenue des Sciences 12, 1400 Yverdon-les-Bains, Switzerland.

"**Latent Defect**" means a non-obvious defect in a Batch not reasonably susceptible to discovery upon receipt of such Batch.

"**Licensed Compound**" or "**MGA012**" means, for purposes of this Agreement and the Commercial Quality Agreement, the specific anti-PD-1 Monoclonal Antibody designated by MacroGenics as "MGA012", as further described in IND # 130952, and designated by Incyte as "retifanlimab".

"**Licensed Compound API**" means the Licensed Compound active pharmaceutical ingredient of a Licensed Product.

"**Licensed Compound Bulk Drug Substance**" means the Licensed Compound API as produced in bulk, in accordance with this Agreement, as well as the Commercial Quality Agreement and the applicable Quality Assurance Measures.

"**Licensed Compound Drug Product**" means the Licensed Compound Bulk Drug Substance in its final finished form.

"**MacroGenics Manufacturing Facility**" means MacroGenics' GMP Manufacturing plant located at 9704 Medical Center Drive, Rockville, Maryland.

"**Manufacture**" means any and all activities and processes related to the manufacturing of Licensed Compound Bulk Drug Substance or Licensed Compound Drug Product for, labeling, packaging, in-process and testing of such Licensed Compound Bulk Drug Substance or Licensed Compound Drug Product, release of the Licensed Compound Bulk Drug Substance or Licensed Compound Drug Product, quality assurance activities related to manufacturing and release of Licensed Compound Bulk Drug Substance or Licensed Compound Drug Product. "**Manufacture**" will exclude Manufacturing Development and Manufacturing Related Activities.

"**Manufacturing Development**" means any of the following with respect to the Licensed Compound Bulk Drug Substance or Licensed Compound Drug Product, as applicable: manufacturing process development

and validation, process improvements, formulation development, associated analytical development and validation and the manufacture and testing of stability and consistency lots (including process development, qualification, and test Batches).

"**Manufacturing Process**" means the manufacturing process for (including any associated Know-How owned or Controlled by MacroGenics or Incyte relating to the then-current process), and necessary or useful for, the Manufacture of the Licensed Compound Bulk Drug Substance and as further Developed under the Collaboration Agreement, the Clinical Supply Agreement and this Agreement.

"Manufacturing Related Activities" means those [***] activities specifically related to [***], including, but not limited to, [***] of which are not otherwise included [***]. "Manufacturing Related Activities" will specifically exclude [***], which is deemed to be a separate and distinct [***] Manufacturing Related Activities.

"**Materials**" means the starting materials or components, raw materials, ingredients and any other materials used in the Manufacture of the Licensed Compound Bulk Drug Substance.

"**Personnel**" means any person or entity employed or engaged by MacroGenics, including without limitation, its employees, contractors, consultants or agents who may perform Manufacturing Related Activities, Manufacturing Development or Manufacturing or otherwise have obligations or rights pursuant to this Agreement.

"[***]" means [***].

"**Product Specifications**" means the written specifications for the Licensed Compound Bulk Drug Substance, as set forth in the Commercial Quality Agreement.

"Price Schedule" means a list that includes [***].

"Project Manager" means the project managers coordinating the activities to perform be performed hereunder and acting as central contact between Incyte and MacroGenics, and who will lead the "**Joint Project Team**."

"**Regulatory Documentation**" means, with respect to any Compound or Product under the Collaboration Agreement, all regulatory filings, applications, notifications, registrations, licenses, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files, Manufacturing records, Regulatory Approvals or other regulatory submissions or supporting documents, including any written correspondence or meeting minutes, made to, made with, or received from an applicable governmental agency or Regulatory Authority relating to such Compound or Product, and all data contained therein.

"[***]" means [***].

"[***]" means [***]**.**

"**Third Party Expenses**" means out-of-pocket expenses incurred by a Party or any of its Affiliates for purchases of items or for services performed by a Third Party on behalf of Incyte or MacroGenics in the course of such Party's performance of this Agreement.

"[***]" means [***].

As used in this Agreement, the following terms will have the meanings ascribed thereto in the respective Sections of this Agreement set forth opposite each such term below. In addition, capitalized terms used but not defined herein will have the meanings set forth in the Collaboration Agreement. In the event of a conflict between a term defined herein and the same term as defined in the Collaboration Agreement, the definition ascribed to such term in this Agreement will control. Capitalized terms not specifically defined in this Agreement or the Collaboration Agreement will have the meaning commonly recognized in the biotechnology industry.

TERM	SECTION
Affiliate	Collaboration Agreement
Agreement	Preamble
Annual Global Commercial Supply Forecast	4.3.b.i (1)
Approved CMO	9.1
Auditee	8.5
Auditor	8.5
Batch Price	7.1
Binding Portion	4.3(e)
Annual Product Review	8.16
Business Day	Collaboration Agreement
Calendar Quarter	Collaboration Agreement
Calendar Year	Collaboration Agreement
CMC	8.9
CMC Development Budget	6.1
CMC Development Plan	Preamble
Collaboration Agreement	Preamble
Collaborator	Collaboration Agreement
Collaborator Combination Studies	Collaboration Agreement
Commercially Reasonable Efforts	Collaboration Agreement
Compound	Collaboration Agreement
Confidential Information	Collaboration Agreement
“Control” or “Controlled”	Collaboration Agreement
Deficiency Notice	5.2
Development	Collaboration Agreement
Discretionary Specification Change	8.3(b)
Effective Date	Preamble
FDA	Collaboration Agreement
Finance Subcommittee	2.3
Funded Collaborator Combination Studies	7.1(a)(i)
GAAP	Collaboration Agreement
“Good Clinical Practices” or “GCP”	Collaboration Agreement
“Good Laboratory Practices” or “GLP”	Collaboration Agreement
Governmental Authority	Collaboration Agreement
Incyte	Preamble
Incyte Combination Studies	Collaboration Agreement
Incyte Facility	9.1
IND	Collaboration Agreement
Information	Collaboration Agreement

TERM	SECTION
Insolvency Event	13.2(b)
JMC	Collaboration Agreement
JPT	2.1
Know-How	Collaboration Agreement
Losses	Collaboration Agreement
MacroGenics	Preamble
MacroGenics Draft Production Schedule Update	4.2(a)
MacroGenics Combination Studies	Collaboration Agreement
Manufacturing Technology Transfer	9.1
Manufacturing Transition Plan	9.1
Monoclonal Antibody	Collaboration Agreement
Monotherapy Studies	Collaboration Agreement
Non-Conforming Licensed Compound	5.2
Notified Law	8.1(c)
Order	Collaboration Agreement
Party, Parties	Preamble
Phase I Study	Collaboration Agreement
Phase II Study	Collaboration Agreement
Phase III Study	Collaboration Agreement
Pipeline Asset	Collaboration Agreement
Pivotal Study	Collaboration Agreement
Prior CDA	Collaboration Agreement
Product	Collaboration Agreement
Production Schedule	3.1(c)
Quality Assurance Measures	8.4(b)
Reconciliation Report	7.1(f)
Regulatory Approval Application	Collaboration Agreement
Regulatory Authority	Collaboration Agreement
Required Specification Change	8.3(a)
Regulatory Submission	8.9
Response Notice	5.3
Rolling Forecast	4.1(a)
Term	13.1
Territory	Collaboration Agreement
Third Party	Collaboration Agreement

2. GOVERNANCE.

2.1 The JMC established by the Parties will oversee, coordinate and facilitate the Manufacture of the Licensed Compound Bulk Substance under this Agreement according to the Collaboration Agreement, including with respect to Section 2.3 of the Collaboration Agreement, except as otherwise specifically set forth in this Agreement.

3. MANUFACTURE AND SUPPLY

3.1 General Principles.

a. Subject to the terms and conditions of this Agreement, during the Term,

i. MacroGenics agrees to use Commercially Reasonable Efforts to Manufacture each Binding Portion; and

ii. Incyte agrees to [***] of each Binding Portion.

b. For clarity, Incyte will be entitled, in its sole discretion, to [***] of Licensed Product for [***]; provided, that, to the extent Incyte releases [***], such Batches will be subject to the terms of the Commercial Quality Agreement. Notwithstanding the preceding, any lots manufactured [***].

c. The Parties acknowledge and agree that Batches of Licensed Compound Bulk Drug Substance supplied hereunder by MacroGenics shall be Manufactured in accordance with the acceptance criteria [***] in this Agreement, which may be updated as mutually agreed to by the JMC ("**Acceptance Criteria**"). The Parties agree that for each Batch Manufactured by MacroGenics for [***] Acceptance Criteria, Incyte will pay [***]. If the [***], Incyte will be [***], including instances in which [***]. The Parties also acknowledge and agree that MacroGenics will have [***] Incyte, its Affiliates or to any of their respective Collaborators and/or licensees [***] the Acceptance Criteria, provided that such Batch [***].

[***].

d. In the event the Manufacturing Process is modified the Parties will mutually agree to updated [***]. Incyte will be solely responsible for, [***], and shall use Commercially Reasonable Efforts to Manufacture [***] of the Licensed Compound Drug Product. including amounts reasonably forecasted by MacroGenics for Commercialization of MacroGenics Combination Regimens.

e. Each Party will use Commercially Reasonable Efforts to perform certain Manufacturing Related Activities as the Parties will mutually agree to in writing as set forth in this Agreement and the Commercial Quality Agreement, as applicable; provided, however, [***] Manufacturing Related Activities [***] to be used in a [***] of such costs and expenses. For the avoidance of doubt, Manufacturing Related Activities will [***].

3.2 MacroGenics Responsibilities. MacroGenics will use Commercially Reasonable Efforts to ensure that the MacroGenics Manufacturing Facility and equipment at the MacroGenics Manufacturing Facility required for the Manufacture of the Licensed Compound Bulk Drug Substance, are maintained in a state of repair and operating efficiency in accordance with the requirements of GMP and Applicable Law. MacroGenics will obtain, at its expense, any facility or other licenses or permits, and any Governmental Authority approvals necessary for the Manufacture and supply of the Licensed Compound Bulk Drug Substance. Unless otherwise agreed by the Parties, MacroGenics will be responsible for procuring all Materials necessary to meet its supply obligations under this Agreement. A delay in delivery by a vendor of Materials to be supplied by MacroGenics will not be considered a delay by MacroGenics. MacroGenics will notify Incyte of any such delay in the delivery of Materials that will result in MacroGenics' inability

to meet its supply obligations hereunder. Notwithstanding the following, [***].

3.3 Incyte Responsibilities. Incyte will provide [***] to MacroGenics in order for MacroGenics to Manufacture Licensed Compound Bulk Drug Substance and Deliver the Batches according [***] set forth in each Binding Portion.

3.4 Subcontracting. MacroGenics may appoint subcontractors to perform its obligations and/or exercise its rights under this Agreement provided that the applicable subcontractor will be required to comply with the applicable terms and conditions of this Agreement. [***] Each Party will be responsible for the compliance of any of its subcontractors with this Agreement. Notwithstanding the foregoing, (i) [***]; and (ii) such appointment will be made in compliance with Section 9.1.

3.5 Operation of Manufacturing Facilities. Subject to MacroGenics' compliance with its obligations under this Agreement, MacroGenics will have the sole discretion in the operation and use of the MacroGenics Manufacturing Facility to fulfill its respective obligations to supply the Licensed Compound Bulk Drug Substance under this Agreement, including with respect to the following:[***]

3.6 Same Manufacturing Facility. MacroGenics will Manufacture all quantities of Licensed Compound Bulk Drug Substance that are required per the terms of this Agreement from the MacroGenics Manufacturing Facility. For clarity, MacroGenics will [***] Licensed Compound Bulk Drug Substance is Manufactured [***].

3.7 Accommodation. From time to time, [***], Incyte may [***] in a Binding Portion. In response to such purchase orders, MacroGenics, [***] Licensed Compound Bulk Drug Substance volumes. If MacroGenics [***] it will use Commercially Reasonable Efforts to do so.

3.8 Shelf Life Requirements. MacroGenics will use reasonable efforts to supply Batches (i) Manufactured [***]; provided, however, that if the shelf life [***] for the Licensed Compound Drug Substance [***], the Parties [***] for Batches when Delivered.

3.9 Manufacturing Related Activities. MacroGenics will perform Manufacturing Related Activities pursuant to Incyte's written requests, or as required by the Product Specifications, GMPs or

b. Applicable Law relating to the regular course of Manufacturing Batches. Manufacturing Related Activities [***].

4. FORECASTING; PRODUCTION SCHEDULE; DELIVERY

4.1 Rolling Drug Substance Forecast.

a. The amounts of Licensed Compound Bulk Drug Substance to be Manufactured by MacroGenics [***] to supply Incyte under this Agreement will be set forth in a [***] rolling forecast ("**Rolling Drug Substance Forecast**"). [***] Calendar Years of each Rolling Drug Substance Forecast are designated (i) [***] as a "**Forecast Year**" individually and "**Forecast Years**" collectively.

i. Each Rolling Drug Substance Forecast shall include the components listed and defined in Table 4.1.a.i.

Table 4.1.a.i		
Component	[***]	[***]

Annual Global Commercial Supply Forecast	[***]	[***]
[***]	[***]	[***]

ii. [***] and the Annual Global Commercial Supply [***];

b. For the [***] and each Calendar Year thereafter, MacroGenics, at its [***], shall [***] Manufacture [***] Annual Global Commercial Supply Forecast. In instances where [***], the number of Batches for [***].

4.2 Initial Rolling Drug Substance Forecast. The initial Rolling Drug Substance Forecast ("**Initial Drug Substance Forecast**") is attached to this Agreement as Exhibit B. [***] Drug Substance Rolling Forecast.

4.3 Updated Rolling Drug Substance Forecast [***] Calendar Quarter the Parties will update the current Rolling Drug Substance Forecast to generate a new Rolling Drug Substance Forecast ("**Updated Rolling Drug Substance Forecast"**).

a. Subject to Sections 4.1 and 4.2, upon the expiration of the Calendar Year in which it is created, each Updated Rolling Drug Substance Forecast will [***].

b. Incyte will [***] Updated Rolling Drug Substance Forecast and [***] MacroGenics [***] Incyte will:

i. Identify for each Calendar Year of such Updated Rolling Drug Substance Forecast:

(1) The Annual Global Commercial Supply Forecast; provided that the Annual Global Commercial Supply Forecast for [***] Rolling Drug Substance Forecast respectively.

(2) [***]; and

(3) Batches requested for [***]; provided that, [***] from [***] Rolling Drug Substance Forecast respectively.

ii. For each Batch Manufactured [***], the Calendar Quarter during which [***].

c. MacroGenics will have the following rights in revising each draft of the Updated Rolling Drug Substance Forecast received from Incyte:

i. [***] Calendar Years, provided that the Parties [***] to address [***] by MacroGenics under this Section 4.3(c)(i) for a Forecast Year will [***] Global Supply Forecast [***] Forecast Year [***] Updated Rolling Drug Substance Forecast;;

ii. [***] Calendar Years in which in the event the [***] Annual Global Commercial Supply Forecast; provided that [***] of the Annual Global Commercial Supply Forecast. In instances where the [***], the number of Batches for the [***].

iii. [***] Licensed Compound Bulk Drug Substance and/or Licensed Drug Product as provided under Section 9.1(d).

iv. [***] the Calendar Quarter [***] in Section 4.3(b)(ii) to reflect available Manufacturing slots. The [***] Calendar Quarter shall be [***], unless mutually agreed by the Parties.

d. After reviewing and revising each draft Updated Rolling Drug Substance Forecast received from Incyte, MacroGenics shall forward such Updated Drug Substance Forecast to Incyte. Upon receipt by Incyte, the binding portions of such Updated Rolling Drug Substance Forecast shall become binding on both Parties with respect to the Calendar Years covered by such Updated Drug Substance Forecast ("Binding Portion").

e. In the event that an Updated Rolling Drug Substance Forecast is not timely completed, the Binding Portions of the current Rolling Drug Substance Forecast will remain in effect until the earlier of its expiration or such Updated Rolling Drug Substance Forecast is completed. In addition, at MacroGenics' sole discretion, Year 4 of the Rolling Drug Substance Forecast currently in effect will become binding as Reserved Capacity, with addition of any additional lots as calculated in 4.3(c).

4.4 [***]. During [***] Rolling Drug Substance Forecast [***] Updated Rolling Drug Substance Forecast by the Parties under Section 4.3.e that same Calendar Year, Incyte will be [***] of such Rolling Drug Substance Forecast by [***]; provided that the [***] for [***] such Rolling Drug Substance Forecast cannot be lower than the current binding [***].

4.5 Purchase Orders. For Batches to be supplied per the Binding Portions, Incyte will submit a written purchase order prior [***] Calendar Month ("**Purchase Order Month**") [***] in which such Batches will be Delivered. [***] Purchase Order Month, MacroGenics will forward the Delivery dates [***]. Within [***] after [***], Incyte will [***] that [***] that is [***] of the Delivery [***]. Upon receipt of such notification, the date identified by such notification will be binding upon both Parties.

a. If Incyte fails to submit the purchase order for a single Batch or multiple Batches [***], MacroGenics will have the sole discretion to determine the Delivery date for such Batch(es).

4.6 Purchase by Affiliates. Incyte's Affiliate, [***] may submit Purchase Orders Purchase Order for Manufacture of a Batch. Upon the mutual written agreement of the Parties, other Affiliates of Incyte may also submit Purchase Orders for a Batch. For Purchase Orders submitted by Affiliates of Incyte:

a. Each Affiliate submitting a Purchase Order shall be identified in writing to MacroGenics prior to or at the time such Purchase Order is submitted;

b. Incyte shall be responsible and liable for paying all amounts due to MacroGenics resulting from Purchase Orders submitted by Affiliates of Incyte and none of its Affiliates will have responsibility or liability to MacroGenics for such payments;

c. Any [***] that result from any Purchase Orders submitted by Affiliates of Incyte [***] shall be deemed under [***] of the Collaboration Agreement to be [***] of the [***] that would have been payable had Incyte submitted such Purchase Orders so that Incyte will pay MacroGenics such additional amounts as necessary to ensure MacroGenics receives the amounts it would have received if [***]; and

d. All other terms and conditions of this Agreement shall continue to apply to the Parties.

4.7 Batch Cancellations or Delays in Receipt of Batches. If Incyte wishes to cancel or delay Manufacture of one or more Batches set out in a Binding Portion, Incyte will promptly notify MacroGenics in writing. Notwithstanding anything to the contrary set forth herein, Incyte will be liable for and [***] of the Batch Price of such cancelled or delayed Batch(es) and any non-cancelable Material charges. Notwithstanding the above, MacroGenics will use Commercially Reasonable Efforts to mitigate any costs associated with the cancellation or delay of Manufacture of any Batch (whether in whole or in part) by Incyte. To the extent MacroGenics is able to reallocate such capacity to manufacture of other products, Incyte will have [***] with respect to cancellation compensation. For clarity, Incyte will remain liable for the performance of the Manufacturing Related Activities [***] by MacroGenics.

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4.8 Delivery. MacroGenics will Deliver each Batch in accordance with the Delivery date specified for such Batch in the applicable purchase order. Incyte will bear the risk of loss or damage to each Batch upon its Delivery. Incyte will arrange to have Batches promptly shipped from the MacroGenics Manufacturing Facility upon their Delivery. If Incyte fails to take Delivery of a Batch within [***] after its Delivery, unless otherwise agreed in writing MacroGenics, may charge a storage fee as outlined in the Price Schedule

5. ACCEPTANCE; NON-CONFORMING LICENSED COMPOUND

5.1 Product Warranty. MacroGenics hereby warrants that, at the time and place of Delivery pursuant to Section 4.7, that each Batch, will be transferred to Incyte free and clear of any security interests, liens or encumbrances.

5.2 Inspection and Acceptance. [***] after Delivery of each Batch, Incyte will, in its sole discretion, (a) conduct a visual inspection of such Batch for [***]; and (b) conduct an inspection of [***] pursuant to the terms of the Commercial Quality Agreement (as applicable). Incyte may reject the Batch in the event that it fails to meet the applicable Product Specifications ("**Non-Conforming Licensed Compound**") by providing written notice to MacroGenics (a "**Deficiency Notice**"). Any Deficiency Notice will state in reasonable detail (reasonably sufficient to enable MacroGenics to identify the nature of the problem or to dispute the same) the nature of such alleged defect. If Incyte does not reject such Batch by providing a Deficiency Notice to MacroGenics within [***] of Incyte's receipt of all documentation per the terms of the Commercial Quality Agreement, Incyte will be deemed to have accepted such Batch. For the avoidance of doubt, Incyte's Quality Assurance group will release [***] of the commercial supplies of Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product; provided that for any Batches, Incyte's Quality Assurance group will complete such release [***] of receipt of all documents required pursuant to the terms set out in the Commercial Quality Agreement.

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5.3 Replacement. Upon receipt of a Deficiency Notice, MacroGenics will have [***] to advise Incyte in writing whether it disagrees in good faith with the contents of such Deficiency Notice (the "**Response Notice**"). If MacroGenics does not respond [***], the Deficiency Notice will be deemed accepted by MacroGenics. If the Parties [***] after Incyte's receipt of a Response Notice from MacroGenics whether the Batch at issue is Non-Conforming Licensed Compound, then the Parties will promptly select a mutually acceptable, independent laboratory to evaluate whether the Batch is Non-Conforming Licensed Compound. If the independent laboratory determines that the Batch is Non-Conforming Licensed Compound, and the non-conformance is due solely to MacroGenics' gross negligence or willful misconduct in the Manufacture of such Batch, MacroGenics will replace, at no additional expense to Incyte, such Non-Conforming Licensed Compound Bulk with a Batch that meets the Product Specifications. If the independent laboratory determines that the Batch is not Non- Conforming Licensed Compound, then Incyte will be deemed to have accepted Delivery of such Batch.

5.4 Batch Failure. Notwithstanding Section 5.3, the allocation of liability for Batch Failures is as follows:

a. In the case of any Batch Failure resulting from MacroGenics' gross negligence or willful misconduct, MacroGenics will be [***].

b. In the case of Batch Failures that occur when MacroGenics [***], Incyte will be [***]. For avoidance of doubt, this includes a [***] resulting from [***].

c. In the case of all other Batch Failures, the liability will be allocated as follows:

i. If [***], Incyte will be liable for the [***] and MacroGenics will be responsible [***]. Thereafter, if there are any [***], the Parties will escalate such issue in accordance with Section 14.10.

ii. [***] Batches are Manufactured per year, Incyte [***] and MacroGenics [***]. Thereafter, if there are any [***], the Parties will escalate such issue in accordance with Section 14.10.

iii. If [***] Batches are Manufactured [***], Incyte [***] and MacroGenics [***]. Thereafter, if there are any [***], the Parties will escalate such issue in accordance with Section 14.10.

5.5 During each [***], the Parties will reconcile the costs associated with Batch Failures that occurred during the prior Calendar Year in accordance with Section 5.4. For clarity, the allocation of liability for Batch Failures set forth herein will exclude (i) in the case of Incyte, any Batch Failures resulting from MacroGenics' gross negligence or willful misconduct; and (ii) in the case of MacroGenics, any Batch Failures that occur when MacroGenics adheres to the Manufacturing Process and/or or Incyte's instructions.

