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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

For the transition period from to

Commission File Number **001-36112**

MACROGENICS, INC.

(Exact name of registrant)

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	MGNX	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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

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

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

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

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

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

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

The aggregate market value of the registrant's common stock, par value $0.01 per share, held by non-affiliates of the registrant on June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $1.6 billion based on the closing price of the registrant's common stock on the Nasdaq Global Select Market on that date. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

The number of shares of the registrant's common stock outstanding on February 22, 2022 was 61,324,258.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of MacroGenics, Inc.'s definitive proxy statement for the 2022 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report.

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

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

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

- the severity and duration of the impact of the COVID-19 global pandemic on our business, operations, clinical programs, manufacturing, financial results and other aspects of our business;
- our plans to develop and commercialize our product candidates;
- the outcomes of our ongoing and planned clinical trials and the timing of those outcomes, including when clinical trials will be initiated or completed, and when data will be reported or regulatory filings will be made;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates and the labeling for any approved products;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to raise additional capital through the capital markets or through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales;
- our expectations regarding product candidates currently being developed by our collaborators;
- 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 and our expectations regarding the outcome of any regulatory or legal proceedings;
- economic, political and other risks associated with our international operations;
- our ability to receive research funding and achieve anticipated milestones under our collaborations;
- our ability to protect and enforce patents and other intellectual property;
- costs of compliance and our failure to comply with new and existing governmental regulations including, but not limited to, tax regulations;
- loss or retirement of key members of management;
- failure to successfully execute our growth strategy, including any delays in our planned future growth; and
- our failure to maintain effective internal controls.

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

specifically decline any obligation to update, republish or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events.

PART I

ITEM 1. BUSINESS

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

Overview

We are a biopharmaceutical company focused on developing and commercializing innovative antibody-based therapeutics for the treatment of cancer. We have a pipeline of product candidates being evaluated in clinical trials sponsored by us or our collaborators. These product candidates include six immuno-oncology programs, many of which were created using our proprietary, antibody-based technology platforms. We believe our product candidates have the potential, if approved for marketing by regulatory authorities, to have a meaningful effect on treating patients' unmet medical needs as monotherapy or, in some cases, in combination with other therapeutic agents. In March 2021, we and our commercialization partner commenced U.S. marketing of MARGENZA (margetuximab-cmkb), a human epidermal growth factor receptor 2 (HER2) receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

We are developing product candidates that target various tumor-associated antigens and immune checkpoint molecules. Our lead pipeline program is MGC018, an antibody-drug conjugate (ADC) that targets B7-H3, a molecule in the B7 family of immune regulator proteins that is widely expressed by several different tumor types. We are also developing enoblituzumab, an Fc-optimized monoclonal antibody (mAb) that targets B7-H3 and 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. Our clinical pipeline includes two bispecific DART product candidates that co-engage both PD-1 and LAG-3, or lymphocyte-activation gene 3 (tebotelimab), and PD-1 and CTLA-4, or cytotoxic T-lymphocyte-associated protein 4 (lorigerlimab). In addition, we are developing MGD024, a next-generation 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). Finally, we and our collaboration partners are developing product candidates for which we retain certain economic rights. These product candidates include IMGC936, a clinical-stage ADC that targets ADAM9, a cell surface protein over-expressed in several solid tumor types; retifanlimab, an anti-PD-1 mAb that we out-licensed and teplizumab, an anti-CD3 monoclonal antibody, sold to a partner.

