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, 2019

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 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 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $829.7 million 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 21, 2020 was 48,984,218.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of MacroGenics, Inc.'s definitive proxy statement for the 2020 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". 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:

- 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 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 dilutive or non-dilutive capital to fund our operations;
- 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™ 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 clinical-stage biopharmaceutical company focused on discovering and developing innovative antibody-based therapeutics designed to modulate the human immune response for the treatment of cancer. We currently have a pipeline of product candidates in human clinical testing, including seven 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 human epidermal growth factor receptor 2 (HER2), which is expressed on some breast, gastroesophageal and other cancer types. Other product candidates that we are developing 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. 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 U.S. Food and Drug Administration (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 and two bispecific DART product candidates that co-engage PD-1 and LAG-3, and PD-1 and CTLA-4, respectively. 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).

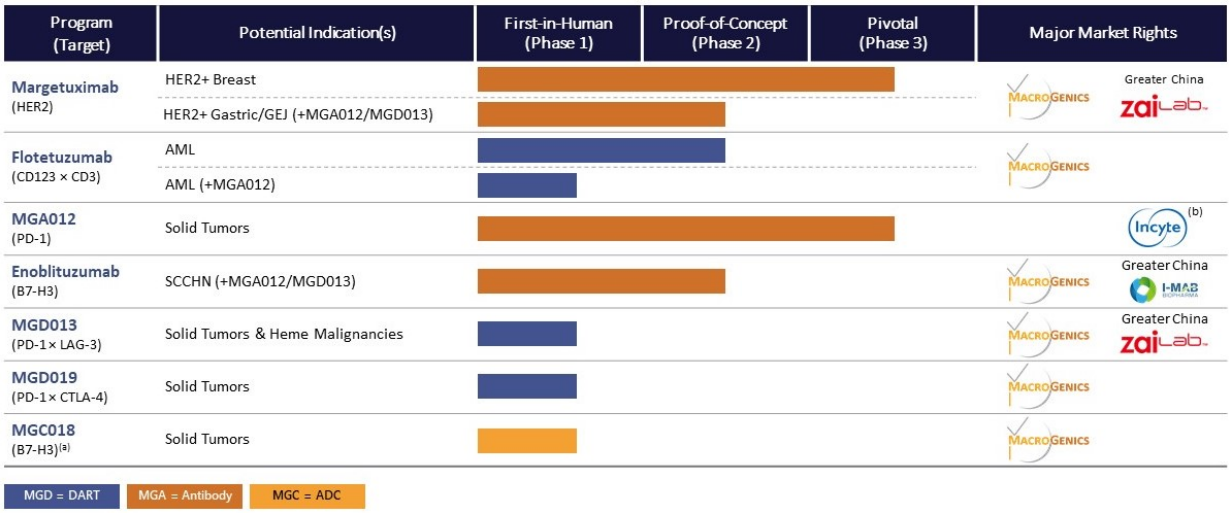
We have created our product candidates based on the following antibody-based technologies:

- 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:



(a) MGC018 is an ADC based on a duocarmycin payload with cleavable peptide linker that was licensed from Synthon Biopharmaceuticals.
(b) MacroGenics retains rights to develop its pipeline assets in combination with MGA012 and to manufacture a portion of global clinical and commercial supply needs of MGA012. Incyte designates this molecule as "INCMGA0012".

Margetuximab

Margetuximab is an investigational, immune-enhancing, monoclonal antibody that targets HER2-expressing tumors, including certain types of breast and gastroesophageal cancers. Margetuximab was designed to provide HER2 blockade with similar HER2 binding and antiproliferative effects as trastuzumab. In addition, we have engineered the constant region (Fc region) of margetuximab using our Fc Optimization platform to enhance the engagement of the immune system through an Fc-dependent mechanism, such as antibody dependent cell-mediated cytotoxicity (ADCC), to increase tumor cell killing. Furthermore, ADCC may also lead to HER2-specific T-cell and antibody responses, facilitating the engagement of both innate and adaptive immune responses.

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.

In December 2019, we submitted a Biologics License Application (BLA) to the FDA for margetuximab for the treatment of patients with metastatic HER2-positive breast cancer in combination with chemotherapy. The BLA submission was based primarily on data from SOPHIA, our Phase 3 clinical trial comparing margetuximab plus chemotherapy versus trastuzumab plus chemotherapy in patients with HER2-positive metastatic breast cancer who have previously been treated with anti-HER2-targeted therapies. In February 2020, the BLA was accepted for review by the FDA. We expect that there will be a Standard Review process and anticipate a Prescription Drug User Fee Act (PDUFA) date by the end of 2020. In addition, we believe that the FDA will require an Oncologic Drugs Advisory Committee (ODAC) and anticipate that meeting will likely occur in the second half of 2020.

The SOPHIA study enrolled 536 patients at approximately 200 trial sites across North America, Europe and Asia. Patients were treated with either margetuximab or trastuzumab in combination with one of four chemotherapy agents (capecitabine, eribulin, gemcitabine or vinorelbine). All study patients had previously received trastuzumab and pertuzumab, and approximately 90% had previously received ado-trastuzumab emtansine. Primary endpoints are sequentially-assessed progression-free survival (PFS), determined by centrally-blinded radiological review, and overall survival (OS). A pre-specified exploratory objective of the study was to evaluate the effect of CD16A (Fcγ receptor) allelic variation on margetuximab activity; approximately 85% of the overall human population, as well as patients enrolled in the SOPHIA study, carry the

CD16A 158F allele, which has been previously associated with diminished clinical response to trastuzumab and other antibodies.

In February 2019, we announced topline PFS results from the SOPHIA trial as of an October 2018 data cut-off. In June 2019, at a medical conference, we presented data from SOPHIA as of the aforementioned October 2018 data cut-off that showed a statistically significant improvement in PFS in patients treated with margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy in the intention-to-treat (ITT) population after 265 PFS events (median PFS=5.8 months versus 4.9 months; hazard ratio [HR]=0.76; 95% confidence interval [CI]: 0.59-0.98; P=0.033). In the pre-specified, exploratory subpopulation of patients carrying the CD16A 158F allele, PFS was prolonged by 1.8 months in the margetuximab arm compared to the trastuzumab arm (median PFS=6.9 months versus 5.1 months; HR=0.68; 95% CI: 0.52-0.90; P=0.005). We also presented data from the planned first interim analysis of OS based on 158 OS events. This interim analysis was not expected to and did not reach statistical significance. In the ITT population, median OS was 18.9 months in the margetuximab arm versus 17.2 months in the trastuzumab arm (HR=0.95; 95% CI: 0.69-1.31). In the pre-specified, exploratory subpopulation of patients carrying the CD16A 158F allele, median OS was 23.6 months in the margetuximab arm versus 16.9 months in the trastuzumab arm (HR=0.82; 95% CI: 0.58-1.17). As a secondary outcome measure in the SOPHIA study, the objective response rate (ORR) in the ITT population was 22% in the margetuximab arm (95% CI: 17.3-27.7%) compared to 16% in the trastuzumab arm (95% CI: 11.8-21.0%).

At a medical conference in December 2019, we presented data from the planned second interim analysis of OS as of a September 2019 cut-off after 270 OS events. In this second interim OS analysis, OS favored margetuximab plus chemotherapy compared with trastuzumab plus chemotherapy in the ITT population; however, these data were not expected to and did not reach statistical significance (median OS=21.6 months versus 19.8 months; HR=0.89; 95% CI: 0.69-1.13; nominal P=0.326). The final pre-specified OS analysis is planned after 385 OS events have accrued, which is projected to occur in the second half of 2020, at which point the results may or may not reach statistical significance. Among the genetically defined exploratory subpopulation of patients carrying a CD16A 158F allele, the median OS at the second interim analysis was prolonged by 4.3 months in the margetuximab arm compared to the trastuzumab arm (23.7 months versus 19.4 months; HR=0.79; 95% CI: 0.61-1.04; nominal P=0.087). Among the approximately 15% of patients who were homozygous for the CD16A 158V allele, the trastuzumab arm performed better than the margetuximab arm.

We believe margetuximab plus chemotherapy has shown a safety profile generally comparable to that of trastuzumab plus chemotherapy in this study. As of the April 2019 data cut-off for safety, Grade 3 or greater adverse events occurred in 142 (54%) patients on the margetuximab arm compared to 140 (53%) patients on the trastuzumab arm. Serious adverse events occurred in 43 (16%) patients on the margetuximab arm compared to 49 (18%) patients on the trastuzumab arm. Infusion-related reactions (IRR) were more common with margetuximab treatment than with trastuzumab (13% versus 3%) and were mostly Grade 1 or 2 and associated with the first dose. A substudy evaluating shorter, 30-minute infusions of margetuximab in Cycle 2 and beyond showed no effect on safety outcomes, including risk or severity of IRR.

In January 2018, the FDA granted Fast Track designation for the investigation of margetuximab for treatment of patients with metastatic or locally advanced HER2 positive breast cancer who have previously been treated with anti-HER2-targeted therapy. Although there are benefits associated with a Fast Track designation, such as more frequent meetings with the FDA to discuss the drug's development plan, we anticipate a Standard Review process for the BLA.