5.6 **Sole Remedy**. Notwithstanding anything to the contrary set forth in this Agreement or the Collaboration Agreement, the remedies set forth in Sections 5.3 and 5.4 will be the exclusive remedies of Incyte, its Affiliates and their respective Collaborators and licensees and will constitute fulfillment of all obligations by MacroGenics to Incyte, its Affiliates and their respective Collaborators and licensees (including any liability for direct, indirect, special, incidental or consequential damages or lost profits), whether in warranty, contract, negligence, tort, strict liability, or otherwise with respect to any nonconformities, defect or deficiency of the Batches.

6. MANUFACTURING DEVELOPMENT ACTIVITIES

6.1 **Governance.** The Parties hereby agree to maintain the Joint Project Team ("**JPT**") established under the Clinical Supply Agreement, consisting of technical representatives from each Party, with its primary purpose being to plan, execute and discuss issues regarding the CMC Development Plan. Any disputes or issues that cannot be readily resolved by the JPT will be referred to the JMC for resolution. Any decision by the JPT which has the effect of amending the CMC Development Plan must be reviewed and approved by the JMC. Each Party will appoint an individual as a Project Manager who will be responsible for leading and coordinating the activities of the JPT and the CMC Development Plan.

6.2 **CMC Development Plan**. All new Manufacturing Development activities to be conducted by MacroGenics under this Agreement will be set forth in the CMC Development Plan which includes an estimated budget for the costs to be incurred by MacroGenics in performing such Manufacturing Development work (the "**CMC Development Budget**"), including any Third Party Expenses. Updates to the CMC Development Plan will be mutually approved by the JMC prior to initiation of any activities not already mutually approved by the JMC. MacroGenics will use Commercially Reasonable Efforts to perform the Manufacturing Development activities set forth in the CMC Development Plan. MacroGenics may not exceed the CMC Development Budget [***] without the Parties agreeing to an amendment to the CMC Development Plan in accordance with Section 6.3 below. MacroGenics will not be obligated to perform any Manufacturing Development activities if the Parties cannot agree to an increase in the CMC Development Budget. In addition, MacroGenics will not be obligated to perform any Manufacturing Development activities that are not specifically set forth in the CMC Development Plan

6.3 For purposes of clarification, the CMC Development Plan undertaken by the Parties under the Clinical Supply Agreement shall continue to be conducted under and governed by the Clinical Supply Agreement.

6.4 **Amendments to CMC Development Plan**. If a Party anticipates or becomes aware of any needed material change needed in the scope or timing of a Manufacturing Development

activity in order to accomplish its purpose, such Party will promptly notify the other Party in writing. The JMC will then mutually agree whether the CMC Development Plan is to be modified. If the Parties agree with an identified change in the scope or timing of the CMC Development Plan, the Parties through the JMC will execute a written amendment to the CMC Development Plan showing or indicating the needed changes in the Manufacturing Development activities, their timelines and the CMC Development Budget. If the JMC declines to amend the CMC Development Plan, including, as applicable, the CMC Development Budget, MacroGenics will not be obligated to perform, and Incyte will not be obligated to pay for, any activities that would have been affected by the amendment until such an amendment has been executed by the Parties. Any amendments to the CMC Development Plan, including to the CMC Development Budget, must be approved by the JMC in writing. Both Parties will act in good faith and respond promptly when considering an amendment requested by the other Party.

6.5 Incyte Responsibilities. As set forth in the CMC Development Plan, Incyte will be responsible for (i) providing information or materials to MacroGenics; and (ii) reviewing and approving any deliverables, documents or other items as promptly as practicable, but [***] applicable item to be reviewed or the request for approval unless otherwise specified by the CMC Development Plan.

6.6 Delays; Cancellation of Work. MacroGenics will not be responsible for any delays caused by failure of Incyte to meet its obligations set forth in Section 6.4, including delays caused by Incyte's failure to respond to any requests for approvals within the time frame set forth in Section 6.4. Incyte may not cancel any Manufacturing Development activities without the Parties mutually agreeing in writing to an amendment to the CMC Development Plan to cancel or terminate such activities. Upon the Parties' mutual written agreement to an amendment to cancel or terminate any Manufacturing Development activities, any materials, FTE Costs to the extent such FTEs are unable to be reallocated [***], Third Party Expenses and other items that cannot reasonably be cancelled or used by MacroGenics for other purposes will be invoiced to and paid for by Incyte.

6.7 No Guarantees. The Parties hereby agree that MacroGenics does not provide any guarantees of success with regard to any of the Manufacturing Development activities or deliverables relating thereto, including that the Manufacturing Development activities can be completed as contemplated in the CMC Development Plan after MacroGenics has used Commercially Reasonable Efforts to do so.

6.8 Incyte will use Commercially Reasonable Efforts to plan for making Drug Product presentations required for MacroGenics Combination Regimens (including, but not limited to [***]) commercially available in a timeline consistent with MacroGenics' anticipated regulatory filings. Such plans shall include, but not be limited to, the following Manufacturing Development activities: [***].

7. PRICE; PAYMENT; TAXES

7.1 Batch Manufacture. For purchase of each Batch, Incyte will pay a price ("**Batch Price**") consisting of [***]. [***] are included in the Price Schedule. The [***] include all corresponding invoices [***] Drug Substance [***]. The [***] includes all charges associated with labor, repairs and maintenance, rent, utilities, depreciation and [***]. The [***] will be invoiced as [***] as set forth in Section in 7.2.a. For sake of clarity, MacroGenics [***]. Both the costs for [***] during Manufacture will be [***]. The Parties will subsequently [***] paid by Incyte with the [***] by MacroGenics for such items. Other than for [***], invoiced costs for [***] will not include [***]. The cost of [***] Manufacture Batches and costs [***] will not be included in [***] and will be invoiced separately.

a. Batch Price Adjustments

i. [***]:

(1) Each Calendar Year [***] after the [***] for the prior Calendar Year; and

(2) to reflect changes in the costs to Manufacture Licensed Compound Bulk Drug Substance resulting from Notified Laws, Required Specification Changes and Discretionary Specification Changes or Process Changes due to other reasons or causes.

ii. [***]:

(1) [***] of each Calendar Year, MacroGenics will send Incyte a written report setting forth (i) [***]

(2) [***].

iii. [***]

(1) The [***] for a Batch that will be used to Manufacture License Compound Drug Product to supply

[***].

b. **[***]**. [***] will be invoiced upon receipt and separately from the Batch Price and will include [***] reimbursement fee to cover costs associated with [***].

c. **Regulatory Activities**. Incyte will pay for activities performed herein at the FTE Rate, plus any Third Party Expenses incurred by MacroGenics to perform regulatory activities and/or address regulatory matters specifically related to each Batch ("**Regulatory Activity Costs**"). The costs of Manufacturing Related Activities and Manufacturing Development Costs are excluded from Regulatory Activity Costs.

d. **Batch Shipping**. The cost of [***]. Should MacroGenics [***] (at MacroGenics' discretion if requested by Incyte), costs incurred by MacroGenics [***]. Costs incurred by MacroGenics for [***].

e. **Manufacturing Development.** Incyte will pay for Manufacturing Development activities performed herein at the FTE Rate, plus any Third Party Expenses incurred by MacroGenics in the performance of such Manufacturing Development activities ("**Manufacturing Development Costs**"). For clarity, the Manufacturing Development costs will include, but will not be limited to, process optimization, analytical characterization and technical transfer support and will exclude costs incurred to Manufacture Batches.

f. **Manufacturing Related Activities**. Incyte will pay for Manufacturing Related Activities performed herein at the FTE rate, plus any Third Party Expenses incurred by MacroGenics in the performance of such Manufacturing Development activities, except as follows:

i. The costs for MacroGenics to conduct the following Manufacturing Related Activities are included [***]:

(1) retrieval, storage and analysis of data and maintenance of such data for mutually agreed upon periods in a database containing applicable information;

(2) reporting to [***], or his/her designee, in accordance with the terms of the Commercial Quality Agreement, any significant atypical results, deviations or adverse trends exhibited during testing;

(3) Annual Product Review that conforms to MacroGenics standard protocol. At Incyte's option and cost, Annual Product Reviews can be performed beyond the scope of MacroGenics' standard protocol at the FTE Rate plus any Third Party Expenses.);

(4) continued process verification that conforms to MacroGenics' standard protocol. At Incyte's option and cost, continued process verification can be performed beyond the scope of MacroGenics' standard protocol at the FTE Rate plus any Third Party Expenses.

ii. Stability pulls will be invoiced [***] included in the Price Schedule.

7.2 Invoicing by MacroGenics

a. Payment for the Batch Price shall be invoiced according to the following schedule:

i. During the [***], the [***] during Manufacture will be invoiced;

ii. [***] will be invoiced [***] to Delivery;

iii. [***] will be invoiced [***] to Delivery;

iv. [***] will be invoiced [***]; and

v. [***] be invoiced [***].

b. Manufacturing Development, Manufacturing Related Activities, [***].

i. [***], MacroGenics will submit an invoice that includes the following costs incurred by MacroGenics during the prior Calendar Quarter:

(1) The total costs (including Third Party Expenses and FTE Costs) incurred by MacroGenics to conduct Manufacturing Development, Manufacturing Related Activities and [***];

(2) [***] to cover costs associated with [***] for purchased [***].

7.3 Payment.

a. All invoices issued by a Party to the other Party will be sent by electronic means and be sent in accordance with any written instructions provided the other Party.

b. Payment of all undisputed amounts due will be due [***] from a Party's receipt of an invoice consistent with the requirements of subsection (a) above. Each Party will [***] of any disputed invoice, setting out in full the reasons such invoice is disputed.

c. All payments due to a Party hereunder will be made in U.S. Dollars by wire transfer of immediately available funds into an account designated by such Party. If a Party does not receive payment of any sum due to it on or before the due date, such Party will notify the other Party, and such other Party will have [***] following receipt of such notice to pay any undisputed amount. Thereafter, interest will accrue on the undisputed sum due to the Party seeking payment until the date of payment [***].

7.4 Financial Audit. Incyte shall have the right to conduct financial audits of MacroGenics' records to confirm the accuracy of invoices submitted to Incyte for payment of amounts under this Agreement other than those for [***]. The conduct of any such audits by Incyte shall be governed by Section 8.12 of the Collaboration Agreement. Incyte shall not have the right to conduct audits of MacroGenics records to confirm the accuracy of or otherwise assess invoices submitted to Incyte for payment of amounts under this Agreement for [***].

7.5 Taxes. Subject to Section 4.6(c), Section 8.11 of the Collaboration Agreement will govern all tax matters under this Agreement.

8. QUALITY CONTROL; REGULATORY; COMPLIANCE

8.1 General.

a. MacroGenics will Manufacture the Batches in accordance with (a) the Product Specifications; (b) the GMPs; (c) Applicable Laws in the United States; and (d) subject to Section 8.1(c), any Notified Law.

b. In the event that Incyte requests MacroGenics to comply with an Applicable Law in the Territory that is not required in the United States, Europe or such other country(-ies) mutually agreed upon by the Parties as subject to GMP as defined herein, Incyte will identify such Applicable Law to MacroGenics (a "**Notified Law**"), together with all available information regarding such Notified Law, so that MacroGenics may understand the nature, scope and requirements of such Notified Law. Incyte and MacroGenics will discuss and work together as to how MacroGenics may come into compliance with such Notified Law using Commercially Reasonable Efforts. All costs and expenses necessary to comply with a Notified Law will be paid by Incyte.

c. If the Parties fail to agree [***] after Incyte's request to comply with a Notified Law as to how MacroGenics may come into compliance with such Notified Law, then MacroGenics will have the final decision-making authority with respect to the resolution of such disagreement, including the ability to decline implementing such compliance with Notified Law.

8.2 Testing of Batches. Prior to release of a Batch to Incyte, MacroGenics or its permitted subcontractor will test such Batch in accordance with the procedures described in the Product Specifications, and will provide Incyte with the applicable executed master batch record and a copy of applicable deviation or other investigatory report, if any, on or before the Delivery date.

8.3 Certificates. MacroGenics will provide Incyte with a Certificate of Analysis and Certificate of Compliance for each Batch released for Delivery to Incyte hereunder. Such certificates will include the information as specified in the Commercial Quality Agreement. Incyte will be under no obligation to accept any Batch without the accompanying certificate.

8.4 Latent Defects. Incyte will have the right to reject a Batch if [***], it discovers a Latent Defect in such Batch which, through the process of root cause analysis, has been determined to have arisen as a direct result of MacroGenics' failure to Manufacture such Batch in accordance with the Product Specifications and Incyte provides notice to MacroGenics of such Latent Defect [***].

8.5 Product Specification Changes.

a. **Required Specification Changes**. If a Governmental Authority in the Territory requires a change to the Product Specifications (a "**Required Specification Change**"), Incyte will promptly notify MacroGenics of such change. MacroGenics will use reasonable efforts to implement such Required Specification Change as promptly as possible within the time frame requested by the Governmental Authority at Incyte's sole cost and expense.

b. **Discretionary Specification Change**. Each Party will be entitled to request a change to the Product Specifications that is not a Required Specification Change (a "**Discretionary Specification Change**"). The requesting Party will submit a written request to the other Party for any such Discretionary Specification Change. If the Parties agree to make such Discretionary Specification Change, MacroGenics will then determine (a) one-time and/or ongoing costs that would be incurred resulting from such Discretionary Specification Change, (b) any resulting planned changes in timing for the Delivery of the Licensed Compound Bulk Drug Substance and (c) the estimated time of implementing such Discretionary Specification Change. MacroGenics will provide such information to Incyte and set forth the costs and other terms on which MacroGenics would be willing to make the Discretionary Specification Change. Upon written approval by Incyte to such terms, the Parties will cooperate in good faith in implementing such Discretionary Specification Change. All costs and expenses incurred by MacroGenics to implement any such Discretionary Specification Change will be at the sole cost and expense of Incyte, which MacroGenics will invoice as Manufacturing Development activities and to the extent the cost to Manufacture Licensed Compound Bulk Drug Substance changes, reflected in the Batch Price.

8.6 Quality Matters.

a. **Commercial Quality Agreement**. Each Party will perform its obligations under the Commercial Quality Agreement to be negotiated in good faith and entered into by and among the Parties on or [***]. In the event of any conflict between this Agreement and the Commercial Quality Agreement, with respect to any quality-related terms and conditions, the Commercial Quality Agreement will control. In the event of a conflict of any other term or conditions, this Agreement will control, unless otherwise agreed to by the Parties in writing.

b. **Quality Assurance**. MacroGenics will use Commercially Reasonable Efforts to implement and perform operating procedures and controls for sampling, stability and other testing of the Licensed Compound Bulk Drug Substance and for validation, documentation and release of the Batches and such other quality assurance and quality control procedures as are required by the specifications, GMP and the Commercial Quality Agreement (collectively, "**Quality Assurance Measures**"), for Commercial supply purposes. . The Quality Assurance Measures shall also govern the manufacturing process used at the [***] to Manufacture Licensed Compound Bulk Drug Substance Manufactured at the [***].

8.7 Audit by Incyte. Upon the reasonable prior written request of Incyte, Incyte will have the right to inspect and audit the MacroGenics Manufacturing Facility and Third Party facilities where the Batches are Manufactured (provided that for such Third Party facilities, to the extent MacroGenics is contractually permitted to grant Incyte such audit right) as set forth in Commercial Quality Agreement, as applicable, and pursuant to such requests to inspect and audit data, records, reports, information, licenses, permits and other documentation relating to the Manufacturing Processes for the purpose of assuring MacroGenics' compliance with its obligations under this Agreement, including compliance with GMPs, as set forth in the Commercial Quality Agreement, [***], or more frequently for cause (i.e., for cause being defined as any instance or reasonable suspicion of existing or imminent violation of the Applicable Laws in the U.S. as demonstrated by reasonably detailed documentation). To the

extent such audit or inspection requires the disclosure of Confidential Information of MacroGenics that specifically references

products or compounds other than the Licensed Compound or Licensed Product, MacroGenics will have the right to require Incyte to engage a Third Party consultant to conduct such audit or inspection who will be contractually obligated by Incyte not to disclose any Confidential Information of MacroGenics that could reasonably lead to the identification of such product.

8.8 Regulatory Authority Inspections.

a. MacroGenics will be responsible for inspections of the MacroGenics Manufacturing Facility by Regulatory Authorities, and will, as soon as reasonably possible following receipt of notice of inspection from a Regulatory Authority, notify Incyte if such inspections are directly related to the Manufacture of the Licensed Compound Bulk Drug Substance or if the results of a non-related inspection could materially impair the ability of MacroGenics to perform in accordance with this Agreement. With respect to inspections specifically related to the Manufacture of Licensed Compound Bulk Drug Substance, MacroGenics will (a) provide Incyte with copies of all documents, reports or communications received from or given to any Regulatory Authority associated therewith; (b) subject to confidentiality obligations as requested by MacroGenics, permit Incyte's representatives to be present on site and participate, as appropriate, based on questions or requests specific to Incyte or Licensed Compound Bulk Drug Substance and as permitted by Regulatory Authorities, in such inspections; and (c) allow Incyte the opportunity and sufficient time [***] to review and provide comments to MacroGenics with respect to matters related to the manufacture of Licensed Compound Bulk Drug Substance and MacroGenics will draft any such correspondence to Regulatory Authorities taking into account Incyte's reasonable comments.

b. Incyte will notify MacroGenics of any inspection of the [***] by a Regulatory Authority related to the Licensed Product and provide a written summary of the outcome of such inspection which will detail instances in which the Manufacture of the Licensed Compound Bulk Drug Substance was not compliant with Applicable Law and the basis of such non-compliance.

8.9 Cure of Deficiencies. MacroGenics will be responsible, at its own expense, for promptly correcting any deficiencies solely related to the MacroGenics Manufacturing Facility identified in any audit or inspection conducted by any Regulatory Authority under this Agreement. Incyte will be responsible for any expenses incurred by MacroGenics in correcting any Product specific deficiencies identified in any audit or inspection conducted by any Regulatory Authority subject to this Agreement,

8.10 Interactions with Regulatory Authorities. Except (a) for approvals and licenses required with respect to the MacroGenics Manufacturing Facility, which will be the responsibility of MacroGenics, or (b) as otherwise provided in the Collaboration Agreement, Incyte will be responsible for the preparation and filing of any Regulatory Documentation, if any, and for all contacts and communications with any Regulatory Authorities with respect to matters specifically relating to the Manufacture of Licensed Product; provided that as set forth in the Collaboration Agreement MacroGenics will continue to be responsible for submissions and interactions with Regulatory Authorities with respect to matters specifically relating to MacroGenics Pipeline Assets. MacroGenics will assist Incyte upon request with any interactions with Regulatory Authorities regarding the Manufacturing Related Activities or Manufacture of the Licensed Compound Bulk Drug Substance. Notwithstanding the foregoing, Incyte will identify, reference and include MacroGenics' subcontractors in Exhibit A in the Regulatory Documentation. MacroGenics will notify Incyte [***] MacroGenics receives any contact or communication from any Regulatory Authority related in any way to the Manufacturing Related Activities or Manufacture of the Licensed Compound Bulk Drug Substance, or which could be reasonably expected to have a materially adverse effect on the Manufacturing Related Activities or Licensed Compound Bulk Drug Substance. MacroGenics

will provide Incyte with copies of any such correspondence or other communication [***] of such communication by MacroGenics. MacroGenics will consult with Incyte regarding

the response to any inquiry or observation from any Regulatory Authority relating to the Manufacturing Related Activities or Manufacture of the Licensed Compound Bulk Drug Substance and, except with respect to matters related to the MacroGenics Manufacturing Facility, will allow Incyte, as appropriate, to participate in any further contacts or communications relating to the Manufacturing Related Activities or Manufacture of the Licensed Compound Bulk Drug Substance. MacroGenics will comply with all reasonable requests and comments by Incyte with respect to all contacts and communications with any Regulatory Authority relating in any way to the Manufacturing Related Activities or Manufacture of the Licensed Compound Bulk Drug Substance. MacroGenics will assist Incyte with drafts of any correspondence or other reports to be submitted to Regulatory Authorities concerning the Manufacturing Related Activities or Manufacture of the Licensed Compound Bulk Drug Substance, for review prior to submission, will consider in good faith Incyte's comments, and will provide final copies to Incyte promptly after submission.

8.11 Regulatory Submission. [***] for Licensed Compound Bulk Drug Substance, which is, or is the equivalent to, the Chemistry, Manufacturing Controls ("**CMC**") portion of an application ("**Regulatory Submission**") that incorporates data generated by MacroGenics, Incyte will provide MacroGenics a copy of the Regulatory Submission to permit MacroGenics to verify its accuracy as it relates to MacroGenics-generated data and that it accurately describes the work that MacroGenics performed under this Agreement. A final copy of the Regulatory Submission will be provided by Incyte to MacroGenics upon submission to the Regulatory Authority.

8.12 Licensed Compound Records; Audit Rights. Section 7.4 of the Collaboration Agreement will govern each Party's record-keeping obligations and audit rights with regard the Licensed Compound.

8.13 Recalls and Voluntary Withdrawals. Section 5.7(a) of the Collaboration Agreement will govern any recalls or voluntary withdrawals of the Licensed Product.

8.14 Product Returns. Incyte will instruct its distributors and customers to direct any returns of Licensed Products to Incyte in accordance with Incyte's standard return policy. MacroGenics will promptly notify Incyte in writing (including all information MacroGenics has relating thereto) if any distributor, customer or other Third Party returns any Licensed Product to MacroGenics. MacroGenics will, at Incyte's expense, promptly forward all such Licensed Product to the location specified by Incyte, and shall take no other action regarding such Licensed Product, unless requested, in writing, by Incyte or required by Applicable Law. After a commercially reasonable period of time safeguarding the Licensed Product so held, MacroGenics may destroy the Licensed Product if it has given written notice of its intention to Incyte and Incyte has not directed otherwise [***].

8.15 Retained Samples. MacroGenics will retain samples from each Batch [***] from the date of Delivery to Incyte, or for such longer period required by Applicable Law for recordkeeping, testing and regulatory purposes or specified in the Commercial Quality Agreement for the Licensed Compound Bulk Drug Substance. Prior to the destruction of any samples no longer required to be retained, MacroGenics will obtain written approval from Incyte.

8.16 Annual Product Review. [***] with respect to the Licensed Compound Bulk Drug Substance during the Term [***] thereafter or so long as MacroGenics Manufactures Licensed Compound Bulk Drug Substance for Incyte, whichever is later, MacroGenics will prepare, and provide to Incyte, an annual review for the Products as required by GMPs and Applicable Laws (each, an " **Annual Product Review**"), as more particularly set forth in the Commercial Quality Agreement.