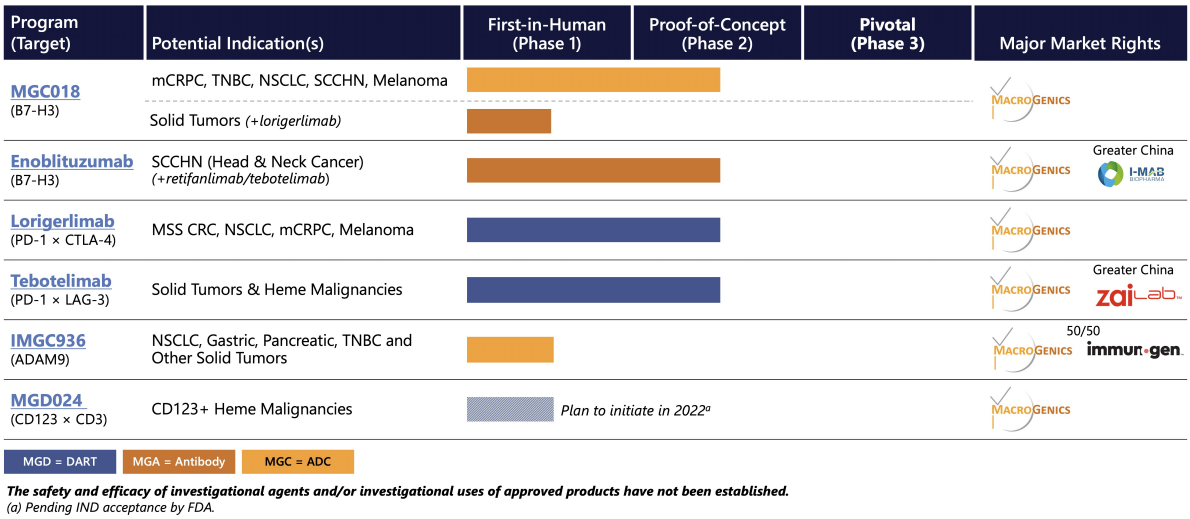
We have created our product candidates based on the following antibody-based technologies:

- 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;
- 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; and
- ADC platforms, which we have licensed from collaboration partners, and which link monoclonal antibodies that specifically target cancer cells with cytotoxins 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, manufacturing and commercialization of breakthrough antibody-based biologics for the treatment of patients with cancer.

Our Pipeline of Immuno-Oncology Clinical Product Candidates for Which We Retain Commercial Rights

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



The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established.
(a) Pending IND acceptance by FDA.

B7-H3 Programs

We have two clinical-stage programs, MGC018 and enoblituzumab, that target B7-H3 (CD276), an immune checkpoint molecule that is overexpressed in cancer tissues while showing limited expression in normal tissues. B7-H3 belongs to the B7 family of immune regulator proteins that is widely expressed by different tumor types and may play a key role in regulating the immune response to various cancers. There are no currently approved therapeutic agents directed against B7-H3.

MGC018

MGC018 is an investigational ADC with a cleavable peptide linker designed to deliver a DNA-alkylating duocarmycin payload to dividing and non-dividing cells on solid tumors that express B7-H3. The underlying ADC technology was licensed from Byondis B.V. After completing a dose escalation study in 2020, we commenced the ongoing Phase 1/2 dose expansion study of MGC018 in patients with metastatic castration-resistant prostate cancer (mCRPC), non-small cell lung cancer (NSCLC), melanoma, squamous cell carcinoma of the head and neck (SCCHN) and triple negative breast cancer (TNBC). The purpose of this ongoing study is to evaluate the safety and tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of the molecule. The Phase 1/2 study dose expansion cohorts are fully enrolled for patients with mCRPC (n=40), and smaller cohorts (n=approximately 20 each) of patients with NSCLC, melanoma, and TNBC, while we continue to recruit patients for the SCCHN cohort. We expect to provide details regarding further development plans in mCRPC, including a potential registration-directed study, in the first half of 2022, following interaction with regulatory agencies in the first quarter of 2022. We also plan to present additional data from the ongoing Phase 1/2 study of MGC018 in the second half of 2022. In addition, we expect to initiate a Phase 1/2 dose escalation study of MGC018 in combination with lorigerlimab (formerly MDG019), a bispecific monoclonal antibody designed to block PD-1 and CTLA-4, in patients with solid tumors.

Dose Escalation Study Results (as of May 2020)

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

At the May 6, 2020 data cut off, preliminary evidence of anti-tumor activity by MGC018 was observed in the dose escalation portion of the study, particularly in patients with advanced mCRPC. Reductions in prostate-specific antigen (PSA) levels of ≥ 50% were observed in five of seven mCRPC patients treated, including one with substantial regression of bone disease. Six mCRPC patients had bone-only disease, and one patient with measurable peripheral disease had a 29% reduction in target lesions that did not qualify as a response per Response Evaluation Criteria in Solid Tumors v1.1 (RECIST). Four PSA responders remained on therapy as of the data cut-off. Patients with mCRPC had received a median of four therapies prior to MGC018, including taxane chemotherapy (six patients) and next-generation hormonal agents (six patients were treated with both abiraterone and enzalutamide, and one with abiraterone only).