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 2018. 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 enhance tumor-specific T-cell immunity and increase anti-tumor activity.

In September 2019, we presented data from our ongoing Phase 2, open-label, dose escalation and expansion study of margetuximab plus pembrolizumab, an anti-PD-1 monoclonal antibody, in patients with advanced HER2-positive GC or GEJ cancer who have previously been treated with chemotherapy and trastuzumab in the metastatic setting. In this study, 92 patients, including 61 patients with GC and 31 patients with GEJ, who had HER2-positive disease, were treated at the recommended phase 2 dose of 15 mg/kg margetuximab and 200 mg pembrolizumab, both administered every three weeks, and were included

in the analysis. HER2 positivity was characterized by a score of 3+ by immunohistochemistry (IHC), or IHC3-positve, or a score of 2+ by IHC and detection by fluorescence in situ hybridization (FISH), or IHC2-positive/FISH-positive. Patients in the study were enrolled irrespective of programmed death-ligand 1 (PD-L1) expression status. We reported data as of July 10, 2019. As of this data cut-off date, the study was ongoing with eight patients remaining on therapy. Acceptable tolerability was observed in this study in patients treated with margetuximab and pembrolizumab. Grade 3 or higher treatment-related adverse events (TRAE) occurred in 19.6% of patients. Response rates, median PFS and OS observed in the ongoing study are summarized in the following table:

	Gastroesophageal Adenocarcinoma (GEA = GC + GEJ)				**Gastric Cancer (GC)**			
	ORR	DCR	Median PFS (months)	Median OS (months)	ORR	DCR	Median PFS (months)	Median OS (months)
All Patients	20*/92 (21.7%)	50/92 (54.4%)	2.7	12.5	18*/61 (29.5%)	40/61 (65.6%)	4.1	13.9
HER2 IHC3+	20*/71 (28.2%)	45/71 (63.4%)	4.3	13.9	18*/55 (32.7%)	38/55 (69.1%)	4.7	14.6
HER2 IHC3+/PD-L1+	12/25 (48.0%)	19/25 (76.0%)	4.8	20.5	12/23 (52.2%)	19/23 (82.6%)	5.5	20.5

*Three unconfirmed responses; ORR includes complete responses (CR) and partial responses (PR); DCR=disease control rate and includes CR, PR and stable disease (SD).

Based on these results, 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 MGA012, an anti-PD-1 monoclonal antibody, in patients with tumors that are both HER2-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 Response Evaluation Criteria in Solid Tumors (RECIST) v 1.1. We expect to obtain initial data in the second half of 2020 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 MGA012 or MGD013, a PD-1 x 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. We expect Zai Lab to initiate Module B in Greater China in the second half of 2020, unless regional coronavirus related precautions or other circumstances delay such initiation . 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. In 2010, we licensed the right to develop and commercialize margetuximab in South Korea to Green Cross Corporation (GC Pharma).

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 acute myeloid leukemia (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.

Acute Myeloid Leukemia (AML)

AML is a hematopoietic stem cell malignancy characterized by uncontrolled clonal proliferation of neoplastic 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 to kill CD123-expressing cells. To achieve this, the DART molecule combines an arm that recognizes CD123 on the target cancer cells, with a portion of an antibody recognizing CD3, an activating protein expressed by normal T cells, which are specialized white blood cells in the human immune system.

Approximately 20,000 new cases of AML were diagnosed in the U.S. in 2019, with a median age of 68 years at diagnosis, according to the Surveillance, Epidemiology, and End Results (SEER) Program of the National Institutes of Health (NIH). Hematopoietic stem cell transplantation represents the only treatment modality with curative potential. Approximately 40-50% of newly diagnosed patients fail to achieve a complete remission (CR) with intensive induction therapy (primary induction failure) or experience disease recurrence after a short remission duration of less than 6 months (early relapsed). A very small number of these patients are expected to respond to salvage therapy. In addition, although new targeted agents 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 2019, we presented data from our Phase 1/2 dose expansion study of flotetuzumab in relapsed/refractory patients with AML. In this study, 30 patients classified as having primary induction failure or early relapsed AML who had received a median of four prior therapies were treated with flotetuzumab at the recommended Phase 2 dose of 500 ng/kg/day by continuous infusion with a lead-in dosing strategy. Data were reported as of the cut-off date of November 1, 2019. The study is currently ongoing, with additional patients being enrolled.

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. Four responders received allogeneic hematopoietic stem cell transplantation as consolidation therapy and remained in remission after 6 to 21 months.

	Responders (N)	**ITT Population (N = 30)**	**Evaluable Patients (N = 28)**
CR	5	16.6%	17.9%
CR + CRh	8	26.7%	28.6%
CR + CRh + CRi	9	30.0%	32.1%

The most common TRAE was infusion-related reaction/cytokine release syndrome (IRR/CRS) that occurred in all (30/30) patients. However, most CRS events observed were of short duration and mild to moderate (grade 1 or 2) in severity, with only one grade 3 event reported in one patient.

We intend to define a potential registration path in the U.S. for the treatment of patients with primary induction failure and early relapsed AML in the first half of 2020, pending discussions with the FDA. The FDA has granted orphan drug designation to flotetuzumab for the treatment of AML.

In addition, we believe our preclinical and translational data provide a scientific rationale for combining flotetuzumab with checkpoint blockade as a potential mechanism for enhanced CD123-directed T cell killing and anti-leukemic activity. We have initiated a Phase 1/2 study of flotetuzumab in combination with MGA012 in patients with relapsed/refractory AML. The study is currently being conducted in countries outside of the U.S.

MGA012

MGA012 (also known as INCMGA0012) 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 MGA012 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. Incyte has stated it is pursuing development of MGA012 monotherapy through potentially registration-enabling studies in squamous carcinoma of the anal canal (SCAC), MSI-high endometrial cancer and Merkel cell carcinoma, with data in SCAC anticipated in the second half of 2020. In addition, we expect Incyte to initiate two Phase 3 studies of MGA012 in combination with chemo-radiation or chemotherapy in patients with advanced or metastatic non-small cell lung cancer (NSCLC), known as POD1UM-301 and

POD1UM-304, respectively. Incyte is also pursuing development of MGA012 in combination with multiple product candidates from its pipeline. We are currently studying MGA012 in combination with margetuximab in patients with GC or GEJ cancer and with flotetuzumab in patients with relapsed/refractory AML.

Enoblituzumab

Enoblituzumab is an investigational, immune-enhancing, monoclonal antibody that targets B7-H3 that has been engineered using our Fc Optimization platform. B7-H3, a protein in the B7 family of immune regulator proteins that is widely expressed by a number of 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 1 clinical study of enoblituzumab and pembrolizumab, an anti-PD-1 monoclonal antibody, to evaluate the combination in patients with B7-H3-expressing melanoma, squamous cell carcinoma of the head and neck (SCCHN), NSCLC and urothelial cancer. The combination of enoblituzumab and 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 and the data cut-off date was October 12, 2018.

As presented in November 2018, in the SCCHN dose expansion cohort, confirmed PRs 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 PRs. Objective response rates 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 plan to evaluate the molecule both in combination with MGA012 and in combination with MGD013 as chemotherapy-free regimens in first-line patients with recurrent and metastatic SCCHN as a lead-in module to a Phase 2/3 study, before proceeding with one of these combinations in the study.

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 MacroGenics.

MGD013

MGD013 is an investigational, first-in-class bispecific DART molecule targeting PD-1 and LAG-3, or lymphocyte-activation gene 3. We have engineered MGD013 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. We are conducting a Phase 1 dose expansion study of MGD013 in up to nine tumor types, including both solid tumors and hematological malignancies. We expect to select one or more indications for further development and submit data from the ongoing study for presentation at a scientific conference in the first half of 2020.

Under our November 2018 license and collaboration agreement with Zai Lab, we also licensed to them the right to develop and commercialize MGD013 in mainland China, Hong Kong, Macau and Taiwan. In February 2020, Zai Lab announced that it had dosed a first patient in a Phase 1b dose escalation and expansion clinical study of MGD013 in combination with niraparib, a PARP (poly [ADP-ribose] polymerase) inhibitor, for the treatment of patients with advanced or metastatic GC or GEJ cancer who failed prior treatment.

MGC018

MGC018 is an investigational ADC that is designed to target solid tumors expressing B7-H3. This molecule uses a duocarmycin payload with a cleavable peptide linker that was licensed from Synthon Biopharmaceuticals. We are conducting a Phase 1 dose escalation study of MGC018. We expect to complete the dose escalation portion of the study in 2020 and then initiate a focused dose expansion in one or more selected tumor types. In addition, MacroGenics expects to submit data from the dose escalation cohorts for presentation at a scientific conference in 2020.

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 DART

molecule in our pipeline that was designed to enable co-blockade of PD-1 and CTLA-4 immune checkpoint molecules co-expressed on T cells. We are currently evaluating MGD019 in a Phase 1 dose escalation study. We expect to complete the dose escalation portion of the study in 2020 and then initiate a focused dose expansion in one or more selected tumor types. In addition, MacroGenics expects to submit data from the dose escalation cohorts for presentation at a scientific conference in 2020.