9. MANUFACTURING TECHNOLOGY TRANSFER

9.1 Manufacturing Technology Transfer. Incyte may request, [***] to MacroGenics that MacroGenics transfer or have transferred the then-current Manufacturing Process to the [***] (the "**Manufacturing Technology Transfer**"). MacroGenics shall not unreasonably withhold its agreement to such request.

a. The Manufacturing Technology Transfer will be sufficient to enable Incyte or such designee to perform the Manufacturing Process and Manufacture of Licensed Compound Bulk Drug Substance, as applicable, in accordance with Applicable Law, as more fully described in this Article 9 and will be subject to a written plan approved by the JMC with respect to such Manufacturing Technology Transfer (the "**Manufacturing Transition Plan**"), with Incyte having final decision-making authority on the Manufacturing Technology Transfer (provided that Incyte may not expand the scope of the Know-How and Information to be transferred pursuant to Section 9.1.b. beyond that which is required hereunder or under the Collaboration Agreement). MacroGenics will have no obligation to perform any activity that is not within the scope of the Manufacturing Transition Plan including with respect to its type, volume, timing and/or completion date that has not been agreed to in writing by MacroGenics. The Parties will use Commercially Reasonable Efforts to effect a Manufacturing Technology Transfer to Incyte pursuant to this Section 9.1. The implementation of the Manufacturing Technology Transfer and Manufacturing Transition Plan will be subject to [***] being in an operational state that is suitable for the Manufacture of the Licensed Compound Bulk Drug Substance.

b. MacroGenics will provide all reasonable assistance requested by Incyte to enable Incyte to implement the Manufacturing Technology Transfer, including by transferring to Incyte all Know-How and Information necessary for such Manufacturing Technology Transfer. In connection with a Manufacturing Technology Transfer, MacroGenics will cause its appropriate employees and representatives of MacroGenics to meet with employees and/or representatives of Incyte at reasonable times to assist with the implementation and use of such Manufacturing Process and with the training of the personnel of the [***] to the extent reasonably necessary or useful for the use and practice of such Manufacturing Process. Incyte will reimburse MacroGenics' FTE Costs and reimburse all reasonable travel and Third Party Expenses incurred by MacroGenics in order to complete the Manufacturing Technology Transfer, [***] from MacroGenics setting forth such costs. Subsequent to the occurrence of the Manufacturing Technology Transfer, at any time during the Term, upon either Party's reasonable request, the other Party will provide to the requesting Party the updated Manufacturing Process (including associated Know-How) Controlled by such other Party necessary or useful for the Manufacture of the Licensed Compound Bulk Drug Substance at Incyte's sole cost and expense.

c. The Manufacturing Technology Transfer will be conducted once. MacroGenics will have no obligation to undertake or assist with any other transfer of the Manufacturing Process whether to the [***].

d. In the event the Clinical Supply Agreement expires or is terminated before this Agreement, MacroGenics shall have the right to include in the Updated Rolling Drug Substance Forecast amounts of [***] to be used for its Development purposes in each case.

i. The Manufacture of, conduct of Related Manufacturing Activities for and purchase of such amounts of Licensed Compound Bulk Drug Substance shall be governed by the provisions of this Agreement *mutatis mutandis*.

ii. The Manufacture of, conduct of Related Manufacturing Activities for and purchase of such amounts of Licensed Compound Bulk Drug Product shall be governed by the provisions of the Clinical Supply Agreement *mutatis mutandis*.

9.2 Modifications to the Manufacturing Process. Any time after the completion of the Manufacturing Technology Transfer during the Term, to the extent that either Party wishes to make any material modifications, improvements or other alterations to the Manufacturing Process ("**Process Change(s)**"), the Parties shall meet to discuss and agree upon implementation of the same. All costs associated with Process Changes will be at Incyte's sole cost. Subject to the aforementioned, the Party implementing a Process Change will use Commercially Reasonable Efforts at Incyte's sole cost and expense to provide access to such Process Change to the other Party, and to reasonably cooperate with the other Party in its efforts to ensure (including through the implementation of subsequent modifications to such Process Change, to the extent required) that the Incyte Manufacturing Facility and the MacroGenics Manufacturing Facilities (as applicable) Manufacture the Licensed Compound Bulk Drug Substance using such Process Change and yield comparable License Compound Bulk Drug Substance as a result. Incyte will be responsible for obtaining any required regulatory approvals resulting from implementation of such modifications.

9.3 Assignability. Incyte will require that all agreements executed between Incyte and any Third Party with respect to such Third Party's performance under this Agreement will permit the assignment of such agreement, in its entirety in the event of termination of the Collaboration Agreement (other than by Incyte pursuant to Section 12.3 or 12.6 of the Collaboration Agreement), to MacroGenics, without any consent rights by such Third Party (subject to MacroGenics agreeing to such assignment and the assumption of relevant obligations under such agreement).

10. CONFIDENTIAL INFORMATION; INTELLECTUAL PROPERTY MATTERS

10.1 Confidentiality. Article 11 of the Collaboration Agreement will govern the confidentiality obligations and use restrictions of the Parties with respect to Confidential Information disclosed under this Agreement and the Commercial Quality Agreement.

10.2 Intellectual Property Matters. Article 9 of the Collaboration Agreement will govern all intellectual property matters arising under this Agreement.

11. REPRESENTATIONS, WARRANTIES AND DISCLAIMERS

11.1 Corporate Action. Each Party represents to the other Party that (a) it is a corporation duly organized and validly existing under the laws of its jurisdiction of organization; (b) the execution and delivery of this Agreement has been authorized by all requisite corporate action; and (c) this Agreement is and will remain a valid and binding obligation of such Party, enforceable in accordance with its terms.

11.2 Absence of Other Contractual Restrictions. Each Party represents and warrants that it is under no contractual or other obligation or restriction that is inconsistent with its execution or performance of this Agreement or the rights granted to such Party under this Agreement. Neither Party will enter into any agreement, either written or oral, that would conflict with its obligations under this Agreement.

11.3 Qualifications of Manufacturer Personnel. MacroGenics represents and covenants that all Personnel will have the proper skill, training and experience to Manufacture and supply the

Licensed Compound Drug Bulk Substance, perform the Manufacturing Related Activities and conduct the Manufacturing Development activities.

11.4 No Debarment. Each Party represents and covenants that it has not been debarred, and has not been threatened with debarment, under Section 306(a) or (b) of the U.S. Generic Drug Enforcement Act of 1992, as amended, or under any comparable law of any other jurisdiction in the Territory, and that it will not knowingly use in any capacity under this Agreement any debarred person or entity.

11.5 Compliance. MacroGenics represents and warrants that the Manufacture, generation, processing, packaging, distribution, transport, treatment, storage, disposal and other handling of any Batches and Materials used to Manufacture or for their Manufacture, until Delivery of such Batches to Incyte will: (i) be in accordance with and conform to GMPs; (ii) be in accordance with and conform to any applicable standards specified by the United States Pharmacopeia and Pharmacopeia Forum and the European Pharmacopeia and Pharmacopeial Forum (and their equivalent standards, Applicable Laws in other jurisdictions, where applicable), and (iii) otherwise conform to any provisions of such Applicable Laws not reflected in GMPs; provided that the Manufacturing Process is in accordance and otherwise conforms with (i) through (iii) of this Section 11.5.

11.6 Maintenance of Manufacturing Facility. During the Term, MacroGenics will maintain the MacroGenics Manufacturing Facility in good condition and in accordance with GMP and all other Applicable Laws.

11.7 Security Measures. Except as otherwise provided herein with respect to data or Incyte Confidential Information, MacroGenics will maintain reasonable security policies at the MacroGenics Manufacturing Facility to protect the integrity of the Materials, Products and all other Incyte assets, tangible and intangible.

11.8 Origin of Materials. To the extent it relies upon materials of foreign origin in its performance of the services or supply of the goods or materials hereunder, MacroGenics has accurately identified, to the best of its knowledge, the ultimate source of such services, goods or materials, including, but not limited to, information relating to its downstream MacroGenics' subcontractors.

11.9 Exclusion of Other Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, MACROGENICS DOES NOT MAKE ANY WARRANTY IN RESPECT OF THE MANUFACTURE AND SUPPLY OF THE LICENSED COMPOUND DRUG BULK SUBSTANCE OR THE PERFORMANCE OF THE MANUFACTURING RELATED ACTIVITIES OR THE MANUFACTURING DEVELOPMENT OR REGULATORY ACTIVITIES CONDUCTED BY MACROGENICS HEREIN, WHETHER EXPRESS OR IMPLIED BY STATUTE, CUSTOM OF THE TRADE OR OTHERWISE, THEIR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE UNDER ANY CONDITIONS, AND ANY SUCH WARRANTIES ARE HEREBY EXPRESSLY EXCLUDED.

12. INDEMNIFICATION AND LIMITATION OF LIABILITY

12.1 Indemnification and Indemnification Procedures. Sections 14.1, 14.2 and 14.3 of the Collaboration Agreement will govern all indemnification matters and indemnification procedures arising from this Agreement.

12.2 LIMITATION OF LIABILITY

a. EXCEPT TO THE EXTENT INCLUDED IN LOSSES RESULTING FROM A THIRD PARTY CLAIM FOR WHICH ONE PARTY IS OBLIGATED TO INDEMNIFY THE OTHER PARTY (OR AN

INDEMNITEE OF SUCH OTHER PARTY) PURSUANT TO SECTION 12.1 AND ANY BREACH OF ARTICLE 10 (CONFIDENTIAL INFORMATION; INTELLECTUAL PROPERTY MATTERS), IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY (OR THE OTHER PARTY'S AFFILIATES, COLLABORATORS, LICENSEES OR SUBLICENSEES) IN CONNECTION WITH THIS AGREEMENT FOR LOST REVENUE, LOST PROFITS, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY, INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

b. MacroGenics' aggregate liability to Incyte, its Affiliates and their respective Collaborators or licensees for any loss or damage suffered by any of them as a result of breach of this Agreement or any other liability (including negligence, misrepresentation or claims under the indemnities) under this Agreement is limited, in the aggregate, to the payments for the Delivery of Licensed Compound Bulk Drug Substance payable to MacroGenics [***] the occurrence of the event giving rise to the claim.

13. TERM AND TERMINATION

13.1 Term. The term ("**Term**") of this Agreement will expire upon expiration of the Royalty Term unless otherwise terminated in accordance with Section 13.2 below or otherwise extended upon mutual written agreement of the Parties; provided, however, if this Agreement is terminated or expires, but the CMC Development Plan is not terminated or completed, then the terms of this Agreement will continue to apply to the then-current CMC Development Plan until such CMC Development Plan is either terminated or completed. For the avoidance of doubt, if this Agreement is terminated or expires, the terms of this Agreement will continue to apply during wrap up activities related to regulatory, patient safety and quality aspects of Commercialization.

13.2 Termination. This Agreement may be terminated prior to the expiration of the Term under the following conditions:

a. Either Party may, without prejudice to any other remedies available to it in law or equity, terminate this Agreement in the event that the other Party has materially breached or defaulted in the performance of any of its obligations under this Agreement. The breaching Party will have [***] after written notice thereof was provided to the breaching Party by the non-breaching Party to remedy such default. Any such termination will become effective at the end of such [***] unless the breaching Party has cured any such breach or default prior to the expiration of such period; or

b. Either Party may terminate this Agreement in its entirety upon providing written notice to the other Party on or after the time that such other Party makes a general assignment for the benefit of creditors, files an insolvency petition in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors, or becomes a party to any proceeding or action of the type described above (each, an **"Insolvency Event**"), and such proceeding or action remains un- dismissed or un-stayed for a period [***].

13.3 **Effects of Termination**. Upon the expiration or earlier termination of this Agreement (a) Incyte will promptly pay to MacroGenics (i) all amounts outstanding and remaining to be paid for the Licensed Compound Bulk Drug Substance Delivered, (ii) activities performed prior to the date of expiration or termination to conduct Manufacturing Related Activities, Manufacturing Development, Batch shipping and regulatory activities, and (iii) the applicable amounts for all work in process and Licensed Compound Bulk Drug Substance Manufactured, but not then Delivered, by MacroGenics; and (b) any Materials purchased by MacroGenics to Manufacture Licensed Compound Bulk Drug Substance in accordance with the then-current Rolling Forecast that cannot be reasonably used for other purposes, and (c) any cancelled Batches.

13.4 **Accrued Obligations**. Neither the termination nor expiration of this Agreement will release either of the Parties from any liability which at the time of such termination or expiration has already accrued to such Party, nor affect in any way the survival of any other right, duty or obligation of either of the Parties which is expressly stated elsewhere in this Agreement to survive such termination or such non-renewal.

13.5 **Survival**. The following provisions will continue in force in accordance with their respective terms notwithstanding the expiration or the termination of this Agreement for any reason: Articles 1, 10 and 12 and Sections 5.2, 5.3, 5.4, 8.10, 8.11, 13.1, 13.3, 13.4, 13.5, 14.5, 14.6, 14.7, 14.8, 14.9, 14.10, 14.11, 14.12.

14. MISCELLANEOUS

14.1 **Assignment**. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment or transfer without the other Party's consent to an Affiliate or to any Third Party that acquires all or substantially all of the business or assets of such Party to which this Agreement relates (whether by merger, reorganization, acquisition, sale or otherwise). Any successor or assignee of rights and/or obligations permitted hereunder will, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment will be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 14.1 will be null, void and of no legal effect.

14.2 **Relationship of the Parties**. It is expressly agreed that MacroGenics, on the one hand, and Incyte, on the other hand, are independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither MacroGenics nor Incyte will have the authority to make any statements, representations or commitments of any kind, or to take any action which will be binding on the other, without the prior written consent of the other Party to do so. All individuals employed by a Party will be employees of that Party and not of the other Party and all costs and obligations incurred by reason of such employment will be for the account and expense of such Party will be null, void and of no legal effect.

14.3 **Insurance**. Section 14.4 of the Collaboration Agreement will govern the insurance obligations of each Party under this Agreement.

14.4 **Force Majeure**. Both Parties will be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of such Force Majeure circumstances to the other Party. Such excuse will be continued so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. Notwithstanding the foregoing, a Party will not be excused from making payments owed

hereunder because of a Force Majeure affecting such Party. If a Force Majeure persists [***], then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement

in order to mitigate the delays caused by such Force Majeure. In the event a Party is prevented from performing its obligations under this Agreement due to Force Majeure [***] according to this Section 14.4 the other Party will have the right to terminate this Agreement upon [***] notice after the expiration of such period. A termination under this Section 14.4 by either Party will be treated as a termination under Section 13.2(b) above and the corresponding provisions for termination under Section 13.2(b) will apply except to the extent the affected Party is prevented from performing due to the Force Majeure.

14.5 Notices. All notices and other communications given or made pursuant hereto will be in writing and will be deemed to have been duly given on the date delivered, if delivered personally, or on the next Business Day after being sent by reputable overnight courier (with delivery tracking provided, signature required and delivery prepaid), in each case, to the Parties at the following addresses, or on the date sent and confirmed by electronic transmission to the fax number specified below (or at such other address or fax number for a Party as will be specified by notice given in accordance with this Section 14.5):

If to Incyte:

[***]

If to MacroGenics:

[***]

14.6 Collaboration Agreement; Entire Agreement; Amendments.

a. The Collaboration Agreement shall govern the provisions of this Agreement and the Parties' rights and obligations hereunder except to the extent a provision of this Agreement amends, modifies or is contrary to a specific provision of the Collaboration Agreement. In particular, the provisions of this Agreement shall take precedent over the provisions of Section 14.5 and Article 7 (Manufacturing) of the Collaboration Agreement. Notwithstanding any other provision of this Agreement, the rights and obligations of the

Parties to receive and to pay amounts under Article 8 (Consideration) of the Collaboration Agreement shall remain unaffected by this Agreement

b. Subject to Section 14.6(a), this Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties with respect to the subject matter hereof and with respect to the. Manufacture and supply of Licensed Compound Drug Substance by MacroGenics to Incyte. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. In the event of any inconsistency between the body of this Agreement and either any Exhibits to this Agreement or any subsequent agreements ancillary to this Agreement, unless otherwise expressly stated to the contrary in such Exhibit or ancillary agreement, the terms contained in this Agreement will control.

c. Notwithstanding any other provision in this Agreement, the Clinical Supply Agreement will, until its expiration or termination in accordance with the terms set forth therein, remain in effect and continue to obligate the Parties with respect to

i. MacroGenics' right to Manufacture Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product for its own, its Affiliates and their licensees' Development and Commercialization purposes respectively;

ii. MacroGenics' right to purchase Licensed Compound Drug Bulk Drug Substance and Licensed Compound Drug Product from Incyte; and

iii. the conduct of the CMC Development Plan set forth under the Clinical Supply Agreement as updated by the Parties;

14.7 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party will not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

14.8 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is timely taken, the provision will be considered severed from this Agreement and will not serve to invalidate any remaining provisions hereof. The Parties will make good faith efforts to replace any such invalidated or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

14.9 Governing Law/Jurisdiction. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof will be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.

14.10 Dispute Resolution.

a. If the Parties fail to resolve any claim, dispute, or controversy of whatever nature arising out of or relating to this Agreement, such claim, dispute or controversy will be resolved in

accordance with the dispute resolution provisions set forth in Article 13 of the Collaboration Agreement.

b. Notwithstanding the above, in the event of a dispute between the Parties with respect to a Batch Failure, the Parties will meet to discuss and agree upon the feasibility of the release of further Batches. Thereafter, if the Parties still disagree as to whether further Batches can be released, the Parties' most senior quality assurance officer, or their respective designated representatives, will confer to review samples and/or batch records, as appropriate. If the disagreement is not resolved, then samples, batch records and other data relating to the batch in dispute will promptly be submitted for testing and evaluation to an independent Third Party (including a testing laboratory qualified to perform such testing using validated methods) approved in writing by both Parties. The cost of testing and evaluation by the Third Party will be borne (x) by MacroGenics if the Products in question are ultimately found to fail to meet the Product Specification as a result of MacroGenics' failure to adhere to the applicable Manufacturing Process and/or Incyte's instructions, or
(y) by Incyte if MacroGenics is found to have adhered to the applicable Manufacturing Process and, if applicable, Incyte's instructions.

14.11 Counterparts/Signatures. This Agreement may be executed in two (2) or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. This Agreement may be executed by .pdf or other electronically transmitted signatures and such signatures will be deemed to bind each Party as if they were the original signatures.

14.12 Construction. Whenever this Agreement refers to a number of days without using a term otherwise defined herein, such number refers to calendar days. Except where the context otherwise requires, (a) wherever used, the singular will include the plural, the plural will include the singular;
(b) the use of any gender will be applicable to all genders; (c) the terms "including," "include," "includes" or "for example" will not limit the generality of any description preceding such term and, as used herein, will have the same meaning as "including, but not limited to," or "including, without limitation"; (d) the words "herein", "hereof" and "hereunder", and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof; (e) the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; (f) the word "will" means "will"; (g) if a period of time is specified and dates from a given day or Business Day, or the day or Business Day of an act or event, it is to be calculated exclusive of that day or Business Day; (h) "Dollar", "USD" or "$" means U.S. Dollars; (i) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement; (j) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein will be interpreted in a correlative manner; (k) "written" includes communications sent and received by facsimile or electronic mail; (l) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein) and (m) references herein to pharmaceutical products, therapies, ingredients, and the like, will include biologics and biopharmaceutical products, therapies, ingredients, and the like, as applicable. The language of this Agreement will be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied for or against either Party. Whenever a provision of this Agreement requires an approval or consent by a Party to this Agreement within a specified time period and notification of such approval or consent is not delivered within such time period, then, unless otherwise specified, the Party whose approval or consent is required will be conclusively deemed to have withheld its approval or consent. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof.

IN WITNESS HEREOF, the Parties have read and agree to be bound by the above terms and conditions and have entered into this Agreement effective as of the Effective Date set forth above.

[***]

Incyte Corporation	**MacroGenics, Inc.**
By: */s/ Herve Hoppenot*	By: */s/ Scott Koenig*
Printed Name: Herve Hoppenot	Printed Name: Scott Koenig, MD, PhD
Title: CEO Date: [***]	Title: CEO Date: [***]

[***]

EXHIBIT A

[***]

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EXHIBIT B

[***]

EXHIBIT C

[***]

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EXHIBIT D

[***]

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CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT BOTH (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED. SUCH EXCLUDED INFORMATION HAS BEEN MARKED WITH "[***]".

EXECUTION VERSION CONFIDENTIAL

PRODUCT COMMERCIALIZATION AGREEMENT

This Product Commercialization Agreement (this "**Agreement**") is made on November 13, 2020 (the "**Effective Date**") by and between **MacroGenics, Inc.**, a Delaware corporation with a place of business at 9704 Medical Center Drive, Rockville, MD 20850 ("**MacroGenics**"), and **Eversana Life Science Services, LLC**, a Wisconsin limited liability company with a place of business at 190 N. Milwaukee Street, Milwaukee, WI 53202 ("**Eversana**"). MacroGenics and Eversana are hereinafter referred to individually as a "**Part**y" and collectively as the "**Parties**".

BACKGROUND

Whereas, MacroGenics is a pharmaceutical company that will seek to market, promote and Commercialize (as defined below) the Product (as defined below) in the Territory (as defined below) upon its approval by the FDA (as defined below);

Whereas, Eversana is a life sciences services company that has experience providing commercialization services related to pharmaceutical products; and

Whereas, MacroGenics wishes to engage Eversana to supervise and manage the day to day Commercialization of the Product in the Territory under the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth below, and other consideration received by the Parties, the Parties hereby agree as follows:

1. DEFINITIONS

For the purposes of this Agreement, the following words and expressions shall have the stated definitions:

1.1. "**AAA**" shall have the meaning set forth in Section 16.3.b.

1.2. "**Act**" means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.), as amended from time to time, together with any rules, regulations, guidances, guidelines and requirements of the FDA as may be in effect from time to time.

1.3. "**Additional Unreimbursed Commercial Costs**" shall have the meaning set forth in Section 5.2.d.

1.4. "**Adjusted Net Revenue**" [***].

1.5. "**Adjusted Revenue Report**" shall have the meaning set forth in Section 5.5.a.

1.6. "**Adjusted Revenue Share Payments**" shall have the meaning set forth in Section 5.4.

1.7. "**Adjusted Revenue Sharing Period**" means the period beginning on the BLA Approval Date and ending on the earlier of (a) the occurrence of the Revenue Threshold, and (b) the expiration or termination of this Agreement.

1.8. "**Administrative Costs**" means [***] MacroGenics's administrative costs, [***].

1.9. "**Adverse Event**" means the development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to the Product, whether or not considered causally related to the Product, the exacerbation of any pre-existing condition(s) occurring following or during the use of the Product or any other adverse event, adverse experience or adverse drug experience described in the FDA's Investigational New Drug safety reporting and post-marketing reporting regulations, 21
C.F.R. § 312.32 and § 314.80, respectively, as they may be amended from time to time. For purposes of this Agreement, without limiting the forgoing, "undesirable medical condition" includes symptoms (e.g., nausea, chest pain), signs (e.g., tachycardia, enlarged liver) or the abnormal results of an investigation (e.g., laboratory findings, electrocardiogram), including unfavorable side effects, toxicity, injury, overdose, sensitivity reactions or failure of the Product to exhibit its expected pharmacologic/biologic effect.

1.10. "**Affiliate**" of a Person means any other Person which (directly or indirectly) is controlled by, controls or is under common control with such Person. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to a Person, means (a) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise, (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a Person, or (c) the power to elect or appoint more than fifty percent (50%) of the members of the board of directors or other governing body of such Person.

1.11. "**Agreement**" shall have the meaning set forth in the Preamble.

1.12. "**Agreement Details**" shall have the meaning set forth in Section 1.34.

1.13. "**Alliance Manager**" shall have the meaning set forth in Section 3.1.