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

Phase 1/2 Dose Expansion Study Results (as of May 2021)

The Phase 1/2 dose expansion study of MGC018 in patients with mCRPC, TNBC and NSCLC was initiated in the fourth quarter of 2020. As of the May 3, 2021 cut-off, updated clinical data from the Phase 1 study of MGC018 was presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting demonstrating anti-tumor activity in patients with melanoma and mCRPC. Preliminary results in the mCRPC cohort expansion showed 11 of 22 patients (50%) had a PSA reduction of 50% or greater, with anti-tumor activity observed in four of seven patients with measurable disease who had their first 9-week imaging results available, including one unconfirmed partial response. Anti-tumor activity was also reported in all three melanoma patients who received 4 mg/kg in dose escalation, with one patient achieving a confirmed partial response.

Phase 1/2 Dose Expansion Study Results (as of August 2021)

Preliminary clinical results from the ongoing Phase 1/2 study of MGC018 in patients with solid tumors was presented at the 2021 European Society for Medical Oncology (ESMO) Meeting. As of the August 16, 2021 data cut-off, a total of 86 patients with advanced solid tumors were enrolled in the cohort expansion of MGC018 at the recommended Phase 2 dose (RP2D) of 3.0 mg/kg, administered intravenously every three weeks. The enrollment included 40 patients with mCRPC, 21 patients with NSCLC, 16 patients with TNBC and nine patients with melanoma. In addition, enrollment of patients with SCCHN had been initiated. The safety analysis included all enrolled patients, whereas the efficacy analysis was limited to mCRPC and NSCLC patients; enrollment was ongoing in the other tumor cohorts. In the cohort expansion, tumor response by investigator per RECIST was evaluated every nine weeks for all patients and PSA was assessed every three weeks in mCRPC.

As of the August 16, 2021 data cut-off, all 40 patients in the mCRPC cohort expansion had been enrolled. Patients had previously received a median of three prior therapies for advanced disease, with all 40 patients having received both chemotherapy and next-generation hormonal therapy. Based on an immunohistochemistry assessment of patient tumor samples, the median B7-H3 H-score (a combined score of the intensity and the proportion of B7-H3 expression, comprising values between 0 and 300) for all mCRPC patients was 223. A total of 39 mCRPC patients were evaluable for PSA response. Reductions in PSA levels of ≥ 50% were observed in 21 of 39 patients (54%). Twenty-four of the 39 patients (62%) remained on treatment as of the data cut-off. Of the 40 patients in the mCRPC cohort, 16 of the 23 patients with measurable disease were evaluable for tumor response by RECIST as of the data cut-off. Ten of these 16 patients (63%) had reductions in their target lesion sums from baseline. Four patients (25%) demonstrated a partial response (PR), consisting of two confirmed and two unconfirmed PRs. Treatment was ongoing in six of 16 patients with evaluable tumor response as of the data cut-off.

As of the August 16, 2021 data cut-off, the NSCLC cohort expansion had been fully enrolled with 21 patients. Patients had previously received a median of two prior therapies for advanced disease, with 15 (71%) having previously received anti-PD-1/PD-L1 therapy. The median B7-H3 H-score for these patients was 139. A total of 16 NSCLC patients were evaluable for tumor response by RECIST. Thirteen of 16 (81%) patients had reductions in their target lesion sums from baseline. Four of these 16 patients (25%) experienced unconfirmed partial responses. Another one of these 16 patients experienced a 30% reduction in target lesions; however, the patient’s non-target lesions were not evaluated due to an obstruction of the bronchus and overall response was not evaluable. Treatment was ongoing in seven of 16 patients as of the data cut-off.

The safety analysis includes all 86 patients enrolled in the cohort expansion as of the August 16, 2021 data cut-off. The median number of doses received by mCRPC patients was 3.5 (range: 1-8); those with NSCLC received 3.0 (range: 1-7). Adverse events for the dose expansion cohorts of 3 mg/kg were generally consistent with those previously reported at ASCO 2021. TRAEs included hematologic and skin toxicities that have been clinically manageable to date. In the cohort expansion study overall, at least one TRAE of any grade was experienced by 78 of 86 patients (91%), with 43 of 86 patients (50%) experiencing a Grade ≥3 TRAE. There were two Grade 5 fatal events: one from an unknown cause and one due to SARS-CoV-2.

The most common TRAEs were fatigue (37% all grades; 1% Grade ≥3), neutropenia (34% all grades; 22% Grade ≥3), palmar plantar erythrodysesthesia syndrome (31% all grades; 4% Grade ≥3), pleural effusion (23% all grades; 1% Grade ≥3), nausea (22% all grades; 1% Grade ≥3), asthenia (20% all grades; 5% Grade ≥3) and thrombocytopenia (14% all grades; 7%

Grade ≥3). The overall results demonstrated a manageable safety profile with a low rate of treatment discontinuation due to TRAEs: only six of 86 (7%) patients had discontinued therapy in the cohort expansion as of the data cut-off date due to TRAEs.