MGD014

MGD014 is a DART molecule that targets the envelope protein of human immunodeficiency virus (HIV) infected cells (Env) and T cells, via their CD3 component, to redirect the immune system's T cells to kill HIV-infected cells. DART molecules 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. We are developing MGD014 under contract number HHSN272201500032C awarded to us in September 2015 by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

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.

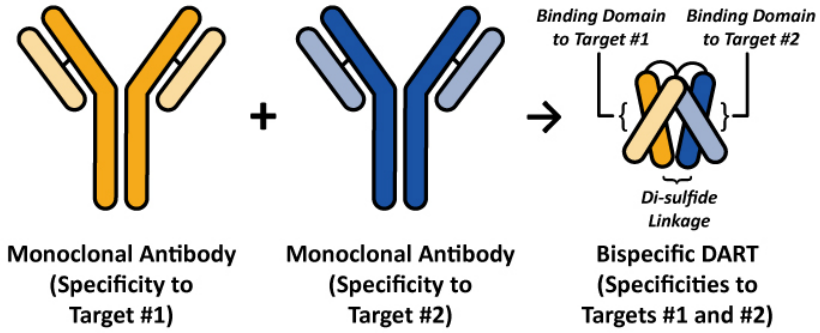
We believe that our platforms position us very well strategically to actively develop approaches for the treatment of both solid tumors and hematologic malignancies.

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:

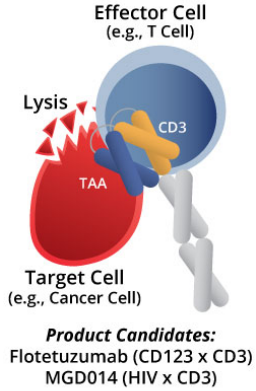


Because cancer cells have developed ways to escape the immune system, we have created DART molecules, which are alternative antibody-like structures with more potent immune properties than the parent antibody molecules from which they are derived. The two variable regions of an antibody are mono-specific 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.

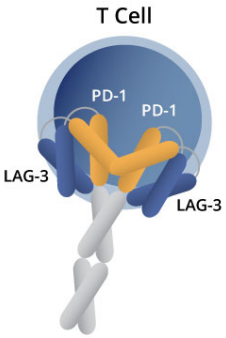
Our DART platform enables us to design multi-specific molecules that seek to exploit different mechanisms of action, including those set forth below.

- *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 chimeric antigen receptor (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:
MGD013 (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, MGD013, MGD019 and MGD014 in clinical trials, as well as others in preclinical development.

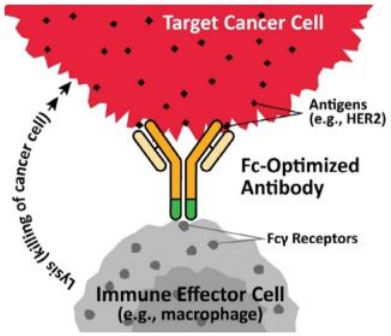
We have also advanced beyond our DART platform to establish a TRIDENT platform, which reflects the continuing evolution of our multi-specific antibody-based targeting expertise. Built on the DART module, the trivalent TRIDENT platform incorporates in an Ig-like format an additional domain capable of 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 clinical-stage antibody product candidates, margetuximab and enoblituzumab. We have preclinical data demonstrating that these Fc variants have substantially improved the activity of these antibodies. In addition, clinical data from our Phase 3 SOPHIA study of margetuximab demonstrated an improvement in PFS over that of trastuzumab, an analog monoclonal antibody with a wild-type, non-engineered Fc domain.

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, 2019, we held 85 patents in the United States with 50 patent applications pending and 562 patents in other countries of the world with 619 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
MGA012	2036*
MGD013	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 expect to apply for patent term extensions on patents covering those products. We intend to seek patent term extensions to any of 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 our drug substance for our clinical trials at our manufacturing facilities located in Rockville, Maryland. For several of our antibody product 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 plan to commercially produce margetuximab at AGC assuming approval of margetuximab. We also intend to commercially produce material for our 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

We currently have no approved products in the United States or any country. 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. We currently have not established a sales, marketing or distribution infrastructure. If we are unable to enter into a third-party commercial arrangement 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, margetuximab 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), Seattle Genetics Inc., Zymeworks, Inc., and Synthon Biopharmaceuticals, many of which have significantly greater resources than we do. Market competition may limit the utilization of margetuximab 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. and 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, Astra Zeneca, 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 Prescription Drug User Fee Act 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 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 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 postmarket 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 PRIority MEdicines (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 February 21, 2020, we had 384 full-time employees, 328 of whom were primarily engaged in research and development activities and 76 of whom had an M.D. or Ph.D. degree.

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

Our business, uncertainties and other factors described below could have a materially adverse effect on our business, financial condition or results of operations and could cause the trading price of our common stock to decline substantially.

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

All of our product candidates are in preclinical or clinical development. Clinical drug development is expensive, time consuming and uncertain and we may ultimately not be able to obtain regulatory approvals for the commercialization of some or all of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration (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, we submitted a BLA for the approval of margetuximab to the FDA in December of 2019. Obtaining approval of a BLA can be a lengthy, expensive and uncertain process, and as a company we had no experience with the preparation of a BLA submission or any other application for marketing approval. In addition, failure to comply with FDA and non-U.S. regulatory requirements may, either before or after product approval, if any, subject our company 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.

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, MGA012, MGC018, MGD013, MGD014, and MGD019, as monotherapies or in combination with other product candidates in 2020. In addition, our collaborators are currently enrolling patients in clinical trials for MGA012, which is being developed by Incyte Corporation, and we anticipate our collaborators will initiate or continue clinical trials including our other product candidates, The commencement of 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 coronavirus outbreak in 2020;
- 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 clinical research organizations (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;
- 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. For example, between December 2018 and January 2019, the FDA imposed a partial clinical hold on our Phase 1 monotherapy study of MGD009, as well as on a combination study of MGD009 and MGA012, which hold was later removed. 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 the complete analysis 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 results in the second half of 2020, 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.

Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or registration trials. For example, we submitted a BLA to the FDA for margetuximab in December 2019. We expect the BLA to be subject to a 12-month target review period from the time of FDA acceptance of the BLA for filing. We also expect that the FDA will convene an advisory committee meeting to discuss the application, and the FDA will take the recommendation of the advisory committee into account in assessing the application. Regardless of any advisory committee recommendation, FDA may decline to approve the BLA for a number of reasons including, if the clinical benefit, safety profile or effectiveness of the drug is not deemed by the FDA to warrant approval. The FDA or other non-U.S. regulatory authorities may disagree with our trial design for SOPHIA or other trials, and our interpretation of data from preclinical studies and clinical trials. In particular, the FDA may not view our data as being clinically meaningful or statistically persuasive. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial. Any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the

performance of costly post-marketing clinical trials. The FDA or other non-U.S. regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

We use new 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. 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 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 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.

Even if we obtain FDA approval of any of our product candidates, 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. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, 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, if approved by regulatory authorities, after the approved product has been marketed. All of our product candidates are still in clinical or preclinical development. 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 any of our product candidates receives marketing approval and 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.

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.

Even if approved, if any of our product candidates do not achieve broad market acceptance among physicians, patients, the medical community, and third-party payors our revenue generated from their sales will be limited.

The commercial success of our product candidates will depend upon their acceptance among physicians, patients, the medical community, and third-party payors. The degree of market acceptance of our product candidates will depend on a number of factors, including:

- limitations or warnings contained in the approved labeling for a product candidate;
- changes in the standard of care for the targeted indications for any of our product candidates;
- limitations in the approved clinical indications for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- sales, marketing and distribution support;
- availability and extent of reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness of our product candidates;
- availability of alternative therapies at similar or lower cost, including generic and over-the-counter products;
- the extent to which the product candidate is approved for inclusion on formularies of hospitals and managed care organizations;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular diseases;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- convenience and ease of administration of our products; and
- potential product liability claims.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients, the medical community, and third party payors, we may not generate sufficient revenue from these products, and we

may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

The manufacture of 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 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.

The process of manufacturing our product candidates for ourselves and our collaborators is extremely susceptible to 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, and difficulties in scaling the production process. 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 our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any adverse developments affecting manufacturing operations for 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 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 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, if any are approved by the FDA, 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 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 candidates, including leading to significant delays in the availability of drug product for 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. 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.

We currently have no sales or distribution infrastructure, and limited marketing, sales, and distribution experience in our organization. If we are unable to develop marketing, sales and distribution capabilities through collaborations or on our own , we will not be successful in commercializing margetuximab or any of our product candidates, if approved.