1.14. "**Anti-Corruption Laws**" means the Foreign Corrupt Practices Act of 1977, as amended, the Anti-Kickback Statute, the False Claims Act, the Department of Health and Human Services Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, released April 2003, the healthcare fraud and false statements provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and any other applicable law, rule, regulation or industry code governing anti-bribery and anti-corruption laws and laws applicable in the Territory for the prevention of kickbacks, fraud, abuse, racketeering, money laundering or terrorism.

1.15. "**Appellate Rules**" shall have the meaning set forth in Section 16.3.b.

1.16. "**Applicable Compliance/Review Policies**" means, with respect to each Party, its written code of ethics and conduct and such policies and standard operating procedures that are adhered to by such Party in connection with the Product and any payments or activities contemplated by this Agreement, as the same may be amended from time to time.

1.17. "**Applicable Law**" means (a) all applicable laws, rules and regulations, including any applicable rules, regulations, guidelines or other requirements of Governmental Authorities that may be in effect in the Territory from time to time during the Term, including (i) the Act,
(ii) the PDMA, (iii) Anti-Corruption Laws, (iv) Medicare and Medicaid coverage and reimbursement provisions of titles XVIII and XIX of the Social Security Act, (v) the federal healthcare program civil money penalty and exclusion authorities, (vi) the Physician Payments Sunshine Act, 42 U.S.C. § 1320a-7h, (vii) all federal, state or local statutes, laws, ordinances, regulations or guidelines relating to employment, safety and health of employees and the withholding and payment of required taxes with respect to employees, and (viii) all federal, state or local statutes, laws, ordinances, regulations or guidelines relating to data protection and privacy, including the United States Department of Health and Human Services privacy rules under the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act, and (b) the PhRMA Code on Interactions with Healthcare Professionals, PhRMA Principles on Direct To Consumer Advertisements; PhRMA Principles on Interactions with Patient Organizations, and PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results.

1.18. "**Approved Subcontractor**" shall have the meaning set forth in Section 3.5.b.

1.19. "**Arbitration Request**" shall have the meaning set forth in Section 16.3.b.

1.20. "**Arising Product Know-How**" means all Know-How (i) specific to the Product arising out of or in connection with either Party's or their respective Affiliates' (including, with respect to Eversana, any Approved Subcontractors') activities under or in connection with this Agreement, (ii) constituting deliverables provided by or on behalf of Eversana or its Affiliates or Approved Subcontractors to MacroGenics as part of the Services, (iii) created or developed by Eversana using MacroGenics Confidential Information and/or MacroGenics Know-How; or (iv) developed or created by Eversana according to MacroGenics' specifications. Arising Product Know-How shall include but not be limited to the following:

a. written and electronic materials (including but not limited to Promotional Materials), and their associated copyrights, that are intended to be used for activities to promote the Product, including for activities such as, but not limited to, presentations during detailing (whether in-person or electronically), conducting display booths, conducting meetings with prescribers in exhibits at conferences and trade shows and sponsoring advertising in journals and publications directed to prescribers;

b. written and electronic Training Materials; and

c. trademarks, logos and Product labeling that identify the Product or MacroGenics.

For clarity, Arising Product Know-How (x) includes Know-How that Eversana creates under or in connection with this Agreement that emphasizes, focuses on or relies on an aspect, characteristic, trait or activity of the Product or discusses the Product in terms of its product class or in comparison to other products, and (y) excludes Eversana Know-How.

1.21. "**BLA**" means a Biologics License Application (as more fully described in 21 CFR §601, *et seq.*, or its successor regulation) filed with the FDA (or any successor application thereto) for approval to market and sell a biologic in the Territory, and all amendments or supplements filed pursuant to the requirements of the FDA.

1.22. "**BLA Approval**" means the approval by the FDA of a BLA for the Product.

1.23. "**BLA Approval Date**" means the date on which MacroGenics receives BLA Approval.

1.24. "**Business Day**" means a day on which companies in the United States are generally open for business.

1.25. "**Channel Management Services**" means the channel management services described in the 3PL Agreement.

1.26. "**Claims**" shall have the meaning set forth in Section 13.1.

1.27. "**COC Notice Period**" shall have the meaning set forth in Section 14.2.f.

1.28. "**Commercial Launch**" means the earlier of (a) the Business Day immediately following the date of the initial Product launch meeting, or (b) [***] the Product first becomes available for purchase in the Territory for therapeutic use.

1.29. "**Commercialization**," "**Commercialize**" and "**Commercializing**" mean any and all customary processes and activities undertaken by a pharmaceutical company to accomplish the commercialization of a pharmaceutical product, including without limitation the storage, third party logistics and distribution, sales, promotion and marketing of the Product, Medical Affairs Activities, managing returns of the Product, Patient Access Programs, and reimbursements. Commercialization expressly excludes activities related to development or testing of the Product or Manufacturing, including but not limited to the conduct of a Phase 4 Study.

1.30. "**Commercialization Budget**" shall have the meaning set forth in Section 3.4.

1.31. "**Commercialization Plan**" shall have the meaning set forth in Section 3.4.

1.32. "**Commercialization Service Fees**" means (a) [***], and
(b) [***]

[***].

1.33. "**Commercialization Services**" means the services set forth in Exhibit B.

1.34. "**Confidential Information**" of a Party (the "**Disclosing Party**") means all business, operational, marketing, financial, technical, manufacturing, scientific, or other information, that, in each case, is confidential or proprietary to the Disclosing Party or any of its Affiliates, is not generally known to the public, and is furnished to the other Party (the "**Receiving Party**") by or on behalf of the Disclosing Party pursuant to this Agreement [***], whether in written, electronic, oral, visual or other form. Confidential Information of a Party may include such Party's and its Affiliates' processes and methods, process specifications and designs, inventions, Know-How, intellectual property, business and marketing plans, financial information, customer data, research and development activities and other materials or information relating to business or activities which are not generally known to the public, and confidential information of Third Parties in the possession of the Disclosing Party. Without limiting the generality of the foregoing, Confidential Information of MacroGenics includes Manufacturing Data regarding the Product. This Agreement, including its provisions, terms and conditions hereof ("**Agreement Details**"), shall be deemed the Confidential Information of both Parties, and each Party shall be deemed both a Disclosing Party and a Receiving Party with respect thereto.

1.35. "**Control**" or "**Controlled by**" shall mean, with respect to any Know-How, Patent Rights or other intellectual property rights, possession by a Party of the ability (whether by ownership, license or other right, other than pursuant to a license granted to such Party under this Agreement) to grant to the other Party a license, sublicense or other access without violating the terms of any agreement or other arrangement with any Third Party.

1.36. "**Corporate Trademarks**" means the trade names, corporate names and corporate logos of MacroGenics or MacroGenics's Affiliates (a) used in the Prescribing Information, or
(b) authorized or approved by MacroGenics for use in Materials that may be provided or generated hereunder.

1.37. "**Dedicated Eversana Personnel**" shall have the meaning set forth in Section 3.6.a.

1.38. **"Deficiency"** shall have the meaning set forth in Section 3.7.

1.39. "**Disclosing Party**" shall have the meaning set forth in Section 1.34.

1.40. "**Disputed Report Response**" shall have the meaning set forth in Section 5.5.b.

1.41. "**Effective Date**" shall have the meaning set forth in the Preamble.

1.42. "**Estimated Reimbursed Commercial Costs**" shall have the meaning set forth in Section 5.2.a.

1.43. "**Estimated Unreimbursed Commercial Costs**" shall have the meaning set forth in Section 5.2.a.

1.44. "**Eversana**" shall have the meaning set forth in the Preamble.

1.45. "**Eversana Compliance/Review Policies**" means Eversana's Applicable Compliance/Review Policies, as approved by the JMC.

1.46. "**Eversana Indemnitees**" shall have the meaning set forth in Section 13.2.a.

1.47. "**Eversana Know-How**" means all Know-How that either: (a) is in Eversana's possession and Control of as of the Effective Date ("**Eversana Pre-Existing Know-How**"); or (b) after the Effective Date during the Term, is independently developed by Eversana outside of providing the Services or performing other activities under this Agreement and without use of any MacroGenics Confidential Information or MacroGenics Know-How and is not specific to the Product. In addition, Eversana Know-How includes any improvement, modification or enhancement of the Eversana Pre-Existing Know-How that is made, generated, developed or invented by Eversana in the course of providing the Services or performing other activities under this Agreement, and is generally applicable to the services Eversana provides to its clients, but (i) does not constitute deliverables provided by or on behalf of Eversana or its Affiliates or Approved Subcontractors to MacroGenics as part of the Services, (ii) is not created or developed by Eversana using MacroGenics Confidential Information and/or MacroGenics Know-How. and (iii) is not developed or created by Eversana according to MacroGenics' specifications.

1.48. "**Eversana Personnel**" means the Key Account Directors, Medical Science Liaisons and any other personnel employed or engaged by Eversana (including supervisory personnel overseeing the activities of such personnel and legal, regulatory and other support personnel) who are or may be involved with activities under this Agreement.

1.49. "**Eversana Pre-Existing Know-How**" shall have the meaning set forth in Section 1.47.

1.50. "**Executive Officers**" means, with respect to MacroGenics, its Chief Executive Officer, and with respect to Eversana, its Chief Executive Officer.

1.51. "**FDA**" means the Unites States Food and Drug Administration and any successor agency thereto.

1.52. "**Fee-for-Service Fees**" shall have the meaning set forth in Section 5.4.

1.53. "**Fees**" means the Pre-Approval Service Fees, the Reconciled Reimbursed Commercial Costs, the Adjusted Revenue Share Payments and the Fee-for-Service Fees.

1.54. "**Field Alert**" means a field alert report, as required under 21 C.F.R. § 314.81(b)(1), as such regulation may be amended from time to time.

1.55. "**Functional Services**" means the services set forth in Exhibit C.

1.56. "**GAAP**" means generally accepted accounting principles in the United States.

1.57. "**Government Official**" to be broadly interpreted, shall mean (a) any elected or appointed government official (*e.g.*, a member of a ministry of health); (b) any employee or person acting for or on behalf of a government, government-controlled entity or enterprise performing a governmental function; (c) any political party, candidate for public office, officer, employee, or person acting for or on behalf of a political party or candidate for public office; (d) any employee or person acting for or on behalf of a public international organization (*e.g.*, the United Nations); or (e) any individual who holds himself or herself out to be the authorized intermediary of any of the foregoing. For clarity, healthcare providers employed by government-owned hospitals shall be considered Government Officials.

1.58. "**Governmental Authority**" means any federal, state or local court, administrative agency, commission or other governmental authority or instrumentality, including the FDA, having authority in the United States over the activities contemplated hereunder. Governmental Authority shall include any Regulatory Authority.

1.59. "**HCP**" means all healthcare professionals, including any physician, physician's assistant, pharmacist, nurse practitioner, clinical nurse specialist or registered nurse holding a degree in an area of nursing, certified registered nurse anesthetist, or certified nurse-midwife.

1.60. "**Higher Cost Service**" shall have the meaning set forth in Section 3.7.

1.61. "**Indemnified Party**" shall have the meaning set forth in Section 13.3.

1.62. "**Indemnifying Party**" shall have the meaning set forth in Section 13.3.

1.63. "**Indemnitees**" shall have the meaning set forth in Section 13.1.

1.64. "**Indemnitor**" shall have the meaning set forth in Section 13.1.

1.65. "**Intellectual Property Rights**" means all intellectual property rights anywhere in the Territory, whether or not registered, including patents, utility models, rights in inventions, trademarks, service marks, rights in trade dress (including product configuration and packaging), rights in business and trade names, rights in domain names, designs, copyrights, trade secrets, rights in Know-How and confidential information, and, in each case, rights of a similar or corresponding character.

1.66. "**Joint Management Committee**" or "**JMC**" has the meaning set forth in Section 4.1.

1.67. "**Key Account Directors**" means the Eversana Personnel designated as "Key Account Directors" under the Commercialization Plan and having the qualifications and responsibilities set forth in the Commercialization Plan.

1.68. "**Know-How**" means patentable and non-patentable inventions, discoveries, technologies, knowledge, trade secrets, experience, skill, techniques, methods, processes (including manufacturing processes), procedures, formulas, compounds, compositions of matter,

assays, tests (including diagnostic tests), materials, specifications, descriptions, results and data (including Manufacturing Data), business or financial information or information of any type whatsoever, in any tangible or intangible form, marketing reports, business plans, standard operating procedures, and procedures; that, in each case, are not generally known to the public.

1.69. "**Liability**" shall have the meaning set forth in Section 9.7.a.

1.70. "**Losses**" shall have the meaning set forth in Section 13.1.

1.71. "**MacroGenics**" shall have the meaning set forth in the Preamble.

1.72. "**MacroGenics Change of Control**" means, with respect to MacroGenics, (a) the acquisition of MacroGenics by another entity by means of any transaction or series of related transactions (including, without limitation, any merger, consolidation in which the majority of the outstanding shares of MacroGenics are exchanged for securities or other consideration issued or provided, or caused to be issued or provided, by the acquiring entity or its subsidiary, but excluding any transaction effected primarily for the purpose of changing MacroGenics's jurisdiction of incorporation), unless MacroGenics's shareholders of record as constituted immediately prior to such transaction or series of related transactions will, immediately after such transaction or series of related transactions hold at least a majority of the voting power of the surviving or acquiring entity, (b) a sale of all or substantially all of the assets of MacroGenics to which this Agreement pertains, or (c) the execution by MacroGenics of a MacroGenics Third Party Exclusive Commercial License Agreement.

1.73. "**MacroGenics Change of Control Partner**" means the entity engaging in a MacroGenics Change of Control.

1.74. "**MacroGenics Know-How**" means all Know-How necessary or useful for the Commercialization of the Product that either: (a) is in MacroGenics's possession and Control as of the Effective Date ("**MacroGenics Pre-Existing Know-How**"); or (b) after the Effective Date, (i) is independently developed by MacroGenics without use of any Eversana Confidential Information or Eversana Know-How, or (ii) is acquired by MacroGenics from a Third Party, and, in each case ((i) and (ii)), comes into MacroGenics's possession and Control during the Term.

1.75. "**MacroGenics Patent Rights**" means all Patent Rights Controlled by MacroGenics as of the Effective Date or during the Term that claim the composition, a method of making, a method of using, the sale or the importation of the Product.

1.76. "**MacroGenics Pre-Existing Know-How**" shall have the meaning set forth in Section 1.74.

1.77. "**MacroGenics Technology**" means MacroGenics Know-How and MacroGenics Patents.

1.78. "**MacroGenics Third Party Exclusive Commercial License Agreement**" means an agreement between MacroGenics and a Third Party which includes an exclusive license to such Third Party or exclusive appointment of such Third Party to be responsible for the majority of the activities comprising the Commercialization Services (which may exclude

distribution trade and channel management) for the Territory. MacroGenics' retention of certain specified rights to Commercialize the Product in the Territory or the obligation to perform certain activities in connection with and in furtherance of such exclusive license shall not be construed as a non-exclusive license or non-exclusive appointment of such Third Party; *provided, however,* that if MacroGenics retains the right to sell, and book sales of, the Product in the Territory, such agreement shall not be considered a MacroGenics Third Party Exclusive Commercial License Agreement.

1.79. "**Manufacture**" and "**Manufacturing**" mean all activities related to the manufacture of a pharmaceutical product for the Territory, including without limitation manufacturing for clinical use or commercial sale, as well as compliance with Applicable Laws relating to the foregoing activities, but expressly excludes activities related to Commercialization.

1.80. "**Manufacturing Data**" means all data, information, material, and documentation developed or generated with respect to the Manufacturing of a pharmaceutical product, including manufacturing and control data and other data and documentation requested by or submitted to a Regulatory Authority.

1.81. "**Materials**" means, collectively, the Promotional Materials and Other Materials.

1.82. "**Materials Review Process**" shall have the meaning set forth in Section 4.3.i.

1.83. "**Medical Affairs Activities**" means activities, including Medical Education Activities, occurring during Commercialization of the Product in connection with the following activities:[***].

1.84. "**Medical Education Activities**" means activities designed to ensure or improve safe and appropriate medical use of, conduct medical education about, or further research regarding,

the Product sold in the Territory or the associated disease states or conditions generally, including by way of example: [***].

1.85. "**Medical Science Liaisons**" or **"MSLs"** means the Eversana Personnel designated as "Medical Science Liaisons" to engage in Medical Affairs Activities under the Commercialization Plan and having the qualifications and responsibilities set forth in the Commercialization Plan.

1.86. "**Net Profit**" means Net Sales, less the following: [***].

1.87. "**Net Sales**" means the gross amounts invoiced by or on behalf of MacroGenics and its Affiliates (including by Eversana or its Affiliates on behalf of MacroGenics), on sales of Products to Third Party purchasers, less the following deductions, if not previously deducted from the invoiced amount, to the extent attributable to the Product ("**Net Sales Deductions**"):

a. Normal and customary trade, quantity, and prompt pay discounts (including initial launch stocking discounts, chargebacks and allowances) actually allowed;

b. Amounts repaid or credited by reason of rejection, returns or recalls of Product, rebates or bona fide price reductions;

c. Rebates and similar payments made with respect to the sales paid for by any Governmental Authority, including but not limited to Federal or state Medicaid, Medicare or similar state program;

d. Redemption costs associated with any voucher, coupon, loyalty card or other co-pay assistance programs for the Product;

e. Administrative fees paid during the relevant time period to group purchasing organizations, pharmacy benefit managers or other relevant customers;

f. Service fees payable under any wholesaler agreement, distribution services agreement, inventory management agreement or similar agreement;

g. Taxes, tariffs, excises, customs duties, and/or other charges imposed by a Governmental Authority on the production, sales, import, delivery or use of the Product (including sales, use, excise and consumption taxes and value added tax);

h. Deductions to gross invoice price of such Product required by Governmental Authorities, and the annual fee on branded prescription pharmaceutical manufacturers and importers under the Affordable Care Act (or, if MacroGenics has other marketed products in addition to the Product, a portion thereof based on an equitable allocation among the Product and all other products sold by MacroGenics);

i. A reasonable reserve up to [***] of the amount invoiced to cover bad debt;

j. The actual cost for transportation costs, distribution expenses, special packaging and related insurance charges; and

k. Any other customary deductions that are consistent with both GAAP and MacroGenics' actual practice (or its Affiliates' or licensees') at the time in calculating and reporting its actual product net sales throughout its businesses, provided that no item shall be deducted pursuant to this clause (k) if included in any another deduction provided for under this definition.

1.88. "**Net Sales Deductions**" has the meaning provided in Section 1.87.

1.89. "**Non-Reimbursable Budget Overages**" means, with respect to a particular calendar quarter during the Adjusted Revenue Sharing Period resulting in an [***] for such calendar quarter that is [***].

1.90. "**Other Materials**" means any and all written, printed, graphic, electronic, audio, video or other materials to be used in connection with Commercialization activities for the Product (or disease state treated by the Product) in the Territory other than Promotional Materials, as developed and approved in accordance with Section 3.9. Other Materials includes Training Materials and materials to be used in connection with Medical Affairs Activities.

1.91. "**Other Reportable Information**" means, other than Adverse Events, any communication or other information that is required to be reported by Eversana to MacroGenics in accordance with the training to be provided under this Agreement.

1.92. "**Out of Scope Services**" shall have the meaning set forth in Section 3.7.

1.93. "**Overage**" shall have the meaning set forth in Section 5.2.d.

1.94. "**Party**" and "**Parties**" shall have the meaning set forth in the Preamble.

1.95. "**Pass-Through Costs**" means amounts payable by Eversana to Third Parties in order to perform the Services, including, without limitation, (a) fees payable to Approved Subcontractors, (b) amounts payable to acquire materials or other resources, (c) travel expenses, and (d) expenses of the types listed under the heading "Pass-Through Expenses"

in Exhibit G. For clarity, Pass-Through Costs shall not include [***] or, except as expressly set forth in clause (d) of the preceding sentence, amounts paid in connection with [***].

1.96. "**Patent Rights"** shall mean patents and patent applications, including provisional applications, continuations, continuations-in-part, continued prosecution applications, divisions, substitutions, reissues, additions, renewals, reexaminations, extensions, term restorations, confirmations, registrations, revalidations, revisions, priority rights, requests for continued examination and supplementary protection certificates granted in relation thereto, as well as utility models, innovation patents, petty patents, patents of addition, inventor's certificates, and equivalents in any country or jurisdiction.

1.97. "**Patient Access Programs**" means programs to assist prescription fulfillment, [***] (the "**Excluded Pharmacy Services**"). For the avoidance of doubt, Excluded Pharmacy Services does not include any of the Patient Access Programs or services related to those programs as described in Exhibits A, B, and C. MacroGenics will enter into a separate agreement with a specialty pharmacy selected by MacroGenics to administer the Excluded Pharmacy Services, and Eversana will coordinate and work cooperatively with such specialty pharmacy, as necessary to fully implement the Excluded Pharmacy Services. The parties agree and understand that if MacroGenics chooses a specialty pharmacy to administer the Excluded Pharmacy Services that is an Affiliate of, controlled or operated by Eversana, such agreement will be entirely separate from the financial and other arrangements made hereunder and that this Agreement and the payments hereunder are not dependent in any way on the execution of a specialty pharmacy agreement with Eversana, or vice-versa.

1.98. "**PDMA**" means the Prescription Drug Marketing Act of 1987, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder and in effect from time to time.

1.99. "**Person**" means any individual, partnership, limited partnership, limited liability company, joint venture, syndicate, sole proprietorship, corporation, unincorporated association, trust, trustee, executor, administrator or other legal personal representative, or any other legal entity, including a Governmental Authority.

1.100. "**Phase 4 Study**" means a clinical trial of a product which trial (a) is not required to be completed prior to obtaining marketing approval of such product; and (b) either (i) is required by the applicable Regulatory Authority as mandatory to be conducted on or after the marketing approval of such product, or (ii) is conducted voluntarily by MacroGenics or an investigator to enhance scientific knowledge of such product (e.g., providing additional

drug profile, safety data or marketing support information, or supporting expansion of product labeling).

1.101. "**Pre-Approval Services**" means the services set forth in Exhibit A to be performed by Eversana before the BLA Approval Date, as the same may be amended, modified or supplemented from time to time in accordance with Section 3.3.

1.102. "**Pre-Approval Service Fees**" means the fees actually incurred by Eversana to perform the Pre-Approval Services according to the fee estimate and the fee structure set forth in Exhibit A, as the same may be amended, modified or supplemented from time to time in accordance with Section 3.3. The Pre-Approval Services performed by a dedicated launch manager shall be at no cost to MacroGenics.

1.103. "**Premises**" means Eversana's corporate office and its warehouse facilities located at either: (a) 10887 Commerce Way, Unit B, Fontana, CA 92336; (b) 4550 and 4580 Mendenhall Road, Memphis, Tennessee 38141; (c) 5650 Challenge Drive, Memphis, TN 38118; or (d) such other facilities as Eversana and MacroGenics may mutually agree.

1.104. "**Prescribing Information**" means the FDA-approved labeling for the Product.

1.105. "**Prior CDA**" means the Confidential Disclosure Agreement, dated as of [***].

1.106. "[***]" means [***].

1.107. "**Prior Quarter Adjustments**" shall have the meaning set forth in Section 5.5.a.

1.108. "**Proceeding**" shall have the meaning set forth in Section 12.3.c.

1.109. "**Product**" means margetuximab.