Enoblituzumab

Enoblituzumab is an investigational monoclonal antibody that targets B7-H3 that has been engineered using our Fc Optimization platform. We are currently evaluating enoblituzumab in combination with checkpoint molecules in patients with SCCHN in an ongoing Phase 2 study. The combination of enoblituzumab and immune checkpoint blockade is designed to engage innate and adaptive immunity to enhance tumor cell killing.

We had initially conducted a Phase 1b/2 clinical study combining enoblituzumab and pembrolizumab, an anti-PD-1 monoclonal antibody, in patients with B7-H3-expressing melanoma, SCCHN, NSCLC and urothelial cancer. A total of 133 patients were treated in the study.

As presented in November 2018 at the Society for Immunotherapy of Cancer (SITC) Annual Meeting, in the SCCHN dose expansion cohort, confirmed PRs were observed in 6 of 18 (33%) 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 (ORRs) ranging from 13% to 16% have previously been reported in SCCHN patients treated with anti-PD-1 agents alone. The combination of enoblituzumab and an anti-PD-1 monoclonal antibody demonstrated acceptable tolerability, with any adverse event ≥ Grade 3 occurring in 27.1% of patients as of the October 12, 2018 data cut-off date. The rate of immune-related adverse events experienced in the trial was comparable to that historically observed by others in patients who received pembrolizumab as monotherapy.

To further inform the development of enoblituzumab, we initiated a Phase 2 study of this agent in patients with relapsed or metastatic SCCHN not curable by local therapy in the first quarter of 2021. This trial includes enoblituzumab in a chemotherapy-free regimen in combination with either retifanlimab, an anti-PD-1 antibody, in patients who are programmed death-ligand 1 (PD-L1) positive or with tebotelimab, a bispecific checkpoint targeting both PD-1 and LAG-3, in patients who are PD-L1 negative. We expect to complete enrollment of the PD-L1 positive patient cohort during the first half of 2022 and provide an update on this cohort during the second half of 2022.

In July 2019, we licensed the right to develop and commercialize enoblituzumab in mainland China, Hong Kong, Macau and Taiwan to I-Mab Biopharma (I-Mab). I-Mab plans to both lead regional studies in its territories as well as participate in global studies conducted by us. In December 2021, I-Mab announced that the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) approved its Investigational New Drug (IND) submission for the initiation of a Phase 2 trial in China for enoblituzumab in combination with pembrolizumab in patients with solid tumors, including NSCLC, urothelial carcinoma and other selected cancers.

T-cell Redirected Bispecific DART Molecules

We are developing a bispecific DART molecule that can simultaneously target T-cells and tumor cell surface antigens to engage and promote redirected T-cell killing of cancer cells. CD123, the interleukin-3 receptor alpha chain, is widely overexpressed in various hematologic malignancies, including AML and myelodysplastic syndrome (MDS), making it an attractive therapeutic target. Various drugs have been developed to target CD123, but none have received U.S. Food and Drug Administration (FDA) approval. We have created two bispecific DART molecules that engage CD3 expressed on immune effector cells, such as T cells, to kill CD123-expressing cancer cells for the potential treatment of certain hematologic malignancies, including AML. One of these DART molecules, flotetuzumab, is being discontinued due to reprioritization to more efficiently utilize our financial and human resources to focus on the next-generation version of the molecule, MGD024.

MGD024

MGD024 is an investigational, next-generation, bispecific CD123 × CD3 DART molecule designed to minimize cytokine-release syndrome, while maintaining anti-tumor cytolytic activity, and permitting intermittent dosing through a longer half-life. In December 2021, we presented preclinical MGD024 data at the American Society of Hematology (ASH) Annual Meeting that showed the potential for anti-tumor activity from the combination of MGD024 with standard of care agents used to treat AML. We submitted an IND to the FDA for MGD024 in the fourth quarter of 2021, and plan to initiate a Phase 1 study of MG024 in patients with hematologic malignancies, pending IND clearance by the FDA.