We currently have no sales and distribution infrastructure and we have limited marketing, sales and distribution experience within our organization. If margetuximab or any of our other product candidates are approved, we may engage a third party collaborator to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in the United States and, potentially, to outsource this function to a third party outside of the United States, or we may choose to establish our own sales, marketing and distribution capabilities in the United States commensurate with the potential market size of the specific product candidate. Either or both of these options would be expensive and time consuming, and would require a significant allocation of resources, including the time and attention of our management. In addition, we would need to devote resources to the development, maintenance, monitoring and enforcement of policies to ensure compliance with various health care laws related to sales and marketing of pharmaceutical products. These costs may be incurred in advance of any approval of our product candidates. In addition, we may not be able to engage a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the engagement of a third party collaborator or the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products.

With respect to certain of our existing and future product candidates, we have entered into collaboration or other licensing arrangements with third party collaborators that have direct sales forces and established distribution systems. To the extent that we enter into additional collaboration agreements, our product revenue may be lower than if we directly marketed or sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into additional arrangements on acceptable terms or at all, we may not be able to successfully commercialize certain approved products. If we are not successful in commercializing approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

We face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than 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. We are currently developing therapeutics that will compete with other drugs and therapies that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other drugs and therapies, some of which we may not currently be aware. 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 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) recently launched in the United Sates in a patient population that may compete with the patient population for which margetuximab has currently submitted a BLA. This 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, certain HER2 biosimilar products are approved in certain countries, including the United States, and others may be approved prior to a margetuximab approval, if any. Even if our product candidates achieve marketing approval, they 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 or product candidates obsolete, less competitive or not economical.

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.

Even if our product candidates are approved for sale by the appropriate regulatory authorities, market acceptance and sales of these products 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 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.

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, 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 (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 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 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, and we expect there will be additional challenges and amendments to the ACA in the future.

In September 2017, members of the United States Congress introduced legislation with the announced intention to repeal major provisions of the ACA. Although it is unclear whether such legislation will ultimately become law, executive or legislative branch attempts to repeal, reform or to repeal and replace the ACA will likely continue. In addition, various other healthcare reform proposals have also emerged at the federal and state level. In addition, recent changes to United States tax laws could negatively impact the ACA. 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 the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new 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 product candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients, and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. 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 future 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.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer 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.

We currently 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.

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. We have no products approved for commercial sale, and to date we have not generated any revenue or profit from product sales. We may never achieve or sustain profitability.

We are a clinical-stage biopharmaceutical company. We have incurred significant losses since our inception. As of December 31, 2019, our accumulated deficit was approximately $642.1 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 margetuximab, if approved, or any of our other product candidates.

To become and remain profitable, we must succeed in developing and commercializing products with significant market potential. This will require us 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 those products 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. 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, 2019, combined with anticipated and potential collaboration payments, will enable us to fund our operations into 2021, assuming all of our programs and collaborations advance as currently contemplated. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and 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, 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 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, 2019, we had federal and state NOL carryforwards of $554.5 million and federal research and development tax credits of $58.2 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 capability for sales, marketing or distribution. We have entered into collaborations with other companies that we believe can provide such capabilities, including our collaboration and license 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 2019, 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, notified us of its intent to terminate its agreement with us. This termination became effective January 15, 2020. All of the risks relating to product development, regulatory approval and commercialization described in this report 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 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 some of our product candidates, we may in the future determine to collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. 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 the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for 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 a product candidate, reduce or delay one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to 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 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 existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Aside from our agreement with Green Cross Corporation, subject to certain specified exceptions, each of our existing therapeutic collaborations contains 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 contract research organizations (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, including, for example, margetuximab. We do not have experience or capabilities in developing or commercializing diagnostics and plan 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 expect to contract with third parties for the manufacture of some of our product candidates for clinical testing in the future and expect to do so for 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 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 advance our product candidate pipeline. We expect to use third parties for the manufacture of certain 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 one of our third party collaborators. We have entered into two long-term 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 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 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 any of our product candidates are approved and 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 our product candidates and to have any such new source approved by the FDA or any other relevant regulatory authorities.

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. 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.

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 margetuximab 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 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 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.

If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws commonly referred to as "fraud and abuse" laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include false claims and anti-kickback statutes.

Federal false claims laws prohibit any person 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. In addition, under the Sunshine Act provisions of the ACA, pharmaceutical manufacturers with one or more products for which payment is available under a federal health care program are subject to federal reporting and disclosure requirements with regard to payments or other transfers of value made to physicians and teaching hospitals. 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. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

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, sham 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, if ever, as we market 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 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 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. At this time, the vast majority of our outstanding equity awards, which are generally issued in the form of stock options, are significantly out-of-the-money, are unlikely to be exercised in the future, and as a result, provide little present value to employees holding such awards. 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 February 21, 2020, we had 384 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 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 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. 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 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; and
- overall fluctuations in U.S. equity markets.

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 225,000 square feet of manufacturing, office and laboratory space in Rockville, Maryland and Brisbane, California. Our headquarters building in Rockville 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 but one 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

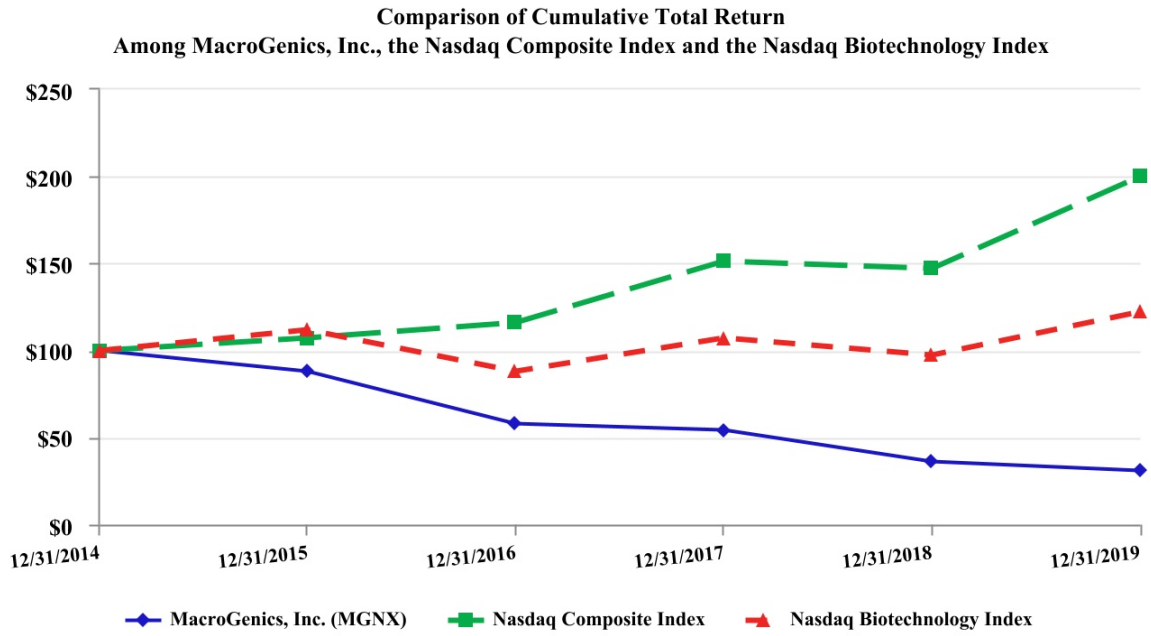
ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on the Nasdaq Global Select Market under the symbol "MGNX". As of February 21, 2020, we had 48,984,218 shares of common stock outstanding held by approximately 69 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, 2014 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

The consolidated statement of operations and comprehensive loss data for the years ended December 31, 2019, 2018 and 2017 and the consolidated balance sheet data as of December 31, 2019 and 2018 presented below have been derived from our audited consolidated financial statements and footnotes included elsewhere in this Annual Report on Form 10-K. The consolidated statement of operations and comprehensive loss data for the years ended December 31, 2016 and 2015 and the consolidated balance sheet data as of December 31, 2017, 2016 and 2015 have been derived from our audited consolidated financial statements which are not included herein. Historical results are not necessarily indicative of future results. The following data should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands, except share and per share data)				
Statement of Operations Data:					
Total revenues	$ 64,188	$ 60,121	$ 157,742	$ 100,854	$ 47,797
Costs and expenses:					
Research and development	195,309	190,827	147,232	98,271	70,186
General and administrative	46,064	40,500	32,653	22,765	15,926
Total costs and expenses	241,373	231,327	179,885	121,036	86,112
Loss from operations	(177,185)	(171,206)	(22,143)	(20,182)	(38,315)
Other income (expense)	25,374	(247)	2,517	42	2
Net loss	(151,811)	(171,453)	(19,626)	(20,140)	(38,313)
Other comprehensive loss:					
Unrealized gain (loss) on investments	19	58	21	(5)	—
Comprehensive loss	$ (151,792)	$ (171,395)	$ (19,605)	$ (20,145)	$ (38,313)
Basic and diluted net loss per common share	$ (3.16)	$ (4.19)	$ (0.54)	$ (0.63)	$ (1.40)
Basic and diluted weighted average number of common shares	48,082,728	40,925,318	36,095,080	31,801,645	27,384,990

	As of December 31,				
	2019	2018	2017	2016	2015
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 215,756	$ 232,863	$ 284,982	$ 339,049	$ 157,591
Total assets	312,501	332,130	311,263	359,269	173,886
Deferred revenue	19,853	40,722	14,306	18,497	30,720
Total stockholders' equity	230,628	242,877	268,751	313,337	121,286

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, 2018 compared to the year ended December 31, 2017, 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, 2018 filed with the SEC on February 26, 2019.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering and developing innovative antibody-based therapeutics designed to modulate the human immune response for the treatment of cancer. We currently have a pipeline of product candidates in human clinical testing, including seven 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, 2019, combined with anticipated and potential collaboration payments, will enable us to fund our operations into 2021 assuming our programs and collaborations advance as currently contemplated. Through the prioritization of programs and ongoing realignment of our resources, we are focused on extending our cash runway into 2022.