1.110. "**Product Copyrights**" means all copyrightable subject matter related to the Product included in the Prescribing Information, the Promotional Materials, the Training Materials or other Materials provided hereunder or otherwise authorized or approved by MacroGenics under this Agreement for use by Eversana in performing the Services.

1.111. "**Product Quality Complaint**" means any and all manufacturing or packaging-related complaints related to the Product, including (a) any complaint involving the possible failure of the Product to meet any of the specifications for the Product, and (b) any dissatisfaction with the design, package or labeling of the Product.

1.112. "**Product Trademarks**" means the Product-specific trademarks owned or Controlled by MacroGenics during the Term in the Territory, including any such Product-specific trademarks (a) used in the Prescribing Information, or (b) authorized or approved by MacroGenics for use in Promotional Materials, Training Materials, or other Materials relating to the Product that may be provided or generated hereunder; but, in each case, excluding the Corporate Trademarks.

1.113. "**Product Training**" means the Product-specific training program for Eversana Personnel conducted in accordance with the Commercialization Plan and Applicable Law, which may include, as determined by the JMC or set forth in the Commercialization Plan, training concerning [***].

1.114. "**Promotional Materials**" means any and all written, printed, graphic, electronic, audio, video or other materials to be used in connection with any promotion activities for the Product in the Territory, as developed and approved in accordance with Section 3.9. For clarity, Promotional Materials may include materials such as detail aids, reprints, and advertisements, as applicable, as approved in accordance with Section 3.9.

1.115. "**Quarterly Invoice**" shall have the meaning set forth in Section 5.2.a.

1.116. "**Rate Sheet**" shall have the meaning set forth in Section 3.4.b(i).

1.117. "**Receiving Party**" shall have the meaning set forth in Section 1.34.

1.118. "**Reconciled Reimbursed Commercial Costs**" means, with respect to each calendar quarter occurring during the Adjusted Revenue Sharing Period, [***].

1.119. "**Reconciled Unreimbursed Commercial Costs**" means, with respect to each calendar quarter occurring during the Adjusted Revenue Sharing Period, [***].

1.120. "**Refund Amount**" shall have the meaning set forth in Section 5.2.c.

1.121. "**Regulatory Authority**" means any national, federal, state, or local governmental or regulatory authority, agency, department, bureau, commission, council or other government entity located in the Territory, including FDA, Centers for Medicare and Medicaid Services (CMS), and the Office of Inspector General of the U.S. Department of Health and Human Services, regulating or otherwise (a) exercising authority with respect to the development, Manufacture, approval, registrations, licensing, or Commercialization of the Product in such regulatory jurisdiction in the Territory, or (b) having legal authority with respect to the exploitation of the Product in the Territory.

1.122. "**Regulatory Documentation**" means all applications, registrations, licenses, authorizations and approvals, all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents and all clinical studies and tests, relating to the Product, and all data contained in any of the foregoing, including all

Regulatory Authority approvals, regulatory drug lists, advertising and promotion documents and related FDA submissions and correspondence, adverse event files and complaint files and related FDA submissions.

1.123. "**Reimbursable Budget Overages**" means, with respect to a particular calendar quarter during the Adjusted Revenue Sharing Period resulting in an Overage, the portion of the Overage for such calendar quarter to the extent attributable to:

a. [***] as set forth in the Commercialization Plan and the Commercialization Budget; provided, that (i) the Commercialization Service Fees for such [***], and (ii) [***] as set forth in the Commercialization Plan and the Commercialization Budget [***]; or

b. [***] set forth in the Commercialization Plan and the Commercialization Budget; provided, that the foregoing shall not apply to any [***].

1.124. "**Report Response Period**" shall have the meaning set forth in Section 5.5.b.

1.125. "**Revenue Measurement Date**" shall have the meaning set forth in Section 14.2.b.

1.126. "**Revenue Threshold**" shall have the meaning set forth in Section 5.4.

1.127. "**Section 3.7 Notice**" shall have the meaning set forth in Section 3.7.

1.128. "**Section 3.7 Proposal**" shall have the meaning set forth in Section 3.7.

1.129. "**Services**" means: (a) the day-to-day supervision and management by Eversana of the Commercialization of the Product in the Territory, including the Pre-Approval Services, the Commercialization Services, and the Functional Services; and (b) the Channel Management Services.

1.130. "**Term**" shall have the meaning set forth in Section 14.1.

1.131. "**Territory**" means the United States and all of its territories and possessions.

1.132. "**Third Party**" means any Person other than MacroGenics, Eversana and their respective Affiliates.

1.133. "**Third Party Commercial Costs**" shall have the meaning set forth in Section 3.7.

1.134. "**Third Party Royalties**" means any and all royalties on sales of the Product in the Territory and other payments that directly attributable or allocable to the Product in the

Territory that, in each case, MacroGenics is required to pay to a Third Party for a license under issued and unexpired Patent Rights controlled by such Third Party, which license is [***]. For clarity, Third Party Royalties [***].

1.135. "**Training Materials**" means the materials [***] to be used in Product Training for Eversana Personnel regarding the Product, as approved pursuant to Section 3.9.

1.136. "**True-Up Amount**" shall have the meaning set forth in Section 5.2.d.

1.137. "**3PL Agreement**" shall have the meaning set forth in Section 3.11.

2. APPOINTMENT AND LICENSE.

2.1. **Appointment**. On and from the Effective Date and for the duration of the Term, MacroGenics hereby appoints Eversana to perform the Services, and Eversana hereby agrees to perform the Services, in accordance with this Agreement and Applicable Law.

2.2. **License Grant**. Subject to the terms and conditions of this Agreement, MacroGenics hereby grants to Eversana:

a. a co-exclusive (with MacroGenics), limited, non-transferable, non-sublicensable (except to Affiliates and Approved Subcontractors as permitted in accordance with Section 3.5), license (i) under the MacroGenics Technology to sell, have sold, offer for sale and otherwise Commercialize the Product in the Territory solely to the extent necessary for Eversana to perform its obligations and provide the Services under this Agreement, and
(ii) to use the Product Trademarks and Product Copyrights in connection with the Commercialization of the Product in the Territory solely to the extent necessary for Eversana to perform its obligations and provide the Services under this Agreement; and

b. a non-exclusive, limited, non-transferable, non-sublicensable (except to Affiliates and Approved Subcontractors as permitted in accordance with Section 3.5), license to use the Corporate Trademarks in connection with the Commercialization of the Product in the Territory solely to the extent necessary for Eversana to perform its obligations and provide the Services under this Agreement.

2.3. **Retained Rights**. Except as specifically set forth in this Agreement, Eversana shall have no other rights with respect to the Product, and for clarity, shall not promote, market or otherwise Commercialize the Product except as Eversana is expressly authorized to do under this Agreement. MacroGenics reserves and retains, for itself, its Affiliates and for any Third Party, all rights in and relating to the Product not expressly granted to Eversana under this Agreement.

2.4. **Other Rights and Obligations**. Eversana acknowledges and agrees that, as between the Parties, MacroGenics owns all right, title and interest in and to (a) the Intellectual Property

Rights in the Product, including the MacroGenics Technology, the Arising Product Know- How, the Product Trademarks, the Corporate Trademarks, and the Product Copyrights, and
(b) all Regulatory Documentation for the Product.

2.5. **Provision of Information and Materials**. MacroGenics shall promptly provide to Eversana at Eversana's request such reasonable and currently available information and materials in MacroGenics' possession and Control relating to the Product as is necessary for Eversana to perform the Services in the Territory in accordance with the terms and conditions of this Agreement and Applicable Law.

2.6. **Assignment of Arising Product Know-How**. As between the Parties, MacroGenics shall own all right, title and interest in the Arising Product Know-How. Eversana shall assign and hereby assigns (and shall cause any applicable Affiliate or Approved Subcontractor to assign) to MacroGenics all of its right, title and interest in and to the Arising Product Know-How arising out of Eversana's (or its Affiliates' or Approved Subcontractors') activities under or in connection with this Agreement. Eversana agrees to (and shall cause any applicable Affiliate or Approved Subcontractor to) execute all documents and take all actions as are reasonably requested by MacroGenics to vest title to the Arising Product Know-How (and content) in MacroGenics (or its designated Affiliate). Upon MacroGenics reasonable request, Eversana shall provide copies of any tangible or electronic Arising Product Know- How specified in such request to MacroGenics.

3. COMMERCIALIZATION

3.1. **Alliance Managers**. Each Party shall designate a single person (each, an "**Alliance Manager**") to oversee contact between the Parties for all matters related to Commercialization of the Product. The Alliance Managers shall: (a) function as a single point of contact in all substantive communications with the other Party; and (b) perform any other functions agreed by the Parties. Each Party may replace its Alliance Manager at any time by written notice to the other Party. The initial Alliance Managers are set forth on
Exhibit E.

3.2. Overview of Roles and Responsibilities.

a. Subject to the terms and conditions of this Agreement, Eversana shall perform the Services in accordance with the then-current Commercialization Plan and Commercialization Budget and the terms of this Agreement and shall be responsible for all costs incurred with respect thereto, subject to the reimbursement and payment obligations set forth in Article 5, Section 14.2.c and Section 14.2.f. Without limiting the foregoing, Eversana shall (i) employ a sufficient number of Eversana Personnel, and ensure that such Eversana Personnel devote the necessary time in promoting, marketing and providing market access for and otherwise Commercializing the Product in the Territory to meet the requirements of the Commercialization Plan, and (ii) perform promotional activities in accordance with the targeting and frequency requirements set forth in the Commercialization Plan.

b. MacroGenics shall provide the functions and responsibilities set forth herein, including Product Manufacturing and obtaining and maintaining all regulatory approvals for the

Product as required by Applicable Law for the Territory, and as is necessary for Eversana to provide the Services in accordance with this Agreement and Applicable Law. Notwithstanding anything to the contrary set forth in this Agreement, MacroGenics makes no guarantee that BLA Approval will occur and that the Product will be Commercialized under this Agreement.

3.3. **Pre-Approval Services**. In anticipation of BLA Approval and the Commercial Launch of the Product in the Territory, Eversana shall provide the Pre-Approval Services described on Exhibit A hereto. The Pre-Approval Services shall [***]. The Parties acknowledge and agree that, in [***] the Pre-Approval Services will be performed and the anticipated collaboration between the Parties with respect to the scope and timeline for the activities to be included in the Pre-Approval Services, (a) MacroGenics may update Exhibit A from time to time upon written notice to Eversana, subject to mutual written agreement on the applicable fees if not already addressed by the fee structure set forth on Exhibit A, and (b) although the Parties may discuss the status of Pre-Approval Services at the JMC, [***].

3.4. **Commercialization Plan and Commercialization Budget**. Eversana shall Commercialize the Product for the approved indication(s) set forth in the label for the Product as part of the Services in accordance with an agreed Commercialization plan (as such plan may be amended from time to time in accordance with this Agreement, the "**Commercialization Plan**"), and a corresponding Commercialization budget (as such budget may be amended from time to time in accordance with this Agreement, the "**Commercialization Budget**").

a. **Content of Commercialization Plan**. The Commercialization Plan shall set forth in detail the activities and the timing and resource deployments necessary to Commercialize the Product in the Territory and otherwise perform the Commercialization Services, Functional Services and Channel Management Services, including, among other things: [***].

Eversana is responsible for all activities under the Commercialization Plan, except for those activities set forth in Exhibit D. The preliminary version of the Commercialization Plan is attached hereto as Exhibit F, which includes a high-level description of the Commercialization Services, Functional Services and Channel Management Services.

b. **Content of Commercialization Budget**. The Commercialization Budget shall set forth a [***] of the fees and Pass-Through Costs corresponding to the activities set forth in the Commercialization Plan, including, among other things:

(i) [***];

(ii) the estimated Pass-Through Costs to be incurred in order to perform the Commercialization Services, Functional Services and Channel Management Services; and

(iii) other supportive detail as reasonably requested by MacroGenics.

The Commercialization Budget shall be organized [***]. The preliminary version of the Commercialization Budget is attached hereto as Exhibit G, which includes a high-level

estimate of the fees and Pass-Through Costs for the Commercialization Services, Functional Services and Channel Management Services, including Eversana's current Rate Sheet for the types of services included in the Commercialization Services, Functional Services and Channel Management Services.

c. **Updates**. Prior to Commercial Launch and on an annual basis thereafter [***], Eversana shall update each Commercialization Plan and Commercialization Budget for the following year. Additionally, Eversana shall update the Commercialization Budget [***]. Eversana shall submit such updated Commercialization Plans and Commercialization Budgets to the JMC for review and approval. [***], the JMC shall either approve the Commercialization Plan and Commercialization Budget prepared by Eversana or approve a modified Commercialization Plan and Commercialization Budget. Any proposed

material changes to a previously approved Commercialization Plan or Commercialization Budget shall not take effect unless and until reviewed and approved by the JMC.

3.5. Use of Affiliates and Third Party Subcontractors.

a. Eversana shall have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates that have been previously disclosed to MacroGenics in writing; provided, that (a) any such Affiliate shall be bound by the obligations set forth in this Agreement, (b) any actions, omissions or conduct by such Affiliate shall be deemed to be actions, omissions or conduct of Eversana, and (c) Eversana shall remain responsible for the performance of its obligations under this Agreement.

b. Eversana shall be permitted to utilize Third Party subcontractors or agents to perform the Services on Eversana's behalf, subject to this Section 3.5.b. Eversana shall include in the Commercialization Plan and the Commercialization Budget the names of any Third Party subcontractors or agents that Eversana proposes to use to perform the Services, the specific Services to be performed by such Third Parties and the estimate for the cost of such Services, including all applicable Pass-Through Costs. The JMC shall have the right to review and approve (or modify) such portions of the Commercialization Plan and Commercialization Budget in accordance with Section 3.4c and Section 4.4. If Eversana desires to engage a Third Party subcontractor or agent to perform the Services outside of the regular process to update the Commercialization Plan and Commercialization Budget, then Eversana shall provide to the JMC in writing the name of such Third Party, the specific Services to be performed by such Third Party and the estimate for the cost of such Services, including all applicable Pass-Through Costs, and the JMC shall have the right to review and approve (or reject) the use of such Third Party in accordance with Section 3.4c and Section 4.4. The following terms and conditions shall apply with respect to any Third Party subcontractor or agent that has been approved by the JMC to perform the Services on Eversana's behalf (an "**Approved Subcontractor**"): (a) each Approved Subcontractor shall be engaged pursuant to a written agreement consistent with the terms of this Agreement to the extent applicable to the Services to be performed by such Approved Subcontractor, including Section 2.6 and Article 11; (b) any actions, omissions or conduct by such Approved Subcontractor shall be deemed to be actions, omissions or conduct of Eversana; and (c) Eversana shall remain responsible for the performance of its obligations under this Agreement.

3.6. Eversana Personnel and Training.

a. In performing the Services, Eversana shall maintain an adequate number of qualified and trained (as specifically required by this Agreement) staff to execute the Services according to the Commercialization Plan and Commercialization Budget and as directed by the JMC. As part of the Commercialization Plan, Eversana shall designate the Eversana Personnel that will be exclusively performing promotional activities for the Product (the "**Dedicated Eversana Personnel**").

b. The Commercialization Plan shall include [***].

c. Eversana shall develop and provide all Training Materials for use hereunder; provided, that the content and format of all Training Materials shall be reviewed and approved by the JMC prior to any use, and the Training Materials shall at all times be in compliance with all applicable Legal Requirements. Eversana shall not use any materials in providing Product Training to Personnel other than the Training Materials reviewed and approved by the JMC. Eversana's use of the Training Materials in connection with training Eversana Personnel under this Agreement shall be in compliance with the terms of this Agreement and the Commercialization Plan. MacroGenics shall own all copyrights and other right, title and interest in and to all Training Materials; provided, that Eversana may use the Training Materials solely for the purposes of performing its obligations under this Agreement and for no other purposes.

d. Eversana shall maintain records related to Product Training [***]. Eversana shall maintain all such attendance records and other Product Training records, including copies of Training Materials used at each Product Training session.

3.7. Use of Third Parties for Commercialization Support.

a. If at any time during the Term, MacroGenics determines in good faith that:

(i) Eversana's performance of particular Commercialization activities for the Product [***];

(ii) [***] for particular Commercialization activities for the Product being provided by Eversana [***]**;** or

(iii) the scope of services required by MacroGenics for particular Commercialization activities for the Product in the [***],

and, in any of such cases, MacroGenics desires [***], then MacroGenics shall first notify Eversana in writing of the alleged Deficiency and the basis therefor, the [***] (a "Section 3.7 Notice").

b. Within [***], Eversana may provide to MacroGenics a written proposal (a "**Section 3.7 Proposal**") to [***], in each case, if Eversana desires to do so in its sole discretion. For clarity, Eversana shall have no obligation to provide any Section 3.7 Proposal. Any Section 3.7 Proposal that Eversana elects to provide shall, as applicable, set forth in reasonable detail (1) [***] set forth in the Section 3.7 Notice, (2) the basis for [***] set forth in the Section 3.7 Notice, or (3) [***] set forth in the Section 3.7 Notice and Eversana's proposed fee structure relating thereto, as applicable. If (a) Eversana does not submit a Section 3.7 Proposal, (b) Eversana notifies MacroGenics that it is not interested in or able to provide the requested support, or (c) MacroGenics determines in its sole discretion that the Section 3.7 Proposal [***] set forth in the Section 3.7 Notice, or provide the [***], as applicable, then MacroGenics shall be entitled [***] and the Commercialization Plan and Commercialization Budget shall be updated accordingly; *provided*, *however*, that if any and all such Commercialization activities for which MacroGenics engages support from any and all such [***], then Eversana shall be entitled to reasonably [***] Eversana remains responsible for performing under this Agreement [***]. Any amounts paid to such Third Party vendor for such support will [***] and shall constitute "**Third Party Commercial Costs**" hereunder. For clarity, this Section 3.7 shall not apply to any Commercialization activities included under (i) Exhibit D or (ii) any services that are not included in the Services. Third Party Commercial Costs [***] of any the aforementioned activities included under (i) and (ii) of this sentence.

3.8. **[***]**. [***].

3.9. **Materials**. Eversana will develop and produce all Materials to be used by Eversana as set forth in the Commercialization Plan, including Promotional Materials and, to the extent compliant with Applicable Laws, Other Materials. All information relating to the Product and MacroGenics provided by MacroGenics to Eversana for use in the Materials shall be accurate and complete in all material respects; provided, that MacroGenics [***]. Following formation of the JMC and prior to the adoption of the Materials Review Process, Eversana shall submit all Materials to the JMC for review and approval before they are used in the performance of the Services. Following the adoption of the Materials Review Process, Eversana shall submit all Materials for review and approval in accordance with the Materials Review Process. All Materials to be used by Eversana pursuant to this Agreement shall at all times be in compliance with Applicable Laws. MacroGenics shall own all Materials and all copyrights therein; provided, that Eversana may use the Materials solely for the purposes of performing its obligations under this Agreement and for no other purposes. Eversana shall promptly notify MacroGenics, and provide MacroGenics with a copy, of any correspondence or other report or complaint received by Eversana from any Regulatory Authority, including the FDA, or any Third Party claiming that any oral or written statements about the Product or any Materials are in violation of Applicable Law or that Eversana Personnel conducting promotion or other Commercialization activities under this Agreement are making statements or claims regarding the Product that are inconsistent with the Materials or permitted use of the Product under Applicable Law.

3.10. **No Registration of Trademarks and Copyrights.** Eversana shall not use (other than in connection with the Services as approved by the JMC), seek to register or register, nor permit any of its Affiliates or Approved Subcontractors to use, seek to register or register, any trademark, service mark, name or logo, including as part of any domain name, social media handle or other identifiers, which is confusingly similar to, or a colorable imitation of, the Product Trademarks, Corporate Trademarks or Product Copyrights in any jurisdiction worldwide. [***].

3.11. **Channel Management Services**. [***] of a channel management services agreement (the "**3PL Agreement**") whereby Eversana shall [***]. The specific terms and conditions related to such Channel Management Services will be set forth in the 3PL Agreement entered into by the Parties. Notwithstanding the foregoing, the Parties acknowledge and agree that, even though the Channel Management Services will be set forth in the 3PL Agreement, the general terms and

conditions set forth in this Agreement shall apply to such Channel Management Services except as expressly agreed otherwise by the Parties.

3.12. Commercialization Covenants.

a. Eversana hereby covenants to MacroGenics that, during the Term in the Territory, it, its Affiliates and the Eversana Personnel will not (i) promote the Product outside of the Territory, (ii) promote the Product other than in compliance with Applicable Law, or
(iii) disparage or present in a negative light the Product in the performance of its obligations hereunder; provided, that nothing herein shall be interpreted to preclude Eversana from
(x) describing any risks of the Product set forth in the label for the Product, or (y) making truthful statements about the Product to the extent required by Applicable Laws, in connection with any litigation or in response to any question, inquiry or request for information when required by legal process (e.g., a valid subpoena or other similar compulsion of law) or as part of a government investigation.

b. Eversana hereby covenants to MacroGenics that during the Term:

(i) it will immediately remove any Eversana Personnel from having any responsibilities relating to promotion of the Product under this Agreement if required by Applicable Laws;

(ii) it will promptly remove any Eversana Personnel from having any responsibilities relating to the promotion of the Product under this Agreement if, following an investigation, it is determined that there has been a significant violation of any Applicable Laws or the Sales and Promotion Policies by such Person; and

(iii) it will not knowingly make any untrue or misleading statements or comments about the Product.

3.13. **Information Data Security Privacy.** Eversana shall process, handle and store, and shall take the measures to ensure the security of, Sensitive Personal Information as provided in Exhibit H (Information) hereto.

4. MANAGEMENT OF THE COLLABORATION

4.1. **Joint Management Committee**. The Parties shall establish a committee (the "**Joint Management Committee**" or "**JMC**") as more fully described in this Article 3.13. The JMC shall have review, oversight, and decision-making responsibilities for all Commercialization activities performed under this Agreement. Each Party agrees to keep the JMC informed of its progress and activities under this Agreement. The JMC shall convene at least once per calendar quarter, or more frequently as requested by either Party's Alliance Manager, to discharge its responsibilities. The Alliance Managers shall meet at least once per month.

4.2. **Membership**. The JMC shall be comprised [***]. Each Party may replace any or all of its representatives on the JMC at any time

upon written notice to the other Party. Each representative of a Party shall have relevant expertise in pharmaceutical drug product Commercialization, and be suitable in seniority and experience and have been delegated the authority to make decisions on behalf of the applicable Party with respect to matters within the scope of the JMC's responsibilities. Any member of the JMC may designate a substitute to attend and perform the functions of that member at any meeting of the JMC. MacroGenics shall designate a chairperson to oversee the operation of the JMC. Such chairperson shall confer with the Alliance Managers of both Parties prior to each JMC meeting to identify issues for review and discussion at each JMC meeting, and circulate a meeting agenda [***].