Flotetuzumab

Flotetuzumab is an investigational bispecific, humanized DART molecule that recognizes both CD123 and CD3. In a single-arm study evaluating flotetuzumab, our first generation, continuous infusion CD123 x CD3 DART molecule, in AML patients who were refractory to induction therapy, activity looked promising with manageable safety. Nonetheless, we recently decided to prioritize the development of MGD024 and discontinue development of flotetuzumab, in view of our belief that MGD024 may offer certain advantages over flotetuzumab, including easier dose administration and the ability to be combined with other agents.

Immune Checkpoint Inhibitors

Checkpoint inhibition has become an important staple of oncology. Our clinical pipeline includes three product candidates in clinical development that target checkpoint molecules for the potential treatment of a broad range of solid tumors. These candidates include two bispecific DART product candidates that co-engage PD-1 and other checkpoint molecules and an anti-PD-1 monoclonal antibody that we have out-licensed to a partner.

Lorigerlimab (formerly MGD019)

Approved monoclonal antibodies that target the immune checkpoints PD-1 and CTLA-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. Lorigerlimab is an investigational, bispecific tetravalent DART molecule designed to enable simultaneous and/or independent blockade of PD-1 and CTLA-4, with potentially enhanced CTLA-4 blockade on T cells co-expressing these immune checkpoint molecules.

We are conducting a Phase 1/2 clinical trial of lorigerlimab in patients with advanced solid tumors. The study is designed to enroll patients with histologically proven, unresectable, locally advanced or metastatic solid tumors for whom no approved therapy with demonstrated clinical benefit is available or patients who are intolerant to standard therapy. Forty-three patients were enrolled in the 3+3+3 dose escalation study within a dose range of 0.03 – 10.0 mg/kg, administered every three weeks initially, in a population of heavily pre-treated patients representing a broad range of different types (23) of solid tumors. A total of 28 patients were treated at doses ≥ 3.0 mg/kg administered every three weeks initially. Of the 18 evaluable patients who received doses ≥ 3.0 mg/kg as of the July 21, 2020 cut-off date, four objective responses were reported, including a confirmed complete response in mCRPC, confirmed PRs in microsatellite stable colorectal cancer (MSS CRC) and metastatic type AB thymoma, and an unconfirmed PR in serous fallopian tube carcinoma. Lorigerlimab was well-tolerated in patients who received less than 10 mg/kg. The most common TRAEs observed were pruritus (23.3%), arthralgia (18.6%), fatigue (18.6%), rash (18.6%), nausea (16.3%) and infusion-related reaction (16.3%) as of the data cut-off. Several Grade 3 adverse events were observed at the 10.0 mg/kg level; however, none were considered dose limiting.

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

We are currently evaluating lorigerlimab in a Phase 1/2 dose expansion study in patients with MSS CRC, mCRPC, melanoma and checkpoint-naive NSCLC at a dose of 6.0 mg/kg, based on data from dose escalation, and expect to provide an update on this study in the second half of 2022. We also expect to initiate a Phase 1 dose escalation study of MGC018 and lorigerlimab in patients with solid tumors.

Tebotelimab

Tebotelimab is an investigational, first-in-class bispecific, tetravalent DART molecule targeting PD-1 and LAG-3. We have engineered tebotelimab to concomitantly or independently bind to PD-1 and LAG-3 and disrupt these non-redundant inhibitory pathways to further restore exhausted T-cell function. Tebotelimab was evaluated in a Phase 1/2 dose expansion study in several tumor types and is currently being studied in combination with enoblituzumab in SCCHN. We expect to provide an update on potential future development plans for tebotelimab in the second half of 2022.

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

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

Immune effector cell activation and LAG-3, PD-1 and PD-L1 expression has been shown to be enhanced in vitro by Fc-engineered margetuximab. An expansion cohort of patients with advanced HER2-positive tumors was treated with margetuximab plus tebotelimab to evaluate whether Fc-engineering can enhance tumor responsiveness to checkpoint blockade and improve clinical outcomes in patients. In November 2020, updated data was presented from the combination study of tebotelimab and margetuximab in patients with advanced HER2-positive neoplasms. In this study, 41 patients had been enrolled. As of the October 5, 2020 data cut-off, there were 28 response-evaluable patients. Evidence of antitumor activity was observed among refractory patients with various HER2-positive tumor types, including eight objective responses (six confirmed) observed in multiple advanced HER2-positive tumor types. The ORR (including unconfirmed responses) was 28.6%, while 64.3% of response-evaluable patients experienced a decrease in target lesion tumor burden. The duration of response for confirmed responders was 4.21–8.97 months, with three patients remaining on treatment as of the data cut-off. Of particular interest, a majority of responding patients had a baseline PD-L1 combined positive score (CPS) ≤ 1. All responding patients carried the less favorable CD16A-158F allotype (i.e., V/F or F/F). Evaluation of baseline LAG-3 and PD-1 mRNA expression and potential association with clinical response analyses are ongoing, and will be important for defining patient enrichment biomarker strategies for further development. The combination of tebotelimab and margetuximab was generally well tolerated, with a safety profile consistent with that of tebotelimab monotherapy.