Through December 31, 2019, we had an accumulated deficit of $642.1 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.

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 MGA012, 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 MGA012 in all indications, while we retain the right to develop our pipeline assets in combination with MGA012. 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 will lead global development of MGA012. Assuming successful development and commercialization of MGA012 by Incyte, we could receive development and regulatory milestones of up to approximately $420.0 million, of which we have already received $15.0 million, and up to $330.0 million in commercial milestones. If MGA012 is 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 MGA012 with Incyte. We retain the right to develop our pipeline assets in combination with MGA012, with Incyte commercializing MGA012 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 MGA012 (Incyte Clinical Supply Agreement). In addition, we retain the right to manufacture a portion of both companies' global commercial supply needs of MGA012.

- *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) 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, MGD013 and the TRIDENT molecule, we could receive up to $140.0 million in development and regulatory milestones. In addition, Zai Lab would pay us tiered royalties at percentage rates of mid-teens to twenty percent for net sales of margetuximab in Zai Lab's territory, mid-teens for net sales of MGD013 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 twenty percent on annual net sales in its territories.

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. We may never succeed in achieving regulatory approval for any of our product candidates. 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

Beginning January 1, 2018, 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. 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 clinical research organizations (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, 2019 and 2018:

	Year Ended December 31,		Increase/(Decrease)	
	2019	2018		
		(dollars in millions)		
Revenue from collaborative and other agreements	$ 62.0	$ 58.6	$ 3.4	6 %
Revenue from government agreements	2.2	1.5	0.7	47 %
Total revenue	**$ 64.2**	**$ 60.1**	**$ 4.1**	**7 %**

The increase of $3.4 million in revenue from collaborative and other agreements for the year ended December 31, 2019 compared to the year ended December 31, 2018 was primarily due to:

- a full year of revenue recognition of the deferred upfront payment under the Zai Lab collaboration and license agreement during the year ended December 31, 2019 compared to only one month during the year ended December 31, 2018;
- revenue recognized during the year ended December 31, 2019 related to manufacturing services performed under the Zai Lab clinical supply agreements;
- increased revenue recognition of the Les Laboratoires Servier and Institut de Recherches Servier (collectively, Servier) flotetuzumab license grant fee during the year ended December 31, 2019 due to Servier's notice of their intention to terminate the agreement effective January 15, 2020; and

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

These increases were partially offset by:

- decreased revenue recognized under the Incyte License Agreement. Revenue recognized during the year ended December 31, 2018 included $15.0 million in milestones and revenue related to certain clinical activities performed; and
- decreased revenue recognized under the Provention Bio, Inc. (Provention) license agreement and Provention asset purchase agreement. Revenue recognized during the year ended December 31, 2018 included $6.1 million recognized when the Company satisfied its performance obligations under the agreements.

Research and Development Expenses

The following represents a comparison of our research and development expenses for the years ended December 31, 2019 and 2018:

	Year Ended December 31,		Increase/(Decrease)	
	2019	2018		
	(dollars in millions)			
Margetuximab	$ 52.2	$ 68.4	$ (16.2)	(24) %
MGD013	22.5	10.3	12.2	118 %
Enoblituzumab	20.7	15.8	4.9	31 %
MGA012	19.7	28.6	(8.9)	(31) %
Flotetuzumab (a)	15.1	14.4	0.7	5 %
MGC018	12.6	7.0	5.6	80 %
MGD009	7.2	8.9	(1.7)	(19) %
MGD019	7.0	5.5	1.5	27 %
MGD007	5.2	6.7	(1.5)	(22) %
Other immune modulator programs	9.7	6.4	3.3	52 %
Discovery and other pipeline programs, collectively	23.4	18.8	4.6	24 %
Total research and development expenses	**$ 195.3**	**$ 190.8**	**$ 4.5**	**2 %**

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

Research and development expenses for the year ended December 31, 2019 increased by $4.5 million compared to the year ended December 31, 2018. This increase was primarily attributable to:

- increased clinical costs related to the preparation for a Phase 2/3 study of enoblituzumab in combination with MGA012;
- increased clinical trial costs related to our ongoing MGD013 Phase 1 study;
- increased costs related to the initiation of a Phase 1 study of MGC018; and
- increased costs related to preclinical development of product candidates in our pipeline.

These increases were partially offset by:

- reduced clinical trial costs due to completed enrollment in our margetuximab Phase 3 SOPHIA study; and
- reduced clinical trial costs for MGA012, as the monotherapy trial was transferred to Incyte in 2018 and decreased development and manufacturing activities.

General and Administrative Expenses

The following represents a comparison of our general and administrative expenses for the years ended December 31, 2019 and 2018:

	Year Ended December 31,		Increase/(Decrease)	
	2019	2018		
	(dollars in millions)			
General and administrative expenses	$ 46.1	$ 40.5	$ 5.6	14 %

General and administrative expenses increased for the year ended December 31, 2019 by $5.6 million compared to 2018 primarily due to an increase in consulting costs related to market research and other commercial preparation activities.

Other Income (Expense)

The change to other income for the year ended December 31, 2019 from other expense for the year ended December 31, 2018 is primarily due to the revaluation of the warrants we received as consideration under the Provention license agreement and Provention asset purchase agreement of $20.1 million.

Liquidity and Capital Resources

We have historically financed our operations primarily through public and private offerings of equity, upfront fees, milestone payments, license option fees and payments for development and manufacturing services from collaborators and reimbursement through government grants and contracts. As of December 31, 2019, we had $215.8 million in cash, cash equivalents and marketable securities. In addition to our existing cash, cash equivalents and marketable securities, we are eligible to receive additional reimbursement from our collaborators, including under various government grants or contracts, for certain research and development services rendered, additional milestone and opt-in payments and grant revenue. However, our ability to receive these milestone payments is dependent upon our ability to successfully complete specified research and development activities and is therefore uncertain at this time.

Funding Requirements

We have not generated any revenue from product sales to date and do not expect to do so until such time as we obtain regulatory approval for and commercialize one or more of our product candidates. As we are currently in the clinical trial stage of development, it may be some time before we expect to generate revenue from product sales and it is uncertain that we ever will. We expect that we will continue to increase our operating expenses in connection with ongoing as well as additional clinical trials and preclinical development of product candidates in our pipeline. We expect to continue our collaboration arrangements and will look for additional collaboration opportunities. We also expect to continue our efforts to pursue additional grants and contracts from the U.S. government in order to further our research and development. Although it is difficult to predict our funding requirements, based upon our current operating plan, we anticipate that our existing cash, cash equivalents and marketable securities as of December 31, 2019, combined with anticipated and potential collaboration payments, will enable us to fund our operations into 2021, assuming all of our programs and collaborations advance as currently contemplated.

Cash Flows

The following table represents a summary of our cash flows for the years ended December 31, 2019 and 2018:

	Year Ended December 31,		Increase/(Decrease)	
	2019	2018		
	(dollars in millions)			
Net cash provided by (used in):				
Operating activities	$ (134.3)	$ (153.2)	$ 18.9	(12) %
Investing activities	(79.4)	56.6	(136.0)	(240) %
Financing activities	120.0	105.0	15.0	14 %
Net increase (decrease) in cash and cash equivalents	**$ (93.7)**	**$ 8.4**	**$ (102.1)**	**(1215) %**

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, 2019 benefiting from the $22.5 million net upfront payment from Zai Lab and the $15.0 million upfront payment from I-Mab, and the year ended December 31, 2018

benefiting from the $15.0 million in milestone payments received from Incyte and the $10.0 million upfront payment from Roche.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2019 is primarily due to purchases of marketable securities, partially offset by maturities of marketable securities. Net cash provided by investing activities during the year ended December 31, 2018 is primarily due to maturities of marketable securities, partially offset by purchases of marketable securities and making leasehold improvements to our facilities, including the build out of a manufacturing suite at our headquarters building in Rockville, Maryland.

Financing Activities

Net cash provided by financing activities for the years ended December 31, 2019 and 2018 reflects net cash proceeds from our securities offerings of approximately $118.7 million and $103.3 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 Rockville, Maryland and Brisbane, California. The following table represents future minimum operating lease payments under non-cancelable operating leases as of December 31, 2019:

	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
			(in millions)		
Operating Leases	$ 42.3	$ 5.9	$ 13.2	$ 12.1	$ 11.1

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, 2019, we had cash, cash equivalents and marketable securities of $215.8 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 on pages F-1 - F-28 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, 2019. 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, 2019, and has concluded that there was no change that occurred during the quarterly period ended December 31, 2019 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, 2019. 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, 2019, 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, 2019 has been audited by Ernst & Young, LLP, an independent registered public accounting firm, as stated in their report which is included herein on page 56.