4.3. **Responsibilities**. The JMC shall perform the following functions:

a. oversee and guide the Services to be provided under this Agreement and confirm Eversana's compliance with the Commercialization Plan;

b. recommend, review and approve amendments or revisions to the Commercialization Plan and the Commercialization Budget;

c. discuss the Services previously performed by Eversana and the Services to be performed by Eversana;

d. discuss the actual costs incurred by Eversana and the Fees paid to Eversana under this Agreement as compared to the estimated budget set forth in the Commercialization Budget;

e. review and discuss Eversana's plans for selecting, training and supervising Eversana Personnel, including Eversana Personnel conducting promotional activities;

f. review and discuss Eversana's plans to promote the Product in the Territory in accordance with the Commercialization Plan;

g. review and discuss Eversana's [***] related to the Product;

h. review and approve the Eversana Compliance/Review Policies;

i. subject to Section 3.9, (i) review and approve Materials, and (ii) develop, adopt and oversee the implementation of a process for the review and approval of Materials, including any necessary legal, regulatory and medical review (the "**Materials Review Process**");

j. form such other subcommittees as the JMC may deem appropriate, provided that all actions and decisions of any such subcommittee shall be subject to the approval of the JMC;

k. attempt to resolve any disputes on an informal basis; and

l. perform such other functions as expressly set forth in this Agreement.

The JMC shall further serve as a forum for discussion and shall perform such other functions agreed to by the Parties. A calendar quarterly business review will be presented by Eversana

to the JMC. Any changes to the Commercialization Plan or Budget (e.g. Product pricing, marketing, distribution plan, etc.) shall require final approval from the JMC.

4.4. **Decisions**. Except as otherwise provided herein, with respect to Commercialization of the Product, [***]. If the JMC cannot agree on a matter within its authority hereunder after it has met and attempted to reach such decision, then, either Party may, by written notice to the other, have such issue referred to the Executive Officers for resolution. The Parties' respective Executive Officers shall meet [***], and shall negotiate in good faith to resolve the matter. If the Executive Officers are unable to resolve the matter [***], then the issue shall be finally resolved by MacroGenics, unless the issue or decision increases Eversana's aggregate annual financial or capital expenditures in excess of [***] of the annual aggregate amount set forth in the then- current and approved Commercialization Budget, in which event the issue shall be resolved [***]. The JMC shall have only such rights, powers and authority as are expressly delegated to it under this Agreement, and such rights, powers and authority shall be subject to the terms and conditions of this Agreement. The JMC shall not be a substitute for the rights of the Parties hereunder. Notwithstanding any other provision of this Agreement to the contrary, the JMC shall not have any right, power or authority: (a) to determine any issue in a manner that would conflict with the express terms and conditions of this Agreement; or (b) to waive, modify or amend the terms and conditions of this Agreement.

5. Fees and Payments

5.1. Pre-Approval Service Fees. MacroGenics shall be responsible for [***], Eversana shall invoice MacroGenics for the Pre-Approval Service Fees that were incurred during such month. MacroGenics shall pay each such invoice [***], provided that if MacroGenics in good faith disputes the invoiced amount or any portion thereof, MacroGenics shall provide written notice thereof, including the amount in dispute and MacroGenics' basis for disputing such amount, and shall pay the undisputed portion of such invoice, in each case, [***]. The Parties shall promptly attempt in good faith to resolve such dispute.

5.2. Reconciled Reimbursed Commercial Costs and Reconciled Unreimbursed Commercial Costs during the Adjusted Revenue Sharing Period.

a. [***], Eversana shall invoice MacroGenics (each such invoice, a "**Quarterly Invoice**") for fifty percent (50%) of the estimated fees and Pass-Through Costs allocated to such calendar quarter for the Commercialization Services, the Functional Services and Channel Management Services according to the Commercialization Budget ("**Estimated Reimbursed Commercial Costs**"). The remaining fifty percent (50%) of the estimated fees and Pass-Through Costs allocated to such calendar quarter shall be referred

to herein as the "**Estimated Unreimbursed Commercial Costs**" and shall be the sole responsibility of Eversana, subject to the payment of any Refund Amounts or True-Up Amounts and Sections 14.2.c and 14.2.f.

[***]

5.3. **Reporting of Product Volume Sold.** Unless otherwise agreed by the JMC, on a monthly basis, Eversana shall report to MacroGenics, [***]

, the number of vials of the Product sold through Eversana's distribution and pharmacy networks during such month.

5.4. **Sharing of Adjusted Net Revenue**. Eversana shall be entitled to receive payments based on tiers of Adjusted Net Revenue ("**Adjusted Revenue Share Payments**") in each calendar year (or portion thereof) during the Adjusted Revenue Sharing Period at the following incremental rates:

Annual Adjusted Net Revenue	**Revenue Share Payment Percentage**
On that portion of Adjusted Net Revenue in a calendar year [***]	[***]
On that portion of Adjusted Net Revenue in a calendar year [***]	[***]
On that portion of Adjusted Net Revenue in a calendar year [***]	[***]

By way of illustration, if Adjusted Net Revenue in a given calendar year is [***], Eversana would be entitled to receive an Adjusted Revenue Share Payment of [***], calculated as follows: [***].

When the total cumulative sum of all Reconciled Reimbursed Commercial Costs and Adjusted Revenue Share Payments equals one hundred twenty five percent (125%) of the total cumulative sum of Reconciled Reimbursed Commercial Costs and Reconciled Unreimbursed Commercial Costs (the "**Revenue Threshold**"), the consideration payable to Eversana for the performance of the Services shall convert to a fee-for-service arrangement under which MacroGenics shall pay to Eversana [***] for the Services performed during the remainder of the Term in accordance with the Commercialization Plan, [***] (the fees and costs payable under such arrangement, collectively, the "**Fee-for-Service Fees**").

5.5. Payment of Adjusted Revenue Payments.

a. [***] the Adjusted Net Revenue Sharing Period, MacroGenics shall submit a written report to Eversana that provides the following information regarding such calendar quarter ("**Adjusted Revenue Report**"):

(i) total Net Sales, including the types and total amount of each type of Net Sales Deduction taken to calculate the total Net Sales;

(ii) Third Party Commercial Costs;

(iii) the Adjusted Revenue Share Payment due to Eversana and the calculations to support such amount;

(iv) any adjustments to Net Sales from the prior calendar quarter; and

(v) any adjustments to the Adjusted Revenue Share Payment from the prior calendar quarter and the calculations to support such amount ("**Prior Quarter Adjustments**").

Concurrently with delivery of each Adjusted Revenue Report, MacroGenics shall pay to Eversana [***], in each case as calculated in such Adjusted Revenue Report. Eversana's receipt and acceptance of any such payment shall be without prejudice to Eversana's rights or MacroGenics' obligations under Sections 5.5.b, 5.5.c, 5.5.d and 10.2.

b. If Eversana in good faith disputes the amounts set forth in any Adjusted Revenue Report and paid by MacroGenics pursuant to Section 5.5.a, Eversana shall deliver written notice to MacroGenics of such dispute ("**Disputed Report Response**") [***] Adjusted Revenue Report ([***], a "**Report Response Period**"). In each Disputed Report Response, Eversana shall state the basis(es) of its dispute(s), identify the specific aspects of such Adjusted Revenue Report with which it disagrees or that it believes are incorrect and provide what it deems to be the proper calculation of the Adjusted Revenue Share Payment and/or Prior Quarter Adjustments. If Eversana fails to submit a Disputed Report Response with respect to an Adjusted Revenue Report before the expiration of the applicable Report Response Period, such Adjusted Revenue Report shall be deemed to have been accepted by Eversana, provided that such deemed acceptance shall be without prejudice to Eversana's rights or MacroGenics' obligations under Section 10.2.

c. [***] Disputed Report Response disputing an Adjusted Revenue Report, MacroGenics shall respond to Eversana in writing as to whether it accepts or rejects such Disputed Report Response. If MacroGenics accepts such Disputed Report Response, it shall pay to Eversana the difference between the amount that Eversana claims is actually due for the applicable calendar quarter as set forth in such Disputed Report Response and the amount paid by MacroGenics to Eversana for such calendar quarter pursuant to Section 5.5.a. If MacroGenics disagrees with such Disputed Report Response, MacroGenics shall state in its response the basis(es) of its rejection(s) and identify the specific aspects of the Disputed Report Response with which it disagrees or believes is incorrect.

d. The Parties shall rely on the dispute resolution procedures provided in Section 16.3 to resolve disagreements regarding an Adjusted Revenue Report for which Eversana has

issued a Disputed Report Response and MacroGenics has rejected such Disputed Response Report.

5.6. **Payment of Fee-for-Service Fees**. Following achievement of the Revenue Threshold, [***], Eversana shall submit a report to MacroGenics that details the Services performed during such calendar quarter and an invoice for the Fee-for-Service Fees due with respect thereto. MacroGenics shall pay each such invoice [***], provided that if MacroGenics in good faith disputes the invoiced amount or any portion thereof, MacroGenics shall provide written notice thereof, including the amount in dispute and MacroGenics' basis for disputing such amount, and shall pay the undisputed portion of such invoice, in each case, [***]. The Parties shall promptly attempt in good faith to resolve such dispute.

5.7. **Taxes**. The amounts payable by a Party to the other Party pursuant to this Agreement shall be paid free and clear of any and all taxes, except for any withholding taxes required by Applicable Law. Except as provided in this Section 5.7, the receiving Party shall be solely responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be deducted from payments and remitted by the paying Party) levied on account of, or measured in whole or in part by reference to, any payments it receives. The paying Party shall deduct or withhold from the payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if the receiving Party is entitled under any applicable tax treaty to a rate reduction of, or the elimination of, applicable withholding tax, it may deliver to the paying Party or the appropriate Governmental Authority (with the assistance of the paying Party to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the paying Party of its obligation to withhold such tax and the paying Party shall apply the reduced rate of withholding or dispense with withholding, as the case may be; provided that the paying Party has received evidence, in a form satisfactory to the paying Party, of the receiving Party's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) [***]. If, in accordance with the foregoing, the paying Party withholds any amount, it shall pay to the receiving Party the balance when due, make timely payment to the proper taxing authority of the withheld amount and send to the receiving Party proof of such payment [***].

5.8. **Fee Increases**. [***], Eversana shall have the right to increase any then-current transaction or monthly fees for a Service provided under this Agreement (excluding Services compensated on an FTE basis) by [***]; provided, that unless MacroGenics' provides its written consent, in no event shall such percentage increase [***].

5.9. Fee Structure.

a. The Parties agree that, with respect to the fees for the Services set forth in the Commercialization Plan: (a) the fees charged by Eversana to MacroGenics hereunder shall be [***]; (b) upon the request of MacroGenics, Eversana shall provide supporting documentation relating to Approved Subcontractors and Pass-Through Costs; (c) for any Service that utilizes shared resources across multiple clients of Eversana, Eversana agrees to charge MacroGenics [***]; and (d) Eversana shall not double count Fees that are charged to MacroGenics [***].

6. REGULATORY MATTERS

6.1. **Ownership of Regulatory Documentation and Approvals**. MacroGenics is solely responsible for and owns all right, title and interest in and to all Regulatory Documentation concerning the Product, including any BLA Approval, and all information contained therein.

6.2. Responsibility for Regulatory Approvals and Regulatory Communications.

a. MacroGenics has the sole right and responsibility for obtaining and maintaining all regulatory approvals, including BLA Approvals, for the Product, and for complying with all regulatory reporting obligations with respect to the Product.

b. MacroGenics has the sole right and obligation to: (i) make any communications, reports, submissions and responses to FDA concerning the Product, including by reporting Adverse Events, Other Reportable Information, Field Alerts, and other Regulatory Documentation; and (ii) take any action (including any investigations) and conduct all communications with all Third Parties that relate to all Product Quality Complaints or complaints related to tampering or contamination with respect to the Product, Adverse Events, Other Reportable Information and Field Alerts with respect to the Product; provided, however, that Eversana shall be responsible for any communications, reports, submissions or responses to Regulatory Authorities that it may be required to make under Applicable Law in connection with performing the Services; and provided, further that Eversana shall, to the extent permitted by Applicable Law, provide MacroGenics with (x) reasonable advance written notice of, and an opportunity to discuss in good faith, any proposed communication with FDA in advance thereof with respect to the Product or any activities of MacroGenics hereunder, or (y) written notice to MacroGenics of any communication with FDA concerning the Product or any activities of MacroGenics hereunder promptly following such communication and attach copies of such communication (whether by FDA or Eversana) to such notice. Notwithstanding the above, all investigations of Eversana employees or agents related to employment matters and Eversana internal policies and procedures may be conducted independently (with prompt notice to MacroGenics) by Eversana, and investigations relating to the Product or potential violations of Applicable Law shall be conducted in collaboration with MacroGenics.

c. Eversana shall cooperate with reasonable requests by MacroGenics and assist MacroGenics in connection with: (i) preparing any and all reports to FDA concerning the Product; (ii) preparing and disseminating all communications to Third Parties concerning the Product; and (iii) investigating and responding to any Product Quality Complaint, Adverse Event, Other Reportable Information, Field Alert, or other compliance inquiry or investigation related to the Product. Except as expressly set forth in Section 6.2.b above, MacroGenics is solely responsible for any and all communications with a Governmental Authority and for ensuring that all such communications comply with Applicable Laws. For purposes of clarification, MacroGenics shall be responsible for any and all regulatory reporting requirements including but not limited to aggregate spend reporting, reporting required by any State, as applicable, and pursuant to the disclosures required under the Patient Protection and Affordable Care Act ("**PPACA**"), even if there are joint disclosure obligations; [***], MacroGenics shall provide Eversana with confirmation that such disclosures were properly made. MacroGenics is also solely responsible for: (x) all state and other municipal disclosures, including those related to drug samples, marketing expenses, product pricing, etc., and (y) all state and local municipal disposal laws related to the Product. Eversana shall reasonably cooperate with and assist MacroGenics, as reasonably requested in connection with such reporting requirements, including by providing MacroGenics, on a monthly basis, with details of Eversana's aggregate spending in connection with the Services provided hereunder, to allow MacroGenics to comply with the reporting requirements set forth above.

d. MacroGenics shall be responsible for (i) making statements, whether written, oral or electronic, to Third Parties regarding Product Quality Complaints, Adverse Events, Other Reportable Information, Field Alerts, or other compliance inquiries or investigations with respect to the Product, and (ii) taking any action concerning any Regulatory Authority approval under which the Product is sold. For clarification, in the event Eversana becomes aware of a Product Quality Complaint, Adverse Event, Other Reportable Information, Field Alert, or other compliance inquiry or investigation with respect to the Product, Eversana is only responsible for informing the Third Party that information in respect thereof has been or will be conveyed by Eversana to MacroGenics.

6.3. Adverse Events, Other Reports and Threatened Governmental Authority Action.

a. Eversana shall report to MacroGenics [***]:

i. an Adverse Event or Other Reportable Information associated with the use of the Product or information in or coming into its possession or control concerning such Adverse Event or Other Reportable Information;

ii. information that might necessitate the filing by MacroGenics of a Field Alert;

iii. information relating to an actual or threatened recall of the Product; or

iv. any Product Quality Complaint associated with the use of the Product.

All such reports shall be made to the attention [***]. MacroGenics may update the individual to whom such reports shall be made by providing written notice thereof to Eversana.

b. Unless restricted or prohibited by Applicable Law or Governmental Authority, Eversana shall promptly notify MacroGenics if it receives information regarding any threatened or pending action regarding the Product by any Governmental Authority in the Territory.

c. All training materials regarding Adverse Events, Other Reportable Information, Field Alerts and Product Quality Complaints to be utilized by Eversana in connection with its provision of the Services shall either be provided by MacroGenics to Eversana or, to the extent Eversana prepares such materials, shall be approved by MacroGenics. These training materials shall include the contact number and method of transferring potential reports and any specific product information related to the Product.

7. PRODUCT MATTERS

7.1. **Orders for Product; Terms of Sale; Returns**. All sales will be recorded in MacroGenics's name. MacroGenics shall have the ultimate responsibility and right to take, accept, reject or cancel orders, fill orders and establish and modify the terms and conditions of the sale of the Product (including with regard to any patient assistance programs and returns), subject to compliance with the approved Commercialization Plan and all action plans previously approved by the JMC. Notwithstanding the foregoing, Eversana shall have the day-to-day responsibility and right to take, accept, reject or cancel orders, and fill orders so long as such actions are consistent with the approved Commercialization Plan, Commercialization Budget and all action plans previously approved by the JMC.

7.2. **Returned Product**. Eversana shall notify MacroGenics of any returned Product, cooperate with MacroGenics regarding the handling of such Product, and follow such other Product return procedures as set forth in the 3PL Agreement.

7.3. **Recalled Product**. Each Party shall promptly notify the other Party in writing of any facts relating to the advisability of the recall, withdrawal or withholding from the market of the Product in the Territory. MacroGenics shall have the sole responsibility and right to determine if any recall, withdrawal or other form of market action is necessary with respect to the Product and shall be solely responsible for taking all actions to effect such recall, withdrawal or market action. At MacroGenics's request, Eversana will cooperate with MacroGenics regarding MacroGenics's handling of any recalls, withdrawals or similar market actions. MacroGenics shall be responsible for all costs incurred in connection with any recalls, withdrawals or market actions concerning the Product except that Eversana shall be responsible for such costs to the extent such recalls, withdrawals or market actions are caused by Eversana's negligence, failure to comply with Applicable Law, or breach of this Agreement.

8. COMPLIANCE MATTERS

8.1. **Obligation to Notify**. Each Party shall promptly notify the other Party upon becoming aware of any potential breach or potential violation by such Party's employees of the Anti- Corruption Laws in the performance of such Party's obligations under this Agreement and shall take such steps as the Parties may reasonably agree to avoid a potential violation of the Anti-Corruption Laws in the performance of obligations under this Agreement.

8.2. **Compliance with Law and Ethical Business Practices**. In addition to the other representations, warranties and covenants made by each Party under this Agreement, each Party hereby represents, warrants and covenants to the other Party that, during the Term in the Territory:

a. it is, and will remain during the Term, licensed, registered and/or qualified under Applicable Law to do business, and has obtained such licenses, consents, authorizations or completed such registrations or made such notifications as may be necessary or required by Applicable Law to perform its obligations under this Agreement;

b. it will perform its obligations under this Agreement in material compliance with this Agreement (including, with respect to Eversana, the Commercialization Plan), Applicable Laws (including the FD&C Act, the Anti-Kickback Statute (42 U.S.C. § 1320a-7b), Civil Monetary Penalty Statute (42 U.S.C. § 1320a-7a), the False Claims Act (31 U.S.C. § 3729 et seq.), comparable state statutes, the regulations promulgated under all such statutes, and the regulations issued by the FDA), and such Party's Applicable Compliance/Review Policies and/or any agreed to compliance related policies or procedures governing Commercialization; and

c. with respect to the Product and any payments or Services provided under this Agreement, such Party has not taken, and during the Term will not take, any action, directly or indirectly, to offer, promise or pay, or authorize the offer or payment of, any money or anything of value in order to improperly or corruptly seek to influence any Government Official in order to gain an improper advantage, and has not accepted, and will not accept in the future such payment.

8.3. **Additional Eversana Covenants**. In addition to the other representations, warranties and covenants made by Eversana under this Agreement, Eversana hereby represents, warrants and covenants to MacroGenics that, during the Term in the Territory:

a. Eversana has implemented and will maintain and enforce a compliance and ethics program designed to prevent and detect violations of Applicable Laws throughout its operations (including Affiliates) and the operations of Eversana Personnel that have responsibility for the payments or the Services provided under this Agreement, including by implementing policies and procedures setting out rules governing interactions with HCPs and Government Officials; the engagement of Third Parties, and where appropriate, due diligence; and the investigation, documentation, and remediation of any allegations, findings, or reports related to a potential violation of its Applicable Compliance/Review Policies. Such compliance program shall include at a minimum, compliance officer,

compliance committee(s), policies and procedures relating to (i) sales, medical, promotional and marketing activities for the Product, (ii) regular auditing and monitoring,
(iii) training on sales, medical, promotional and marketing activities and the relevant legal requirements regarding such activities, (iv) methods to raise questions or concerns internally (e.g., via a hotline) without fear of retribution or retaliation, (v) processes for investigating and documenting any compliance concerns or allegations raised, findings or reports related to a potential violation of Applicable Laws, and (vi) taking remedial, corrective action and/or disciplinary action, as appropriate;

b. in the event that Eversana receives a report of or otherwise becomes aware of a potential violation of its Applicable Compliance/Review Policies, Eversana will perform an investigation in accordance with its established policies and procedures and will take all necessary and appropriate responsive, and corrective actions, including disciplinary actions (up to and including termination of any employee, contractor, agent, sub-contractor, customer, vendor or other Person that Eversana believes was responsible);

c. Eversana has implemented, and will at all times during the Term maintain, adequate policies and procedures describing the materials and information that may be distributed or discussed by the Eversana Personnel related to the Product and the manner in which such Persons should handle unsolicited requests for information related to off-label uses of the Product, which policies and procedures shall be designed to ensure compliance with Applicable Laws;

d. Eversana regularly reviews its Applicable Compliance/Review Policies as part of its internal processes of improvement, and, from time to time, benchmarks them against the standards of the industry;

e. Eversana has implemented, and will at all times during the Term maintain, adequate systems, policies, and procedures to screen before hire and annually thereafter all prospective and current Eversana Personnel conducting activities with respect to the Product against (i) the List of Excluded Individuals/Entities compiled by the Office of the Inspector General in the Department of Health and Human Services and (ii) the General Services Administration's List of Parties Excluded from Federal Programs, which policies and procedures require Eversana's prospective and current Eversana Personnel conducting activities with respect to the Product to disclose immediately to Eversana that such Representative is or may become debarred, suspended or excluded;

f. in connection with this Agreement, Eversana's compensation system for the Eversana Personnel that perform any marketing, promotion or sales activities related to the Product is designed to ensure that financial incentives do not inappropriately motivate such Eversana Personnel to engage in improper or illegal promotion, sales or marketing of the Product (including off-label promotion of the Product); and

g. in connection with this Agreement, Eversana's call planning system for the Eversana Personnel that call upon HCPs or health care institutions for any promotional or sales activities related to the Product is designed to ensure that such Eversana Personnel do not

call upon HCPs or health care institutions that are not likely to prescribe or use the Product for an on-label use.

8.4. **Notice of Investigations**. Each Party shall promptly notify the other Party in the event that it becomes subject to or aware of any FDA or other Governmental Authority inspection, investigation, or other inquiry or a FDA warning letter, untitled letter, or other material governmental notice or communication relating to the Services or the Product promptly after the Party becomes aware of such inspection, investigation, inquiry, letter, notice, or communication, except to the extent that the disclosing Party's counsel reasonably believes that such disclosure to the other Party could violate Applicable Laws (including privacy laws) or have a significant adverse impact on the disclosing Party's legal position or defense (including the loss of attorney-client privilege) with respect to any such inspection, investigation or other inquiry. In the event that the Party determines that disclosure could violate Applicable Laws (including privacy laws) or have a significant adverse impact on the disclosing Party's legal position or defense (including the loss of attorney-client privilege), the Party shall promptly notify the other Party that it is exercising its right not to make such disclosure.

9. INDEPENDENT CONTRACTOR

9.1. **Independent Contractor Status**. The status of each Party under this Agreement shall be that of an independent contractor. Except as otherwise set forth herein, neither Party shall have the right to enter into any agreements on behalf of the other Party, nor shall it represent to any Person that it has any such right or authority.