In December 2020, data was presented from the ongoing tebotelimab Phase 1/2 dose expansion study in patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL). LAG-3 has been shown to be highly expressed in DLBCL and has emerged as a therapeutic target of interest in this population, while PD-1-targeted therapy has yielded modest efficacy. There remains significant unmet need for patients with relapsed/refractory (R/R) DLBCL. In this study, 20 DLBCL patients were enrolled, half of whom were chimeric antigen receptor (CAR) T cell therapy experienced. As of the October 23, 2020 data cut-off, there were 13 response-evaluable patients. A preliminary ORR of 53.8% (7 of 13 patients) was observed, including responses in five of seven CAR T cell-naïve patients and in two of six CAR T cell experienced patients, the latter of whom both had complete responses. A preliminary duration of response of up to 168 days was observed, with six of seven ongoing responses as of the cut-off date. In the study, baseline LAG-3 expression appeared to associate with clinical response, with additional analyses ongoing. Tebotelimab was generally well-tolerated among heavily pre-treated R/R DLBCL patients, with manageable infusion-related reactions and no evidence of tumor lysis syndrome. The most common TRAE was pyrexia, which occurred in three (15%) patients. A single Grade 3 TRAE of anemia was observed.

As part of our November 2018 license and collaboration agreement with Zai Lab Limited (Zai Lab), we licensed to them the right to develop and commercialize tebotelimab in mainland China, Hong Kong, Macau and Taiwan. Zai Lab has led regional studies evaluating tebotelimab in various indications in its territory. Zai lab recently informed us that they have decided to discontinue development of tebotelimab for indications they were enrolling in their territory and is evaluating future development plans in other indications.

Margetuximab

We and our commercial partner, Eversana Life Science Services, LLC (Eversana), are currently marketing MARGENZA (margetuximab-cmkb), in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. Margetuximab is an Fc-engineered, mAb that targets the HER2 oncoprotein. HER2 is expressed by tumor cells in breast, gastroesophageal and other solid tumors.

As part of our November 2018 license and collaboration agreement, Zai Lab has the rights to develop margetuximab in mainland China, Hong Kong, Macau and Taiwan. On January 6, 2022, Zai Lab announced that the China NMPA had accepted the New Drug Application (NDA) for margetuximab for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease, in combination with chemotherapy.

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

Based on results from an earlier study combining margetuximab and pembrolizumab, an anti-PD-1 mAb, in patients with advanced HER2-positive gastroesophageal adenocarcinoma (GEA) who had previously been treated with chemotherapy and trastuzumab, we initiated the MAHOGANY study in September 2019. This was a Phase 2/3 registration-directed clinical trial to evaluate, in Module A, margetuximab in combination with retifanlimab, an anti-PD-1 mAb, in patients with tumors that were both HER2 IHC3-positive and PD-L1 positive. This approach was designed as a chemotherapy-free regimen intended to engage both innate and adaptive immunity for the treatment of patients with gastric cancer (GC) or gastroesophageal junction (GEJ) cancer in the first-line setting.

In September 2021, we presented data from Part 1, Module A of the Phase 2/3 MAHOGANY clinical trial of margetuximab at the 2021 ESMO Virtual Conference. The efficacy data and safety cutoff dates were July 19 and August 3, 2021, respectively. Tumor shrinkage was observed in 32 of 41 patients (78%) with at least one post-baseline target lesion measurement. Twenty-one of 40 patients (53%) achieved confirmed responses by independent review, exceeding prespecified futility boundary for the trial. Median duration of response was 10.3 months as of data cutoff. Margetuximab plus retifanlimab was well tolerated with Grade 3 TRAEs in 19% of patients; no Grade 4 TRAEs or treatment-related deaths.

While the results from the initial portion of Module A of this trial were encouraging, we subsequently decided and announced in November 2021 to prioritize other pipeline product candidates and not proceed with the next phase of this trial.
Zai Lab has decided to discontinue enrollment of Module B of the MAHOGANY study based on their review of both the clinical data and the changing treatment landscape.