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, 2019, 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, 2019, 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, 2019 and 2018, 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, 2019, and the related notes and our report dated February 25, 2020, 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, 2020

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 2020 annual meeting of stockholders (the 2020 Proxy Statement).

ITEM 11. EXECUTIVE COMPENSATION

We incorporate herein by reference the relevant information concerning executive compensation to be included in the 2020 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 2020 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 2020 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 2020 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, 2020
/s/ James Karrels James Karrels	Senior Vice President, Chief Financial Officer and Secretary (Principal Financial Officer)	February 25, 2020
/s/ Lynn Cilinski Lynn Cilinski	Vice President, Controller and Treasurer (Principal Accounting Officer)	February 25, 2020
/s/ Paulo Costa Paulo Costa	Director	February 25, 2020
/s/ Karen Ferrante, M.D. Karen Ferrante, M.D.	Director	February 25, 2020
/s/ Matthew Fust Matthew Fust	Director	February 25, 2020
/s/ Kenneth Galbraith Kenneth Galbraith	Director	February 25, 2020
/s/ Edward Hurwitz Edward Hurwitz	Director	February 25, 2020
/s/ Scott Jackson Scott Jackson	Director	February 25, 2020
/s/ Jay Siegel, M.D. Jay Siegel, M.D.	Director	February 25, 2020
/s/ David Stump, M.D. David Stump, M.D.	Director	February 25, 2020

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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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, 2020 expressed an unqualified opinion thereon.

Adoption of Accounting Standards Update (ASU) No. 2014-09

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for revenue from contracts with customers in 2018 due to the adoption of ASU No. 2014-09, "Revenues from Contracts with Customers," as amended (Topic 606).

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, 2019 is included in accrued expenses of $27.1 million on the consolidated balance sheet, and the Company's related 2019 clinical trial expenses are included in research and development costs and expenses of $195.3 million on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2019. 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, 2019. 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, 2020

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

	December 31,	
	2019	**2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 126,472	$ 220,128
Marketable securities	89,284	12,735
Accounts receivable	12,744	29,583
Prepaid expenses and other current assets	11,285	6,678
Total current assets	239,785	269,124
Property, equipment and software, net	48,211	56,712
Other assets	24,505	6,294
Total assets	$ 312,501	$ 332,130
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,308	$ 4,005
Accrued expenses and other current liabilities	27,139	33,196
Deferred revenue	10,700	21,721
Deferred rent	—	1,018
Lease Liabilities	3,020	—
Total current liabilities	45,167	59,940
Deferred revenue, net of current portion	9,153	19,001
Lease liabilities, net of current portion	27,553	—
Deferred rent, net of current portion	—	10,312
Total liabilities	81,873	89,253
Stockholders' equity:		
Common stock, $0.01 par value -- 125,000,000 shares authorized, 48,958,763 and 42,353,301 shares outstanding at December 31, 2019 and December 31, 2018, respectively	490	424
Additional paid-in capital	872,204	732,727
Accumulated other comprehensive income (loss)	16	(3)
Accumulated deficit	(642,082)	(490,271)
Total stockholders' equity	230,628	242,877
Total liabilities and stockholders' equity	$ 312,501	$ 332,130

See accompanying notes.

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

	Year Ended December 31,		
	2019	**2018**	**2017**
Revenues:			
Revenue from collaborative and other agreements	$ 62,024	$ 58,644	$ 155,516
Revenue from government agreements	2,164	1,477	2,226
Total revenues	64,188	60,121	157,742
Costs and expenses:			
Research and development	195,309	190,827	147,232
General and administrative	46,064	40,500	32,653
Total costs and expenses	241,373	231,327	179,885
Loss from operations	(177,185)	(171,206)	(22,143)
Other income (expense)	25,374	(247)	2,517
Net loss	(151,811)	(171,453)	(19,626)
Other comprehensive loss:			
Unrealized gain on investments	19	58	21
Comprehensive loss	$ (151,792)	$ (171,395)	$ (19,605)
Basic and diluted net loss per common share	$ (3.16)	$ (4.19)	$ (0.54)
Basic and diluted weighted average number of common shares	48,082,728	40,925,318	36,095,080

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, 2016	34,870,607	$ 349	—	$ —	$ 561,198	$ (292,714)	$ (82)	$ 268,751
Share-based compensation	—	—	—	—	14,744	—	—	14,744
Issuance of common stock, net of offering costs	1,699,284	17	—	—	34,227	—	—	34,244
Stock plan related activity	289,186	3	1,862	(40)	1,141	—	—	1,104
Retirement of treasury stock	—	—	(1,862)	40	(40)	—	—	—
Unrealized gain on investments	—	—	—	—	—	—	21	21
Net loss	—	—	—	—	—	(19,626)	—	(19,626)
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

See accompanying notes.

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

	Year Ended December 31,		
	2019	**2018**	**2017**
Operating activities			
Net loss	$ (151,811)	$ (171,453)	$ (19,626)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	10,845	8,279	7,228
Share-based compensation	19,571	16,520	14,744
Changes in operating assets and liabilities:			
Accounts receivable	16,839	(15,941)	(10,878)
Prepaid expenses	(4,878)	(3,255)	332
Other assets	(1,578)	(4,580)	262
Accounts payable	787	1,554	(1,544)
Accrued expenses	(6,057)	3,506	12,832
Lease liabilities	2,881	—	—
Deferred revenue	(20,869)	13,405	6,533
Deferred rent	—	(971)	6,115
Other liabilities	—	(298)	(1,593)
Net cash provided by (used in) operating activities	(134,270)	(153,234)	14,405
Cash flows from investing activities			
Purchases of marketable securities	(264,399)	(132,750)	(135,122)
Proceeds from sales and maturities of marketable securities	189,330	214,348	242,401
Purchases of property, equipment and software	(4,289)	(24,954)	(29,403)
Net cash provided by (used in) investing activities	(79,358)	56,644	77,876
Cash flows from financing activities			
Proceeds from issuance of common stock, net of offering costs	118,657	103,259	34,244
Proceeds from stock option exercises and ESPP purchases	1,315	1,992	1,144
Purchase of treasury stock	—	(260)	(40)
Net cash provided by financing activities	119,972	104,991	35,348
Net change in cash and cash equivalents	(93,656)	8,401	127,629
Cash and cash equivalents at beginning of period	220,128	211,727	84,098
Cash and cash equivalents at end of period	$ 126,472	$ 220,128	$ 211,727
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 discovering and developing innovative antibody-based therapeutics designed to modulate the human immune response for the treatment of cancer. The Company currently has a pipeline of investigational product candidates in human clinical testing that have been created primarily using its proprietary, antibody-based technology platforms. The Company believes its programs 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 monoclonal antibody-based therapeutics for cancer, autoimmune and infectious diseases.

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).

At each balance sheet date, the Company assesses available-for-sale securities in an unrealized loss position to determine whether the unrealized loss is other-than-temporary. The Company considers factors including: the significance of the decline in value compared to the cost basis, underlying factors contributing to a decline in the prices of securities in a single asset class, the length of time the market value of the security has been less than its cost basis, the security's relative performance versus its peers, sector or asset class, expected market volatility and the market and economy in general. The Company also evaluates whether it is more likely than not that it will be required to sell a security prior to recovery of its fair value. An impairment loss is recognized at the time the Company determines that a decline in the fair value below its cost basis is other-than-temporary. There were no unrealized losses at December 31, 2019 or 2018 that the Company determined to be other-than-temporary.

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, 2019 or 2018, 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 the Financial Accounting Standards Board (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, 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 [a]	$ 162,506	$ 46,149	$ 116,357	$ —

	Fair Value Measurement at December 31, 2018			
	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	$ 46,257	$ 46,257	$ —	$ —
U.S Treasury securities	12,488	—	12,488	—
Corporate debt securities	100,214	—	100,214	—
Common stock warrants	1,890	—	—	$ 1,890
Total assets measured at fair value [b]	$ 160,849	$ 46,257	$ 112,702	$ 1,890

(a) 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.

(b) Total assets measured at fair value at December 31, 2018 includes approximately $146.2 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,		
	2019	2018	2017
Incyte Corporation (Incyte)	35%	68%	96%
Zai Lab Limited (Zai Lab)	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,	
	2019	2018
Incyte	62%	16%
Zai Lab	23%	76%

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, 2019, 2018 and 2017, 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

Beginning on January 1, 2018, the Company recognizes revenue under Accounting Standards Update (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. 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, clinical research organization (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,		
	2019	**2018**	**2017**
Stock options and RSUs	7,159,494	5,273,964	4,504,642

Recently Adopted Accounting Standards

In May 2014, the FASB issued ASC 606. The Company adopted ASC 606 on January 1, 2018 using the modified retrospective method for all contracts that were not completed as of January 1, 2018. For contracts that were modified before the effective date, the Company reflected the aggregate effect of all modifications when identifying performance obligations and allocating transaction price in accordance with available practical expedients. Comparative prior period information continues to be reported under the accounting standards in effect for the period presented.