9.2. Eversana and its directors, officers, employees and any persons providing Services under the Agreement are at all times independent contractors with respect to MacroGenics. Persons provided by Eversana to perform the Services shall not be deemed employees of MacroGenics. Neither this Agreement nor the Services to be rendered hereunder shall for any purpose whatsoever or in any way or manner create any employer-employee relationship between Eversana, its directors, officers, employees and any persons providing Services under this Agreement, on the one hand, and MacroGenics, on the other hand. MacroGenics understands that Eversana may utilize independent contractors in connection with its performance of the Services, subject to Section 3.5.

9.3. Eversana is, and at all times shall remain, solely responsible for the human resource and performance management functions of all Eversana personnel provided to perform the Services. Eversana shall be solely responsible for all disciplinary, probationary and termination actions taken by it, and for the formulation, content and dissemination of all employment policies and rules (including written disciplinary, probationary and termination policies) applicable to its employees, agents and contractors, including its employees, agents and contractors who perform the Services hereunder.

9.4. Eversana shall obtain and maintain worker's compensation insurance and other insurance required for Eversana Personnel and acknowledges that under this Agreement MacroGenics does not, and shall not, obtain or maintain such insurance, all of which shall be Eversana's sole responsibility.

9.5. The Parties agree that Eversana Personnel are not, and are not intended to be or be treated as employees of MacroGenics and that no such individual is, or is intended to be, eligible to participate in any benefits programs or in any MacroGenics "employee benefit plans" (as defined in Section 3(3) of ERISA).

9.6. Except as otherwise set out in this Agreement, MacroGenics shall have no responsibility to Eversana or any Eversana Personnel for any compensation, expense reimbursements or benefits (including, without limitation, vacation and holiday remuneration, healthcare coverage or insurance, life insurance, pension or profit-sharing benefits and disability benefits, payroll-related or withholding taxes, or any governmental charges or benefits (including, without limitation, unemployment and disability insurance contributions or benefits and workers compensation contributions or benefits) that may be imposed upon or be related to the performance by Eversana or its employees, agents or contractors of Eversana's obligations under this Agreement, all of which shall be the sole responsibility of Eversana. To clarify, MacroGenics will not withhold any income tax or payroll tax of any kind on behalf of Eversana.

9.7. Limitations.

a. Notwithstanding anything to the contrary in this Article 9, Eversana shall have no obligation or responsibility for any damages, liability, loss and costs, including but not limited to attorney's fees (collectively, "**Liability**") to the extent such Liability is attributed to either: (i) discriminatory and/or intentional acts of MacroGenics, its employees, agents or contractors; or (ii) any benefits payable under any MacroGenics benefit plan, including any bonus, stock option, stock purchase, incentive, deferred compensation, supplemental retirement, severance or other similar fringe or employee benefit plan, program or arrangements that may be sponsored at any time by MacroGenics that cause, or are either alleged to cause or interpreted by any court or Governmental Authority to cause, any Eversana Personnel to be reclassified as an employee of MacroGenics. In the event any Liability is alleged against Eversana or its employees that is attributable to MacroGenics (as set forth in clauses (i) and (ii) of this Section 9.7.a), MacroGenics shall indemnify, defend, and hold harmless Eversana and its directors, officers, employees and contractors.

b. Notwithstanding anything to the contrary in this Article 9, MacroGenics shall have no obligation or responsibility for any Liability to the extent such Liability is attributed to either: (i) discriminatory and/or intentional acts of Eversana, its employees, agents or contractors; or (ii) any benefits payable under any Eversana benefit plan, including any bonus, stock option, stock purchase, incentive, deferred compensation, supplemental retirement, severance or other similar fringe or employee benefit plan, program or arrangements that may be sponsored at any time by Eversana that cause, or are either alleged to cause or interpreted by any court or Governmental Authority to cause, any MacroGenics personnel to be reclassified as an employee of Eversana. In the event any Liability is alleged against MacroGenics or its employees that is attributable to Eversana (as set forth in clauses (i) and (ii) of this Section 9.7.b), Eversana shall indemnify, defend, and hold harmless MacroGenics and its directors, officers, employees and contractors.

10. STATEMENTS, RECORD-KEEPING AND AUDITS

10.1. **MacroGenics Records**. MacroGenics shall keep complete and accurate books and records of Net Profits (including all amounts used to calculate Net Profits), Adjusted Net Revenue, Revenue Share Payments and all other financial information necessary to determine the payments to be made under this Agreement. MacroGenics shall keep such books and records, or shall cause such books and records to be kept, for a period [***]. All financial books and records kept by MacroGenics hereunder shall be maintained in accordance with GAAP, consistently applied.

10.2. **Audits of MacroGenics**. At the request of Eversana, MacroGenics shall, and shall cause its Affiliates to, permit an independent auditor designated by Eversana, at reasonable times and upon at least [***] prior notice, to audit the books and records maintained pursuant to Section 10.1 to ensure the accuracy of all calendar quarterly reports and payments made hereunder. Each such audit may occur [***] and [***]. Eversana may exercise its audit right during the Term [***]. The cost of any such audit shall be borne by Eversana unless the audit reveals that Eversana has been underpaid [***], in which case MacroGenics shall reimburse Eversana for any third party costs reasonably incurred in connection with the audit, [***].

10.3. **Eversana Records**. Eversana shall keep, or shall cause to be kept, complete and accurate books and records (financial and otherwise) pertaining to the performance of the Services, including with respect to regulatory and compliance matters and any amounts used to calculate the Fees, in sufficient detail to verify compliance with its obligations hereunder and to calculate and verify all amounts payable hereunder. Eversana shall keep such books and records, or shall cause such books and records to be kept, [***]. All financial books and records kept by Eversana hereunder shall be maintained in accordance with GAAP, consistently applied.

10.4. **Audits of Eversana**. At the request of MacroGenics, Eversana shall, and shall cause its Affiliates to, permit an independent auditor designated by MacroGenics, at reasonable times and [***], to audit the books and records maintained pursuant to Section 10.3 to ensure Eversana's compliance with this Agreement, including the accuracy of all reports and payments made hereunder. Each such audit [***]; provided, that if any such audit reveals that Eversana is or was not in material compliance with Applicable Law or the Eversana Compliance/Review Policies with respect to the performance of its obligations under this Agreement, MacroGenics shall have the right to conduct such additional audits as may be reasonably required by MacroGenics to determine whether Eversana has appropriately remedied such non-compliance. MacroGenics may exercise its audit right during the Term and [***]. The cost of such audit shall be borne by MacroGenics unless the audit reveals that Eversana has been overpaid as a result of an

inaccuracy in Eversana's reports to MacroGenics [***], in which case Eversana shall reimburse MacroGenics for any third party costs reasonably incurred in connection with the audit, [***].

11. CONFIDENTIALITY

11.1. Maintaining Confidentiality. Confidential Information disclosed under this Agreement shall remain the property of the Disclosing Party. At all times during the Term [***], the Receiving Party shall use the Confidential Information solely for the purposes set forth in this Agreement and shall not disclose such Confidential Information to any Third Party except as permitted under this Agreement or with the Disclosing Party's prior written consent. The Receiving Party shall use at least the same care for maintaining confidentiality of the Confidential Information as it uses to maintain the confidentiality of its own Confidential Information of similar value, but in no event less than commercially reasonable measures within the pharmaceutical industry.

11.2. **Exceptions to Confidentiality**. The Receiving Party's obligations set forth in this Agreement shall not extend to any Confidential Information of the Disclosing Party that the Receiving Party can demonstrate by competent evidence:

a. was in the Receiving Party's possession and at its free disposal prior to disclosure by the Disclosing Party;

b. was in the public domain at the time of disclosure by the Disclosing Party;

c. subsequently comes into the public domain through no fault, action or omission of the Receiving Party in breach of this Agreement;

d. becomes available to the Receiving Party without any obligation of confidentiality from a Third Party that is not known to have a confidentiality obligation to the Disclosing Party; or

e. was developed independently by the Receiving Party without use of or reliance on any Confidential Information disclosed or furnished by the Disclosing Party, as evidenced by the Receiving Party's contemporaneously-maintained written records.

11.3. **Authorized Disclosure**. The Receiving Party may disclose Confidential Information, including the Agreement Details, to the extent that such disclosure is:

a. to its directors, officers, employees, advisers, consultants, attorneys, auditors, agents, contractors, or representatives that reasonably need to know the information for the purposes set out in this Agreement, and who are subject to obligations of confidentiality and non-use substantially as protective as those set forth in this Agreement;

b. to its Affiliates, including their directors, officers, employees, advisors, consultants, agents, contractors or representatives, to the extent they reasonably need to know the information for the purposes set out in this Agreement, and who are subject to confidentiality and non- use obligations substantially as protective as those set forth in this Agreement;

c. to its directors, officers, employees, advisers, consultants, legal counsel or auditors who need to know the Confidential Information for the purpose of the Receiving Party's internal compliance or auditing functions and who are subject to obligations of confidentiality and non-use substantially as protective as those set forth in this Agreement;

d. [***], who are subject to confidentiality and non-use obligations substantially as protective as those set forth in this Agreement; except that with respect to Third Party investors, under obligations of confidentiality and non-use that are typical for the circumstances;

e. [***] who are subject to obligations of confidentiality and non-use substantially as protective as those set forth in this Agreement;

f. as required by laws, rules of public stock exchanges or court orders, provided that the Receiving Party may disclose only such portion of the Confidential Information as is legally required, and provided further that (i) the Receiving Party shall provide the Disclosing Party with as much advance written notice of such requirement as is reasonably possible and a reasonable opportunity to object to or limit such disclosure, and (ii) at the Disclosing Party's request and expense, cooperates with the Disclosing Party's lawful efforts to contest such requirement or to obtain a protective order or other confidential treatment of the Confidential Information required to be disclosed. The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with any securities authority or other Governmental Authority or any stock exchange on which securities issued by a Party or its Affiliate are traded, and each Party will use reasonable efforts to seek and obtain confidential treatment for the terms proposed to be redacted; provided, that nothing herein shall prevent a Party from making disclosures to any securities authority or stock exchange, as the case may be, to the extent such Party determines, on the advice of legal counsel, that disclosure is reasonably necessary to comply with Applicable Laws, including disclosure requirements of the U.S. Securities and Exchange Commission, or with the requirements of any stock exchange on which securities issued by a Party or its Affiliates are traded; and provided further that the Parties will use their reasonable efforts to file redacted versions with any Governmental Authorities which are consistent with redacted versions previously filed with any other Governmental Authority.

11.4. **Return or Destruction of Confidential Information**. On or after the effective date of the expiration or termination of this Agreement for any reason, at the Disclosing Party's written

request, the Receiving Party shall either, with respect to Confidential Information to which such Receiving Party does not retain rights under the surviving provisions of this Agreement:

(b) promptly destroy all copies of such Confidential Information in the possession or control of the Receiving Party and confirm such destruction in writing to the Disclosing Party; or

(c) promptly deliver to the Disclosing Party, at the Receiving Party's sole cost and expense, all copies of such Confidential Information in the possession or control of the Receiving Party. Notwithstanding the foregoing, the Receiving Party shall be permitted to retain such Confidential Information (i) to the extent necessary or useful for purposes of performing any continuing obligations or exercising any ongoing rights hereunder and, in any event, a single copy of such Confidential Information for archival purposes, and (ii) any computer records or files containing such Confidential Information that have been created solely by the Receiving Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with the Receiving Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 11.1.

11.5. Use of Name and Disclosure of Agreement Details.

Subject to this Section 11.5, except as necessary to perform a Party's obligations under this Agreement or as expressly permitted under this Agreement, each Party (a) shall keep the existence, terms, and the subject matter (including the applicable transactions) covered by this Agreement confidential and shall not disclose such information to any other Person through a press release or otherwise, and (b) shall not mention or otherwise use the name or any trademark of the other Party or its Affiliates in connection with this Agreement, in each case ((a) and (b)), without the prior written consent of the other Party in each instance (which shall not be unreasonably withheld, conditioned or delayed). The restrictions imposed by this Section 11.5 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law or the requirements of a national securities exchange or another similar regulatory body, provided that any such disclosure shall be governed by Section 11.3f. Nor shall the restrictions imposed by this Section 11.5 prohibit either Party from announcing this Agreement to the public promptly following the Effective Date, including such key terms and other items appropriate for such a public release, in each case subject to the written consent of the other Party, which shall not be unreasonably withheld. Further, the restrictions imposed on each Party under this Section 11.5 are not intended, and shall not be construed, to prohibit a Party from (x) identifying the other Party in its internal business communications, provided that any Confidential Information in such communications remains subject to this Article 11, or (y) disclosing (i) information for which consent has previously been obtained, and (ii) information of a similar nature to that which has been previously disclosed publicly with respect to this Agreement, each of which ((i) and (ii)) shall not require advance approval.

12. REPRESENTATIONS AND WARRANTIES

12.1. **Mutual Representations and Warranties**. Each Party represents and warrants to the other Party that as of the Effective Date:

a. it is duly organized, validly existing in good standing under the laws of the place of its establishment or incorporation;

b. it has full authority to enter into this Agreement and to perform its obligations under this Agreement and the provisions of this Agreement are legally binding upon it from the Effective Date;

c. its execution of this Agreement and performance of its obligations under it will not violate (i) any provision of its business license, articles of incorporation, articles of association or similar organizational documents; (ii) any Applicable Laws or any authorization or approval from a Governmental Authority; and (iii) any contract to which it is a party or to which it is subject, or result in a default under any such contract;

d. no lawsuit, arbitration or other legal or governmental proceeding is pending or, to its knowledge, threatened against it that would affect its ability to perform its obligations under this Agreement;

e. it has not been debarred and is not subject to debarment pursuant to Section 306 of the Act or who is the subject of a conviction described in such section;

f. it and its Affiliates are in compliance with (x) the PhRMA Code on Interactions with Healthcare Professionals and (y) all state codes or requirements that limit or regulate interactions with HCPs;

g. it has not been debarred, suspended or excluded from any federal health care program, including Medicare, Medicaid and the Civilian Health and Medical Program of the Uniformed Services. If it or any of its employees who are involved in performing the Services or working with the other Party in connection with the program described herein, is debarred, suspended or excluded during the Term or such Party reasonably believes debarment, suspension or exclusion is contemplated, such Party shall immediately notify the other Party in writing upon it becoming aware of such debarment, suspension or exclusion. If a Party is so debarred, suspended or excluded, or in the case of any employee of such Party who is debarred, suspended or excluded, if the applicable Party permits such employee to continue to perform any Services or work on the program described herein, then the other Party shall have the right to terminate this Agreement upon written notice to such Party. Any termination of this Agreement pursuant to this Section 12.1.g shall be treated as a termination by the terminating Party pursuant to Section 14.2.d as if the other Party had committed a material breach, except that in such event no cure period shall apply and the terminating Party shall have the right to effect such termination immediately upon written notice to other Party; and

h. it will comply in all material respects with Applicable Laws in performing its obligations and exercising its rights hereunder.

12.2. **MacroGenics Representations and Warranties**. MacroGenics represents and warrants to Eversana that as of the Effective Date:

a. MacroGenics has not received any written communication alleging that the manufacture, packaging, distribution, sale or use of the Product in the Territory, or that the use of any registered trademark or registered copyright within the Product Trademarks, Corporate Trademarks or Product Copyrights, infringes or misappropriates the Intellectual Property Rights or other rights of any Third Party; and

b. MacroGenics has the right to Commercialize the Product in the Territory and to grant to Eversana the right to provide the Services as set forth herein.

12.3. **Eversana's Representations and Warranties**. Eversana represents and warrants to MacroGenics that as of the Effective Date:

a. it has adequate cash flow and otherwise has the financial resources, capacity and capabilities to timely and adequately perform its obligations hereunder;

b. it has not received written notice from any Third Party alleging that the use of the Eversana Pre-Existing Know-How infringes or misappropriates the Intellectual Property Rights or other rights of any Third Party;

c. except as would not reasonably be expected to have a material adverse effect on the performance of the Services, (i) as of the Effective Date, neither it nor any of its Affiliates
(x) is being investigated, and there are no ongoing investigations, by any Regulatory Authority or other Governmental Authority in the Territory specifically or primarily relating to the promotion of any pharmaceutical or biologic product in the Territory, nor (y) has it or any of its Affiliates received written notice that any Regulatory Authority or other Governmental Authority in the Territory intends to conduct any such investigation, and (ii) neither it nor any of its Affiliates (x) is a party or the subject of any action, suit or other proceeding (collectively, "**Proceeding**") that is pending as of the Effective Date or was pending or filed at any time [***], that alleges that it or any of its Affiliates have violated any Applicable Laws in the Territory in connection with the promotion of any pharmaceutical or biologic product in the Territory, nor (y) has it or any of its Affiliates received any threats in writing of any such Proceeding as of the Effective Date or at any time [***]; and

d. there is no action, suit, proceeding or investigation pending or, to its knowledge, threatened before any court or administrative agency against MacroGenics or its Affiliates which could, directly or indirectly, reasonably be expected to materially affect its ability to perform its obligations hereunder.

12.4. **DISCLAIMER OF WARRANTIES**. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE.

WITHOUT LIMITATION OF THE FOREGOING, MACROGENICS MAKES NO WARRANTY THAT THE BLA APPROVAL WILL OCCUR, THAT THE PRODUCT WILL BE SUCCESSFUL OR THAT EVERSANA WILL RECEIVE ANY, OR ANY AMOUNT OF, ADJUSTED REVENUE SHARE PAYMENTS.

13. INDEMNIFICATION, LIMITATION OF LIABILITY AND INSURANCE

13.1. **Mutual Indemnity**. Each Party (in such capacity, the "**Indemnitor**") shall indemnify, hold harmless and defend the other Party, its Affiliates, and its and their respective directors, officers, employees, representatives and agents (collectively, the "**Indemnitees**"), from and against any and all losses, damages, liabilities, judgments, fines, and amounts paid in settlement, including any associated costs and expenses, including reasonable attorneys' fees (collectively, "**Losses**"), to which any Indemnitee may become subject as a result of any claim, demand, suit, action or proceeding brought or initiated by a Third Party against them ("**Claims**") to the extent that such Losses arise out of: (a) the negligence, fraud or willful misconduct of any of the Indemnitor, its Affiliates, or its or their respective directors, officers, employees, representatives and agents in performing any obligations under this Agreement; or (b) a breach by the Indemnitor of any representation, warranty, covenant or other agreement made by the Indemnitor in this Agreement; except, in each case, to the extent such Losses result from the negligence, recklessness or willful misconduct of any Indemnitee or the breach by any Indemnitee of any warranty, representation, covenant or agreement made by the Indemnitee in this Agreement.

13.2. MacroGenics Indemnity.

a. MacroGenics shall indemnify, hold harmless and defend Eversana, its Affiliates, and its and their respective directors, officers, employees, representatives and agents (collectively, the "**Eversana Indemnitees**") from and against any and all Losses to which any Eversana Indemnitee may become subject as a result of any Claim to the extent that such Losses arise out of any infringement of the Intellectual Property Rights of a Third Party based on the Commercialization of the Product under this Agreement.

b. The Parties hereto acknowledge that Eversana has not had and will not have any role in the development, Manufacture, selection of a brand name, labeling or packaging of the Product and that, as between the Parties, MacroGenics shall have the sole liability for any product liability or similar claims (regardless of the legal theory (including but not limited to strict liability) upon which such claims may be brought) with respect to Product. Accordingly, MacroGenics shall indemnify, hold harmless and defend Eversana Indemnitees from and against any and all Losses to which any Eversana Indemnitee may become subject as a result of any Claim caused by or attributable in whole or part to, or alleged to have been caused by or attributable in whole or part to:

(i) any defect(s) in the Manufacture of any Product, inherent safety risks of any Product or dangerous side effects of the Product;

(ii) the Manufacturing, selection of a brand name, labeling and packaging of the Product; ; and

(iii) any actual or asserted violation of the Federal Food, Drug and Cosmetic Act or any other Applicable Law by virtue of which the Product is alleged or determined to be adulterated, misbranded, mislabeled or otherwise not in full compliance with Applicable Law; and

(iv) Eversana's use of or reliance, in accordance with this Agreement, upon: (A) the Prescribing Information as determined by the FDA; or (B) and Promotional Materials; or (C) Other Materials provided by MacroGenics hereunder or otherwise authorized or approved by MacroGenics under this Agreement for use by Eversana in performing the Services.

c. MacroGenics shall indemnify, hold harmless and defend Eversana Indemnitees from and against any and all Losses incurred by Eversana in connection with any of the following events or circumstances, except to the extent that a breach by Eversana of its express obligations or covenants contained in this Agreement is a cause of such event or occurrence: (i) any inspection, investigation or inquiry by any Regulatory Authority or other Governmental Authority regarding or directed to MacroGenics or the Product or its business practices; or (ii) any court, Regulatory Authority or Governmental Authority order, subpoena, interrogatory, demand, request for admission or other process of law directed to Eversana and specifically attributable to MacroGenics or its Product or business practices.

13.3. **Procedures**. Any indemnified party submitting an indemnity claim under this Section 13, as applicable ("**Indemnified Party**") shall: (a) promptly notify the indemnifying Party ("**Indemnifying Party**"), of such claim in writing and furnish the Indemnifying Party with a copy of the applicable communication, notice or other action relating to the event for which indemnity is sought; provided, that no failure to provide such notice pursuant to this clause
(b) shall relieve the Indemnifying Party of its indemnification obligations, except to the extent such failure materially prejudices the Indemnifying Party's ability to defend or settle the claim; (b) give the Indemnifying Party the authority, information and assistance necessary to defend or settle such suit or proceeding in such a manner as the Indemnifying Party shall determine; and (c) give the Indemnifying Party sole control of the defense (including the right to select counsel, at the Indemnifying Party's expense) and the sole right to compromise and settle such suit or proceeding; provided, however, that in the case of the foregoing clauses (b) and (c), the Indemnifying Party shall not, without the written consent of the Indemnified Party, compromise or settle any suit or proceeding unless such compromise or settlement (i) is solely for monetary damages (for which the Indemnifying Party shall be responsible), (ii) does not impose injunctive or other equitable relief against the Indemnified Party, (iii) does not acknowledge any fault by the Indemnified Party, and
(iv) includes an unconditional release of the Indemnified Party from all liability on claims that are the subject matter of such proceeding. The Indemnified Party (in its capacity as such) may participate in the defense at its own expense.

13.4. **Limitation of Liability**. NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS AGREEMENT, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW AND EXCEPT IN THE CASE OF FRAUD OR WILLFUL MISCONDUCT, OR A BREACH OF ARTICLE 11, NEITHER PARTY NOR ANY OF ITS

AFFILIATES SHALL BE LIABLE TO THE OTHER PARTY OR THEIR AFFILIATES, FOR ANY CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE, INDIRECT OR MULTIPLE DAMAGES, AND OTHER THAN MACROGENICS'S PAYMENT OBLIGATIONS HEREUNDER, FOR: (i) LOSS OF PROFITS, REVENUE OR INCOME, DIMINUTION IN VALUE OR LOSS OF BUSINESS OPPORTUNITY (IN EACH CASE, WHETHER OR NOT FORESEEABLE AT THE EFFECTIVE DATE) OR (ii) ANY DAMAGES CALCULATED BY REFERENCE TO A MULTIPLIER OF REVENUE, PROFITS, OR SIMILAR METHODOLOGY, CONNECTED WITH OR RESULTING FROM ANY BREACH OF THIS AGREEMENT, OR ANY ACTIONS UNDERTAKEN IN CONNECTION WITH, OR RELATED HERETO, INCLUDING ANY SUCH DAMAGES WHICH ARE BASED UPON BREACH OF CONTRACT, TORT, BREACH OF WARRANTY, STRICT LIABILITY, STATUTE, OPERATION OF LAW OR ANY OTHER
THEORY OF RECOVERY; *provided, however,* that the foregoing shall not be construed to limit either Party's indemnification obligations set forth above in this Section 13.