Partnered Programs

Retifanlimab

Retifanlimab is an investigational mAb 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 helping to restore the immune system's ability to detect and kill tumor cells. In 2017, we licensed retifanlimab to Incyte Corporation (Incyte) under a global collaboration and license agreement, although we retain the right to develop the molecule in combination with product candidates from our pipeline.

In January 2021, Incyte announced that the FDA had accepted for Priority Review its Biologics License Application (BLA) for retifanlimab as a potential treatment for adult patients with locally advanced or metastatic squamous cell carcinoma of the anal canal (SCAC) who have progressed on, or who are intolerant of, platinum-based chemotherapy.

On July 23, 2021, Incyte announced that the FDA had issued a Complete Response Letter (CRL) regarding its BLA for retifanlimab. Incyte’s announcement indicated that the FDA determined that additional data were needed to demonstrate the clinical benefit of retifanlimab for the submitted indication, and that Incyte was reviewing the CRL and would discuss next steps with the FDA. Incyte subsequently withdrew its European application for marketing authorization of retifanlimab for the treatment of SCAC. Incyte has stated it is pursuing development of retifanlimab in potentially registration-enabling studies beyond SCAC, including in patients with microsatellite instability-high, or MSI-high, endometrial cancer, Merkel cell carcinoma and non-small cell lung cancer. Incyte is also pursuing development of retifanlimab in combination with multiple product candidates from its pipeline.

During the first quarter of 2021, we initiated a Phase 2 study of enoblituzumab in a chemotherapy-free regimen in combination with retifanlimab in front-line SCCHN patients who are PD-L1 positive and with tebotelimab in SCCHN patients who are PD-L1 negative.

IMGC936

IMGC936 is an ADC that targets ADAM9, a cell surface protein over-expressed in several solid tumor types. IMGC936 is being advanced under a co-development agreement with ImmunoGen, Inc. (ImmunoGen). Under the 50/50

collaboration, ImmunoGen is leading clinical development and the Phase 1 dose escalation study is currently enrolling patients with select advanced solid tumors and ImmunoGen has indicated they anticipate disclosing initial data in 2022.

Teplizumab

In 2018, we entered into an asset purchase agreement with Provention Bio, Inc. (Provention) pursuant to which they acquired our interest in teplizumab, a monoclonal antibody we had been developing for the treatment of type 1 diabetes. Teplizumab has been granted Breakthrough Therapy Designation by the FDA and PRIority MEdicines (PRIME) designation by the European Medicines Agency. We are entitled to received future milestones payments and royalties on net sales.

In January 2021, Provention announced that a BLA for teplizumab for the delay or prevention of clinical type 1 diabetes (T1D) in at-risk individuals had been filed by the FDA, which granted Provention's request for Priority Review. Provention is currently also evaluating teplizumab in patients with newly diagnosed insulin-dependent T1D in the Phase 3 PROTECT study, which has been fully recruited. Provention has indicated that it expects to report top line data from the Phase 3 PROTECT study in the second half of 2023.

On July 2, 2021, the FDA issued a CRL for teplizumab's BLA for the delay of clinical T1D in at-risk individuals. The CRL did not cite any clinical deficiencies related to the efficacy and safety data packages submitted to the BLA. However, pharmacokinetic (PK) drug product comparability considerations remain outstanding, according to a statement released by Provention. In September 2021, Prevention disclosed that it had completed the collection of data from a PK/pharmacodynamic (PD) sub-study in the ongoing PROTECT Phase 3 trial in newly diagnosed T1D patients.

In July 2021, Provention announced that teplizumab was awarded an Innovation Passport for the delay of clinical T1D in at-risk individuals.

On February 22, 2022, Provention announced that it had resubmitted the BLA for teplizumab for the delay of clinical T1D in at-risk individuals. Provention indicated that the purpose of the resubmission was to address the FDA's PK comparability considerations contained in the CRL, as well as the CRL's Chemical, Manufacturing, and Controls (CMC) and product quality considerations. The BLA resubmission followed Provention's Type B meeting with the FDA earlier in the year.