As a result of applying the modified retrospective method to adopt the new guidance, the following adjustments were made to accounts on the consolidated balance sheet as of January 1, 2018 (in thousands):

	Pre-Adoption	**ASC 606 Adjustment**	**Post-Adoption**
Deferred revenue, current	$ 7,202	$ 540	$ 7,742
Deferred revenue, net of current portion	13,637	5,939	19,576
Accumulated deficit	(312,340)	(6,478)	(318,818)

The transition adjustment resulted primarily from changes in the pattern of revenue recognition for upfront fees and license grant fees.

The following table shows the impact of adoption to the consolidated statement of income and balance sheet (in thousands):

	Year Ended December 31, 2018		
	As Reported	Balances Without Adoption of ASC 606	Effect of Change Higher/(Lower)
Revenue from collaborative agreements	$ 58,644	$ 58,104	$ 540
Net loss	(171,453)	(171,993)	(540)
Basic and diluted net loss per common share	$ (4.19)	$ (4.20)	$ 0.01

	As of December 31, 2018		
	As Reported	Balances Without Adoption of ASC 606	Effect of Change Higher/(Lower)
Deferred revenue, current	$ 21,721	$ 22,210	$ (489)
Deferred revenue, net of current portion	19,001	12,573	6,428
Accumulated deficit	(490,271)	$ (484,332)	$ (5,939)

The following table presents changes in the Company's contract liabilities during the year ended December 31, 2018 (in thousands):

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Deferred revenue (current and non-current)	$ 27,318	$ 22,992	$ (9,588)	$ 40,722

During the year ended December 31, 2018, the Company recognized $9.6 million in revenue as a result of changes in the contract liability balance.

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.

Recently Issued Accounting Standards

In June 2016, the FASB issued 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 standard is effective for interim and annual periods beginning after December 15, 2019 and requires a modified-retrospective approach with a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period. Based on the composition of the Company's investment portfolio, current market conditions and historical credit loss activity, the adoption of ASU 2016-13 is not expected to have a material impact on its consolidated financial position, results of operations or the related disclosures.

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. This standard is effective for interim and annual periods beginning after December 15, 2019. Entities have the option to apply this standard prospectively to all implementation costs incurred after the date of adoption or retrospectively. The Company is evaluating this new standard, but does not expect it to have a significant impact on its financial statement presentation or results.

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 guidance will be effective for fiscal years beginning after December 15, 2019. Early adoption is permitted and should be applied retrospectively. The Company does not anticipate the adoption of this standard will have a material impact on its consolidated financial statements.

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, 2019 and 2018 were as follows (in thousands):

	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

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities	$ 12,738	$ —	$ (3)	$ 12,735

All of the Company's available-for-sale securities held at December 31, 2019 and 2018 had maturity dates of less than one year.

All available-for-sale securities in an unrealized loss position as of December 31, 2019 and 2018 were in a loss position for less than twelve months. There were no unrealized losses at December 31, 2019 or 2018 that the Company determined to be other-than-temporary. The Company recorded interest income of $3.4 million, $2.3 million and $2.4 million during the years ended December 31, 2019, 2018 and 2017, 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,	
	2019	2018
Computer equipment	$ 2,430	$ 2,360
Software	7,513	7,011
Furniture and office equipment	713	668
Motor Vehicles	50	—
Lab equipment	38,368	36,062
Leasehold improvements	48,675	48,328
Construction in progress	187	218
Property, equipment and software	97,936	94,647
Less accumulated depreciation and amortization	(49,725)	(37,935)
Property, equipment and software, net	$ 48,211	$ 56,712

There was $0.1 million in property, equipment and software at December 31, 2019 that was purchased in 2019 but was not paid for by year end. The property, equipment and software balance at December 31, 2018 includes approximately $0.6 million in assets that were purchased in 2018 but were not paid for by year end. Depreciation and amortization expense related to property, equipment and software for the years ended December 31, 2019, 2018 and 2017 was $12.3 million, $9.2 million and $7.0 million, respectively.

5. Leases

The Company has non-cancelable operating leases for manufacturing, laboratory and office space in Rockville, Maryland and a non-cancelable operating lease for laboratory and office space in Brisbane, California. A portion of the space under one of these leases is subleased to a third party. All but one of these leases include one or more options to renew, with those renewal periods ranging from five to fourteen years. At December 31, 2019, the Company's weighted-average remaining lease term relating to its operating leases is 5.6 years, with a weighted-average discount rate of 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. The Company made cash payments of $6.4 million for operating leases during the year ended December 31, 2019. As of December 31, 2019, the Company’s ROU assets were valued at $20.2 million and are included in Other assets on the consolidated balance sheet.

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

Operating lease cost	$ 5,463
Variable lease cost	1,366
Sublease income	(942)
Net lease cost	$ 5,887

As of December 31, 2019, the maturities of our operating lease liabilities were as follows (in thousands):

2020	5,913
2021	6,507
2022	6,688
2023	6,536
2024	5,588
Thereafter	11,068
Total lease payments	42,300
Present value adjustment	(11,727)
Lease liabilities	$ 30,573

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, 2019 or 2018.

In April 2017, the Company entered into a definitive agreement with an institutional healthcare investor to purchase 1,100,000 shares of its common stock at a purchase price of $21.50 per share in a registered direct offering. Proceeds to the Company, before deducting estimated offering expenses, were $23.7 million. The shares were offered pursuant to the Company's effective shelf registration on Form S-3 that was filed with the Securities and Exchange Commission (SEC) on November 2, 2016.

In May 2017, the Company entered into a sales agreement with an agent to sell, from time to time, shares of its common stock having an aggregate sales price of up to $75.0 million through an "at the market offering" (ATM Offering) as defined in Rule 415 under the Securities Act of 1933, as amended. 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 SEC on November 2, 2016. During the year ended December 31, 2017, the Company sold 599,284 shares of common stock resulting in net proceeds of approximately $10.8 million related to the ATM Offering.

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.

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, 2019,

employees purchased 61,417 shares of common stock under the 2016 ESPP for net proceeds to the Company of approximately $0.7 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, 2019, under the 2003 Plan, there were options to purchase an aggregate of 550,572 shares of common stock outstanding at a weighted average exercise price of $2.32 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, 2019, the maximum number of shares of common stock authorized to be issued by the Company under the 2013 Plan was increased to 9,932,263. 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, 2019, under the 2013 Plan, there were options to purchase an aggregate of 6,156,422 shares of common stock outstanding at a weighted average exercise price of $24.12 per share.

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

	Year Ended December 31,		
	2019	**2018**	**2017**
Research and development	$ 10,023	$ 7,919	$ 7,388
General and administrative	9,548	8,601	7,356
Total stock-based compensation expense	$ 19,571	$ 16,520	$ 14,744

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,		
	2019	**2018**	**2017**
Expected dividend yield	0%	0%	0%
Expected volatility	74% - 76%	68% - 72%	67% - 68%
Risk-free interest rate	1.4% - 2.6%	2.4% - 3.1%	1.9% - 2.3%
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. As the Company does not yet have sufficient history of its own volatility, the Company has identified several public entities of similar size, complexity and stage of development and estimates volatility based on the volatility of these companies.

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 2019:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2018	5,273,964	$ 22.23	6.8	
Granted	1,946,770	20.81		
Exercised	(219,045)	3.03		
Forfeited or expired	(294,695)	24.72		
Outstanding, December 31, 2019	6,706,994	22.33	6.9	$ 4,749
December 31, 2019:				
Exercisable	4,298,178	22.21	5.9	4,712
Vested and expected to vest	6,446,218	22.31	6.9	4,746

During 2019, 2018 and 2017 the Company issued 219,045, 274,362 and 253,036 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 $0.7 million, $0.9 million and $0.5 million during 2019, 2018 and 2017, respectively.

The weighted-average grant-date fair value of options granted during 2019, 2018 and 2017 was $13.98, $17.90 and $12.53 per share, respectively. The total intrinsic value of options exercised during 2019, 2018 and 2017 was approximately $2.9 million, $5.2 million and $4.2 million, respectively. The total fair value of stock options which vested during 2019, 2018 and 2017 was $17.7 million, $16.4 million and $14.6 million, respectively. As of December 31, 2019, the total unrecognized compensation expense related to non-vested stock options, net of related forfeiture estimates, was $30.2 million, which the Company expects to recognize over a weighted-average period of approximately 2.6 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. No RSUs were granted during the years ended December 31, 2018 and 2017.

The following table summarizes RSU activity for 2019:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding, December 31, 2018	—	—
Granted	467,600	$ 15.32
Exercised	—	—
Forfeited or expired	(15,100)	15.32
Outstanding, December 31, 2019	452,500	15.32

At December 31, 2019, there was $5.3 million of total unrecognized compensation cost related to unvested RSUs, which the Company expects to recognize over a remaining weighted-average period of 1.6 years.