EACH PARTY FURTHER ACKNOWLEDGES AND AGREES THAT EACH PARTY'S [***]; *provided, however,* that the foregoing shall not be construed to limit either Party's indemnification obligations set forth above in this Section 13 or either Party's liability in the case of fraud or willful misconduct.

13.5. **Insurance**. Each Party shall at all times maintain general liability insurance policies or self- insurance in such amounts and with such scope of coverage as are normal and customary in the pharmaceutical industry for a Person of comparable size and engaged in activities comparable to the activities in which such Party engages hereunder. As of the BLA Approval Date, MacroGenics shall maintain Product Liability insurance [***], it being understood and agreed that Eversana shall not need to obtain any product liability insurance during the Term. If requested by the other Party, the insured Party shall furnish a certificate of insurance or other reasonable proof of coverage (which may be a certificate or other evidence issued by a Party under a program of self-insurance) evidencing the requisite coverage required under this Section 13.5 during the Term. The insurance policies shall be under an occurrence form, but if only a claims-made form is available to a Party, then such Party shall continue to maintain such insurance after the expiration or termination of this Agreement for a period of [***].

14. TERM AND TERMINATION

14.1. **Term.** The Agreement shall take effect as of the Effective Date and shall remain in effect for a term of five (5) years from the BLA Approval Date unless earlier terminated as provided hereunder (the "**Term**").

14.2. **Termination**. This Agreement may be terminated as follows:

a. **Termination for Late Approval**. Eversana shall have the right to terminate this Agreement if BLA Approval does not occur by June 30, 2021 by providing written notice thereof [***].

b. **Termination for Revenue Shortfall**. At any time after [***] following the date of Commercial Launch (the date when such period ends, the "**Revenue Measurement Date**"), either Party shall be entitled to terminate this Agreement if Net Profits are [***], by providing the other Party with [***] prior written notice.

c. **Termination for Convenience**. No earlier than twenty four (24) months from the BLA Approval Date, MacroGenics may terminate this Agreement by providing Eversana with [***] (which notice may not be provided earlier than [***]) and making a one-time payment to Eversana equal to the difference between: (i) one hundred twenty-five percent (125%) of the sum of the cumulative Reconciled Reimbursed Commercial Costs received by Eversana and the cumulative Reconciled Unreimbursed Commercial Costs incurred by Eversana, in each case during the thirty (30) month period following the BLA Approval Date; and (ii) the sum of the cumulative Reconciled Reimbursed Commercial Costs and the cumulative Adjusted Revenue Share Payments received by Eversana or payable to Eversana up to the effective date of such termination. However, [***], then no payment shall be due to Eversana pursuant to this Section 14.2.c.

d. **Termination upon Material Breach.** Either Party may terminate this Agreement if the other Party materially breaches this Agreement, and such breach is not cured [***] from the other Party of written notice specifying in detail the nature and extent of the alleged material breach.

e. **Termination for Insolvency**. Either Party may terminate this Agreement [***] on written notice if the other Party (or, if applicable, a parent of such other Party) shall file in any court or Governmental Authority, pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the other Party or of its assets, or if the other Party (or, if applicable, a parent of such other Party) shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall [***], or if the other Party (or, if applicable, a parent of such other Party) shall be a party to any dissolution or liquidation, or if the other Party (or, if applicable, a parent of such other Party) shall make a general assignment for the benefit of its creditors.

f. **Termination for MacroGenics Change of Control.** In the event of a MacroGenics Change of Control, MacroGenics will have the option to terminate this Agreement by

providing Eversana [***] written notice of such termination (the "**COC Notice Period**").

(i) During the COC Notice Period, the Parties shall cooperate with each other to ensure an orderly transition of responsibilities for the Services to an entity specified by MacroGenics as the MacroGenics Change of Control Partner.

(ii) [***] of providing Eversana with written notice of such termination, MacroGenics shall pay Eversana for any unpaid Services rendered through the date of such notice, which shall be defined as follows: (x) if the [***] through the date of such notice less the cumulative [***], provided that if such calculated amount is a negative number, then no payment shall be due to Eversana pursuant to this subsection; or (y) if the [***], any unpaid [***] due to Eversana for performance of the Services through the date of such notice.

(iii) Following written notice of termination by MacroGenics under this Section 14.2.f, MacroGenics (x) shall cease making [***], and (y) shall be invoiced for [***] for the Services performed during the COC Notice Period, such amounts to be paid in advance of the Services [***].

(iv) If (x) the [***] of the [***] earned by Eversana for Services performed during the COC Notice Period is [***] and the [***], the sum of the [***] earned by Eversana) [***], then MacroGenics shall make an [***], provided that if such [***] is more than such [***], then no payment shall be due to Eversana pursuant to this subsection. Such [***] shall be due once the applicable Commercialization responsibilities have been transitioned back to MacroGenics and/or the MacroGenics Change of Control Partner, but in any event, [***].

g. Either Party may terminate this Agreement [***] to the other Party if:

(i) the Product is subject to a recall in the Territory based on material safety concerns and such recall continues [***];

(ii) MacroGenics withdraws the Product from the market in the Territory for a [***];

(iii) Commercial Launch has not occurred [***], provided that a written notice of termination is given [***], and provided further that the foregoing termination right shall not be available to Eversana if Commercial Launch has not occurred within such time period due primarily to Eversana's failure to perform its obligations under this Agreement; or

(iv) there is any change in Applicable Law that makes performance of a Party's material obligations as contemplated in this Agreement illegal or commercially impractical.

14.3. Effect of Termination or Expiration.

a. Upon the expiration or termination of this Agreement, the following terms and conditions shall apply, subject in all cases to Section 14.3.b below:

(i) The appointment of Eversana to perform the Services under Section 2.1 shall terminate and Eversana shall promptly cease all performance of the Services.

(ii) The licenses granted to Eversana under Section 2.2 shall terminate and Eversana shall promptly discontinue the use of any MacroGenics Know-How, Product Trademarks, Product Copyrights, and Corporate Trademarks.

(iii) At MacroGenics's election and subject to compliance with Section 10.3, Eversana either shall (x) promptly return to MacroGenics, or (y) promptly destroy and certify to MacroGenics such destruction of, all Arising Product Know-How, Materials and other documentation related to the Product or the activities provided for by this Agreement.

(iv) At MacroGenics' request, Eversana either shall (x) destroy or (y) return any remaining Product supply.

b. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit any remedies that may otherwise be available in law or equity.

14.4. **Accrued Rights**. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration, including, without limitation, each Party's rights to any amounts owed by the other Party hereunder. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. If payments attributable to Services or reconciliations under Section 5.2.b performed before the termination or expiration remain unpaid upon the termination or expiration of the Agreement, including but not limited to reimbursement of Reconciled Reimbursed Commercial Costs (if applicable) and Adjusted Revenue Share Payments, the

Party owing such payments shall make such payments promptly after the termination or expiration of this Agreement. In the event of termination, Eversana will use reasonable efforts to terminate work being performed by Approved Subcontractors and other related commitments entered into by Eversana but MacroGenics will be responsible for all non-refundable costs and non-cancelable commitments incurred by Eversana with respect thereto (according to the Commercialization Budget if such termination occurs before the occurrence of the Revenue Threshold).

14.5. **Survival**. The rights and obligations of the Parties set forth in Section 1 (Definitions), Section 2.3 (Retained Rights), Section 2.4 (Other Rights and Obligations), Section 2.6 (Assignment of Arising Product Know-How) the last sentence of Section 3.6.c (Eversana Personnel and Training) (to the extent relating to MacroGenics's ownership of all Training Materials and all copyrights therein), Section 3.8 (Employment Covenants), Section 3.9 (Materials) (to the extent relating to MacroGenics's ownership of all Materials and all copyrights therein), Section 3.13 (Information Data Security Privacy), Article 5 (Fees and Payments) (subject to Section 14.4 above), Section 6.1 (Ownership of Regulatory Documentation and Approvals), Section 7.3 (Recalled Product) Section 8.4 (Notice of Investigations), Section 9.6, Section 9.7 (Limitations), Section 10.1 (MacroGenics Records), Section 10.2 (Audits of MacroGenics), Section 10.3 (Eversana Records), Section 10.4 (Audits of Eversana), Section 11 (Confidentiality), Section 12.4 (Disclaimer of Warranties), Section 13 (Indemnification, Limitation of Liability and Insurance), Section 14.2 (Termination), Section 14.3 (Effect of Termination or Expiration), Section 14.4 (Accrued Rights), Section 14.5 (Survival), Section 15 (Notice), and Section 16 (General Provisions) shall survive the termination or expiration of this Agreement.

15. NOTICE

Any notice or written communication provided for in this Agreement by a Party to the other Party, including but not limited to any and all offers, writings, or notices to be given hereunder, shall be made by registered mail or by courier service delivered letter, promptly transmitted or addressed to the appropriate Party. The date of receipt of a notice or communication hereunder shall be the date of delivery confirmed by the USPS or the courier service in the case of a courier service delivered letter. All notices and communications shall be sent to the appropriate address set forth below, until the same is changed by notice given in writing to the other Party effective as above

Notice to MacroGenics:

Address: [***]

With a copy to: [***]

Notice to Eversana: [***] Address: [***]

With a copy to: [***]

16. GENERAL PROVISIONS

16.1. **Force Majeure**. Except as otherwise set out in this Agreement, no Party to this Agreement shall have any liability whatsoever or (without prejudice to any payments of monies due) be deemed to be in default for any delays or failures in performance of any of its obligations under this Agreement to the extent such delay or failure is caused by or results from causes beyond the reasonable control of the affected Party, potentially including pandemics. embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any Governmental Authority (including government shut down) or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical. The affected Party shall use all commercially reasonable efforts to remedy the event or limit the effects of the said event of force majeure upon the other Party in a timely manner. When such circumstances arise, the Parties shall negotiate in good faith any modifications of the terms of this Agreement that may be necessary or appropriate in order to arrive at an equitable solution. If any force majeure event continues [***] that prevents the performance of any material obligation of or receipt of any material benefit (including, without limitation, payment) by a Party under this Agreement, the Party not affected by the force majeure event shall have the right to terminate this Agreement upon [***] to the other Party.

16.2. **Governing Law**. This Agreement shall in all respects be governed by and interpreted according to the laws of the State of New York and the United States without regard to or application of conflict-of-law rules or principles.

16.3. Dispute Resolution.

a. In the event that there is a dispute, controversy, or claim between the Parties arising out of or relating to this Agreement, or its interpretation, performance, nonperformance or any breach of any respective obligations hereunder, excluding any dispute at the JMC level (to which the procedures in Section 4.4 shall apply), then the Parties shall seek to resolve such dispute through prompt negotiations between the Executive Officers. The Executive Officers will meet in-person and use good faith efforts to resolve any such dispute (for clarity, excluding any dispute at the JMC level) [***]. If the Executive Officers are unable to resolve such dispute within [***], then either Party may have the dispute settled by binding arbitration pursuant to Section 16.3.b.

b. A Party intending to commence an arbitration proceeding to resolve a dispute must first provide written notice (the "**Arbitration Request**") to the other Party of such intention, setting forth the issues for resolution. From the date of the Arbitration Request until such time as the dispute has become finally settled, the time period during which a Breaching Party must cure an alleged breach that is the subject matter of the dispute shall be suspended.

(i) Unless otherwise agreed by the Parties, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining [***], and no such claim shall be subject to arbitration pursuant to this Section, and [***].

(ii) The arbitration shall be held [***]. The arbitration shall be conducted [***], (b) not be or have been an employee, consultant, officer, director or stockholder of either Party or any Affiliate of either Party, and (c) not have a conflict of interest under any applicable rules of ethics. The arbitrator shall be selected by mutual agreement of the Parties, provided that if the Parties cannot agree on the arbitrator [***], the arbitrator shall be selected by the [***]. The arbitrator may proceed to an award, notwithstanding the failure of either Party to participate in the proceedings. The arbitrator shall, [***], issue a written award. The arbitrator shall be authorized to [***]. The arbitrator also shall be authorized to [***], but is not authorized

to reform, modify or change this Agreement. The award of the arbitrator [***], and [***] that are the subject of the arbitration proceeding and the award (except for those remedies set forth in this Agreement); provided, however, [***]. Judgment on the award rendered by the arbitrator may be enforced in any court having competent jurisdiction thereof following the conclusion of the appeal process or the expiration of time for filing a notice of appeal pursuant to the Appellate Rules, whichever is later. Notwithstanding anything contained in this Section 16.3.b to the contrary, each Party shall have the right to institute judicial proceedings against the other Party or anyone acting by, through or under such other Party, in order to confirm an award of the arbitrator, to enforce the instituting Party's rights hereunder through specific performance, injunction or other equitable relief, or to collect any monetary award of the arbitrator.

(iii) Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators.

(iv) Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrators on the ultimate merits of any dispute.

(v) All proceedings and decisions of the arbitrators shall be deemed Confidential Information of each of the Parties, and shall be subject to Article 11.

16.4. **Integration**. This Agreement together with the Exhibits attached hereto, constitutes the entire agreement between the Parties relating to the subject matter hereof and supersedes all prior agreements, understandings and discussions, whether oral or written, of the Parties with respect to the subject matter hereof, including the [***]. All activities undertaken by the Parties under the [***] under this Agreement and governed and subject to the terms and conditions of this Agreement. Any modification of this Agreement shall be effective only when in writing and signed by the Parties.

16.5. **Assignability**. Neither Party may assign this Agreement without the prior written consent of the other Party, except either Party may assign this Agreement in whole or in part to any Affiliate of such Party without the consent of the other Party. Further, either Party may assign this Agreement, and all of its rights and obligations, without the consent of the other Party, to its successor in interest by way of merger, acquisition, or sale of all or substantially all of its business or assets; provided, that the assigning Party provides the other Party with written notice of such assignment [***].

16.6. **Severability**. If any provision contained in this Agreement shall, for any reason, be held invalid, illegal or unenforceable, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement, but this Agreement shall be construed by limiting such invalid, illegal or unenforceable provision, or if such is not possible, by deleting such invalid, illegal or unenforceable provision from this Agreement; provided that (a) such provision shall be deemed to be replaced by a provision which achieves the original intent of the Parties to the fullest extent possible; (ii) should this Agreement as a result of such deletion no longer reasonably correspond to the good faith intent of the Parties, either Party may propose amendments to the other provisions of this Agreement in order to have the Agreement correspond to such good faith intent and the Parties shall negotiate in good faith such amendments.

16.7. **Waiver**. No course of dealing or failing of either Party to strictly enforce any term, right or condition of this Agreement in any instance shall be construed as a general waiver or relinquishment of such term, right or condition. Such waiver or relinquishment (either generally or any given instance and either retroactively or prospectively) shall only be effective if made expressly in writing by the Party with reference to the specific term, right or condition.

16.8. **No Third Party Rights**. The provisions of this Agreement are for the sole benefit of the Parties, their successors and permitted assignees, and they shall not be construed as conferring any rights in any other Persons except as otherwise expressly provided in this Agreement.

16.9. **Interpretation**. The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. The term “including” or “includes” as used in this Agreement means including, without limiting the generality of any description preceding such term, and the word “or” has the inclusive meaning represented by the phrase “and/or.” Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. All references to days in this Agreement shall mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices, reports and disclosures required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement, shall be in the English language.

16.10. **Costs and Expenses**. Each Party shall, unless specifically otherwise agreed hereunder, bear their own costs and expenses connected with such Party’s activities and performance under this Agreement.

16.11. **Counterparts**. This Agreement [***], but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

MacroGenics, Inc.

By: */s/ Scott Koenig*
Name: Scott Koenig, M.D., Ph.D.
Title: President and Chief Executive Officer

Eversana Life Science Services, LLC

By: */s/ Gregory Skalicky*
Name: Gregory Skalicky
Title: Chief Revenue Officer

EXHIBIT A

[***]

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EXHIBIT B

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EXHIBIT C

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EXHIBIT D

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EXHIBIT E

[***]

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EXHIBIT F

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EXHIBIT G

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EXHIBIT H INFORMATION DATA SECURITY

1. Definitions

(a) **"Authorized Persons"** means Eversana's employees, contractors, subcontractors, agents, representatives and auditors who have a need to know or otherwise access Secure Information to enable Eversana to perform its obligations under the Product Commercialization Agreement, and who are bound in writing by confidentiality and other obligations sufficient to protect Secure Information in accordance with the terms and conditions of the Product Commercialization Agreement.

(b) **"Data Breach"** means any unauthorized access to or disclosure or acquisition of Secure Information.

(c) **"Personal Information"** means information that Eversana receives pursuant to providing the Services that: (a) directly or indirectly identifies an individual (including, for example, names, signatures, addresses, telephone numbers, email addresses, and other unique identifiers); or (b) can be used to authenticate an individual (including, without limitation, employee identification numbers, and other personal identifiers), in case of both subclauses (a) and (b), including Sensitive Personal Information as defined herein. MacroGenics' or Eversana's business contact information is not by itself Personal Information.

(d) "**Secure Information**" means Confidential Information and Sensitive Personal Information.

(e) **"Security Incident"** means any act or omission that materially compromises the security, confidentiality, or integrity of Secure Information stored or managed on MacroGenics behalf or the physical, technical, administrative, or organizational safeguards put in place by Eversana (or any Authorized Persons), that relate to the protection of the security, confidentiality, or integrity of Secure Information. The parties agree that "Security Incident" does not include the existence and occurrence of unsuccessful Security Incidents, including, without limitation, activity such as pings and other broadcast attacks on Eversana's firewall, port scans, unsuccessful log-on attempts, denial of service and any combination of the above, so long as no such unsuccessful Security Incident results in unauthorized access, use, disclosure, modification or destruction of Secure Information or interference with information system operations related to the Secure Information.

(f) **"Sensitive Personal Information"** means an individual's (a) state or government- issued identification number, including Social Security number, driver's license number; (b) financial or credit information; or (c) biometric, genetic, health, or health insurance data

2. Information Security.

(a) Eversana will comply with Applicable Laws in its creation, collection, receipt, access, use, storage, disposal, and disclosure of Secure Information.

(b) Eversana will employ commercially reasonable security measures to protect Secure Information in accordance with accepted applicable industry standards and Eversana's information security policy as amended from time to time ("**Information Security Policy**"), a current copy of which will be provided to MacroGenics upon written request. As necessary, Eversana will employ additional security measures to protect Secure Information.

(c) Eversana agrees and warrants that it will implement administrative, physical and technical safeguards to protect Secure Information that are no less rigorous than accepted industry practices, including, as an example, the International Organizational Standardization's standards: ISO 27001 and ISO 27002 or other applicable established industry standards for information security and shall ensure that all such safeguards comply with Applicable Laws, as well as the terms and conditions of the Product Commercialization Agreement. At a minimum, Eversana's safeguards for the protection of Secure Information shall include: (i) limiting access of Secure Information to authorized employees and Authorized Persons; (ii) securing business facilities, data centers, paper files, servers, back-up systems and computing equipment, including but not limited to all mobile devices and other equipment with information storage capability; (iii) implementing network, device, application, database and platform security; (iv) securing information transmission, storage and disposal; (v) implementing authentication and access controls within media, applications, operating systems and equipment; (vi) encrypting transmitted Secure Information pursuant to accepted industry practices; (vii) strictly segregating Sensitive Personal Information from information from Eversana or its other customers so Sensitive Personal Information is not comingled; (viii) implementing appropriate personnel security and integrity procedures and practices, including but not limited to, conducting background checks consistent with Applicable Laws and Regulations; and (ix) providing privacy and information security training to Eversana's Authorized Persons.

2. Data Breach or Security Incident Procedures.

(a) Eversana currently maintains and will continue to maintain a cyber incident breach response plan in accordance with industry standards ("**Cyber Incident Response Plan**"). [***] and Eversana will implement the procedures required under such Cyber Incident Response Plan on the occurrence of an actual Data Breach or Security Incident.

(b) Eversana will provide MacroGenics with the [***] and [***] with an actual Data Breach of Security Incident.

(c) Eversana will [***] (i) an actual Data Breach or Security Incident or (ii) a potential Data Breach or Security Incident [***].

(d) [***], the parties will coordinate with each other, as necessary, to investigate the Data Breach or Security Incident in accordance with Eversana's current Cyber Incident Response Plan.

(e) To the extent Eversana [***] Data Breach or Security Incident, Eversana [***] by an actual Data Breach or Security Incident.

(f) Other than as required by Applicable Laws, Eversana agrees that [***].

3. **Security Controls Review or Audit. [***]**. As part of this assessment, MacroGenics will [***]. In the event of a Data Breach or Security Incident, MacroGenics [***].

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-8 No. 333-192277) pertaining to the 2000 Stock Option and Incentive Plan, the 2003 Equity Incentive Plan, and 2013 Equity Incentive Plan of MacroGenics, Inc.;
2. Registration Statements (Form S-8 No. 333-202470, Form S-8 No. 333-209812, Form S-8 No. 333-217620, Form S-8 No. 333-223682 and Form S-8 No. 333-230292, Form S-8 No. 333-237127) pertaining to the 2013 Equity Incentive Plan of MacroGenics, Inc.;
3. Registration Statement (Form S-8 No. 333-214386) pertaining to the 2016 Employee Stock Purchase Plan of MacroGenics, Inc.;
4. Registration Statement (Form S-3 No. 333-249851) of MacroGenics, Inc.

of our reports dated February 25, 2021, with respect to the consolidated financial statements of MacroGenics, Inc. and the effectiveness of internal control over financial reporting of MacroGenics, Inc. included in this Annual Report (Form 10-K) of MacroGenics, Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Baltimore, Maryland
February 25, 2021

EXHIBIT 31.1

I, Scott Koenig, certify that:

1. I have reviewed this Annual Report on Form 10-K for the period ended December 31, 2020 of MacroGenics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Scott Koenig

Scott Koenig, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Dated: February 25, 2021

EXHIBIT 31.2

I, James Karrels, certify that:

1. I have reviewed this Annual Report on Form 10-K for the period ended December 31, 2020 of MacroGenics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions)

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ James Karrels

James Karrels

Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

Dated: February 25, 2021

EXHIBIT 32.1

Certification of Principal Executive Officer Pursuant to 18 U.S.C. 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)

I, Scott Koenig, President and Chief Executive Officer (principal executive officer) of MacroGenics, Inc. (the "Registrant"), certify, to the best of my knowledge, based upon a review of the Annual Report on Form 10-K for the period ended December 31, 2020 of the Registrant (the "Report"), that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ Scott Koenig
Name: Scott Koenig, M.D., Ph.D.
Date: February 25, 2021

EXHIBIT 32.2

Certification of Principal Financial Officer Pursuant to 18 U.S.C. 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)

I, James Karrels, Senior Vice President and Chief Financial Officer (principal financial officer) of MacroGenics, Inc. (the "Registrant"), certify, to the best of my knowledge, based upon a review of the Annual Report on Form 10-K for the period ended December 31, 2020 of the Registrant (the "Report"), that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ James Karrels
Name: James Karrels
Date: February 25, 2021