8. Income Taxes

For the years ended December 31, 2019, 2018 and 2017 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,	
	2019	2018
Deferred income tax assets:		
Federal U.S. net operating loss carryforward	$ 116,436	$ 87,284
State net operating loss carryforward	31,110	22,809
Research and development credit, net	35,580	29,750
Orphan drug credit, net	22,881	22,580
Operating lease liabilities	8,413	—
Deferred revenue	367	3,736
Other	9,123	9,972
Gross deferred income tax assets	223,910	176,131
Valuation allowance	(214,893)	(172,457)
Net deferred income tax assets	9,017	3,674
Deferred income tax liabilities:		
Depreciation	(438)	(1,911)
Operating lease ROU assets	(5,547)	—
Prepaid expenditures	(3,032)	(1,763)
Gross deferred income tax liabilities	(9,017)	(3,674)
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, 2019, the Company has U.S. federal and state net operating loss (NOL) carryforwards of approximately $554.5 million. Of these NOLs, $237.8 million will expire in various years beginning in 2025 through 2037. $316.7 million of NOLs were generated post December 31, 2017 and carryforward indefinitely. In addition, the Company has U.S. federal tax credits of $58.2 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, 2019, $13.5 million of the Company's U.S. Federal NOLs are limited for use over the years 2020 – 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 $541.0 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,		
	2019	2018	2017
United States federal tax at statutory rate	$ (31,880)	$ (36,005)	$ (6,869)
State taxes (net of federal benefit)	(9,524)	(11,133)	(735)
Deferred income tax adjustments	2,004	(4,435)	607
Deferred state blended rate adjustments	—	—	(485)
Deferred federal rate change reduction in corporate rate	—	—	39,447
Research credit, net	(5,830)	(8,466)	(8,455)
Orphan drug credit, net	(301)	(872)	(1,853)
Other permanent items	1,206	148	276
Equity-based compensation	1,889	758	2,067
Change in valuation allowance	42,436	60,005	(24,000)
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,		
	2019	2018	2017
Beginning balance	$ 4,318	$ 3,395	$ 2,465
Increases for current year tax positions	637	642	569
Increases/(decreases) for prior year tax positions	(5)	281	361
Ending balance	$ 4,950	$ 4,318	$ 3,395

As of December 31, 2019 and 2018, of the total gross unrecognized tax benefits, approximately $4.9 million and $4.3 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, 2019, 2018 and 2017, 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 net operating losses and tax credits.

9. Collaboration and Other Agreements

Incyte

In October 2017, the Company entered into an exclusive global collaboration and license agreement with Incyte for MGA012 (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 MGA012 in all indications, while the Company retains the right to develop its pipeline assets in combination with MGA012. 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 MGA012. 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. As of December 31, 2019, the Company has recognized $15.0 million in development milestones under this agreement. If 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 MGA012, with Incyte commercializing MGA012 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 MGA012, subject to a separate commercial supply agreement to be negotiated. Finally, Incyte funded the Company's activities related to the ongoing monotherapy clinical study and will continue to fund certain related clinical activities.

Upon the adoption of ASC 606 on January 1, 2018, the Company evaluated the Incyte Agreement under the provisions of ASC 606 and identified the following two performance obligations under the agreement: (i) the license of MGA012 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 MGA012 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, 2019 there were no adjustments to the transaction price of the Incyte Agreement.

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 over the period from the effective date of the agreement until such time as the clinical activities were transferred to Incyte using an input method according to research and development costs incurred to date compared to estimated total research and development costs. These clinical activities were substantially completed in 2018. Prior to the adoption of ASC 606 on January 1, 2018, the accounting for this agreement did not materially differ from the accounting under ASC 606. The Company recognized revenue of $0.1 million and $18.8 million under the Incyte Agreement during the years ended December 31, 2019 and 2018, respectively. 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 MGA012 (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 MGA012. 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. During the years ended December 31, 2019 and 2018, the Company recognized revenue of $22.1 million and $22.2 million, respectively, for services performed under this agreement.

Servier

In September 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 INDs for flotetuzumab and MGD007 were cleared by the Food and Drug Administration (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 year ended December 31, 2019. During the years ended December 31, 2018 and 2017, the Company recognized revenue of $1.9 million and $1.1 million, respectively, related to the MGD007 option. No revenue was deferred related to the MGD007 option at December 31, 2018.

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 is 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, 2019, 2018 and 2017 the Company recognized revenue of $11.6 million, $1.2 million, and $1.4 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.

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, 2018 and 2017, the Company recorded approximately $3.6 million, $6.0 million and $3.2 million, respectively, as an offset to research and development expense under this collaborative arrangement.

Zai Lab

In November 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) 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, less foreign withholding tax of $2.5 million. Assuming successful development and commercialization of margetuximab, MGD013 and the TRIDENT molecule, the Company could receive up to $140.0 million in development and regulatory milestones. 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 MGD013 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 MGD013: (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 MGD013 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 $25.0 million (less foreign withholding tax of $2.5 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 relatively short-term nature of the recognition period, the revenue associated with the MGD013 performance obligation is being recognized on a straight-line basis as the Company performs research and development activities under the agreement. The fixed consideration related to the margetuximab performance obligation is also being recognized on a straight-line basis as the Company performs research and development activities under the agreement. 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 will be recognized upon certain regulatory achievements. During the years ended December 31, 2019 and 2018, the Company recognized revenue of $16.1 million and $1.3 million, respectively, related to the Zai Lab Agreement. At December 31, 2019, $5.0 million of revenue was deferred under this agreement, all of which was current. In February 2020, Zai Lab announced that the first patients were

dosed in two separate clinical studies; one utilizing MGD013 and one utilizing margetuximab. The Company is entitled to a total of $4.0 million as a result of these milestones (less foreign withholding tax).

During the year ended December 31, 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 MGD013 (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 that contract: to perform services related to manufacturing the clinical supply of margetuximab and MGD013. 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 year ended December 31, 2019, the Company recognized revenue of $2.2 million related to the Zai Lab Clinical Supply Agreements.

I-Mab Biopharma

In July 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 twenty percent 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 will pay the Company for the cost of this study as the costs are incurred 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 year ended December 31, 2019, the Company recognized revenue of $2.3 million related to the I-Mab Agreement. 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.

Roche

In December 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 August 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 which was received in January 2018. The Company will also be eligible to receive up to $370.0 million in potential milestone payments and royalties on future sales. As of December 31, 2019, 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. 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. There was no revenue deferred under this agreement at December 31, 2019. At December 31, 2018, $6.0 million was deferred under this agreement, $4.0 million of which was current and $2.0 million of which was non-current.

Provention Bio, Inc.

In May 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, 2019, 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 May 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, 2019, 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 and transferred the MGD010 license and teplizumab assets to Provention in 2018. The warrants were revalued at each reporting period based on current Black-Scholes parameters until the warrants were exercised in July 2019. The resulting increase or decrease is reflected in Other income (expense) on the consolidated statement of operations and comprehensive loss. The warrants were valued at $1.9 million as of December 31, 2018, and were reported in Other assets on the consolidated balance sheet. During 2019, through the date that they were exercised, the Company recorded an increase in the valuation of the warrants of approximately $20.1 million. 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 at December 31, 2019.

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. During the year ended December 31, 2017, NIAID exercised the first option in the amount of $10.8 million. The Company recognized revenue of $2.2 million, $1.3 million and $1.7 million under this contract during the years ended December 31, 2019, 2018 and 2017, 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. The complaint asserts a putative class period stemming from February 6, 2019 to June 3, 2019. On November 12, 2019, the Employees’ Retirement System of the City of Baton Rouge and Parish of East Baton Rouge sought appointment as lead plaintiff, which motion remains pending. 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, $1.3 million and $1.1 million for the years ended December 31, 2019, 2018 and 2017, respectively.

12. Quarterly Financial Information (unaudited)

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
	(in thousands, except per share data)			
2019				
Revenue	$ 9,662	$ 10,593	$ 18,741	$ 25,192
Net loss	(45,017)	(31,767)	(44,631)	(30,396)
Net loss per share, basic and diluted	$ (0.99)	$ (0.65)	$ (0.91)	$ (0.62)
2018				
Revenue	$ 4,695	$ 18,834	$ 20,798	$ 15,794
Net loss	(49,536)	(43,244)	(34,029)	(44,644)
Net loss per share, basic and diluted	$ (1.34)	$ (1.03)	$ (0.81)	$ (1.06)

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 Jon Wigginton, M.D. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 4, 2016)
10.13+	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)
10.14+	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)
10.15†	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)
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.
+ 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, 2019, 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. As of December 31, 2019, 48,958,763 shares of our Common Stock were issued and outstanding.

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 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) 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. 333-235691) of MacroGenics, Inc.

of our reports dated February 25, 2020, 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, 2019.

/s/ Ernst & Young LLP

Baltimore, Maryland
February 25, 2020

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, 2019 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, 2020

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, 2019 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, 2020

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, 2019 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, 2020

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, 2019 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, 2020