PRV-3279

In 2018, we also entered into a license agreement with Provention pursuant to which we granted them exclusive global rights for the purpose of developing and commercializing PRV-3279 (formerly MGD010), a CD32B × CD79B DART molecule being developed for the treatment of autoimmune indications. Provention is initially developing PRV-3279 for the interception of systemic lupus erythematosus (SLE), a chronic autoimmune disorder characterized by an abnormal overactivation of B cells and subsequent pathologic production of auto-antibodies. Provention has disclosed that it believes PRV-3279 also has the potential to prevent or reduce the immunogenicity of biotherapeutics, including but not limited to gene therapy vectors and transgenes. In January 2022, Provention announced the initiation of the Phase 2a PREVAIL-2 study of PRV-3279 in SLE patients. Provention has indicated that it expects to report data from PREVAIL-2 in the first half of 2024.

HIV DART Molecules

We are developing MGD014 and MGD020 under a contract awarded to us in September 2015 by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. These bispecific DART molecules are designed to target the viral envelope (Env) protein of human immunodeficiency virus (HIV) infected cells and CD3 on T cells to redirect the immune system's T cells to kill HIV-infected cells. These molecules may become a key part of a strategy to reduce or eliminate latent HIV reservoirs in conjunction with latency-reversing agents currently under development. MGD014 and MGD020 target the gp120 and gp41 subunits of HIV Env, respectively. A Phase 1 study of MGD014 in persons with HIV maintained on antiretroviral therapy has been completed and a Phase 1 study of MGD020 alone and combined with MGD014 will initiate in 2022.

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.

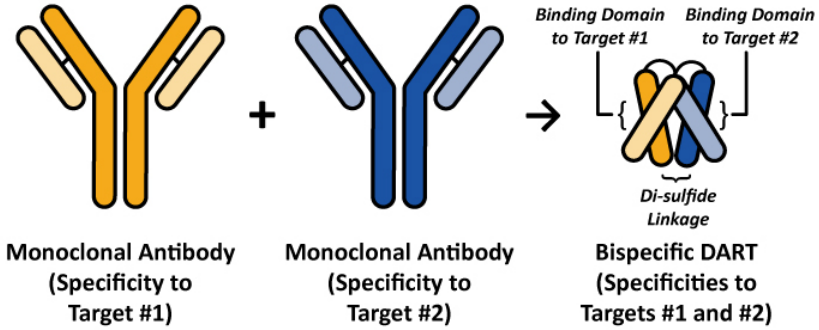
We believe that our platforms position us very well strategically to actively develop approaches for the treatment of both solid tumors and hematologic malignancies.

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:

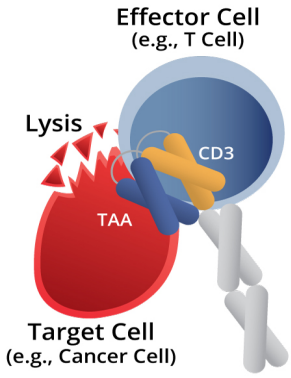


Because cancer cells have developed ways to escape the immune system, we have created DART molecules, which are alternative antibody-like structures with more potent immune properties than the parent antibody molecules from which they are derived. The two variable regions of an antibody are mono-specific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

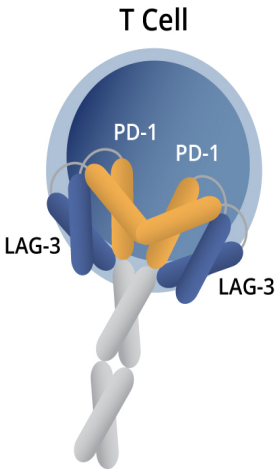
Our DART platform enables us to design multi-specific molecules that seek to exploit different mechanisms of action, including those set forth below.

- *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 MGD024, are manufactured using a conventional antibody platform without the complexity of having to genetically modify T cells from individual patients, as would be required by approaches such as CAR T cells. We have continued to evolve our bispecific platform with the introduction of a next-generation CD3-engaging DART technology designed to recruit, engage and activate T cells to kill tumor target cells with reduced release of pro-inflammatory cytokines. This next-generation CD3 DART platform is aimed at addressing cytokine-release syndrome, the most frequent and often dose-limiting adverse event associated with CD3-engaging molecules. We believe the next-generation CD3 DART platform could expand the therapeutic window of CD3-engaing DART molecules and further increase their potential application in oncology.



Product Candidates:
MGD024 (CD123 × CD3)
MGD014 (HIV × CD3)

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



Product Candidates:
Tebotelimab (PD-1 × LAG-3)
Lorigerlimab (PD-1 × 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 lorigerlimab, MGD024, tebotelimab, and MGD014 in clinical trials, as well as others in preclinical development.

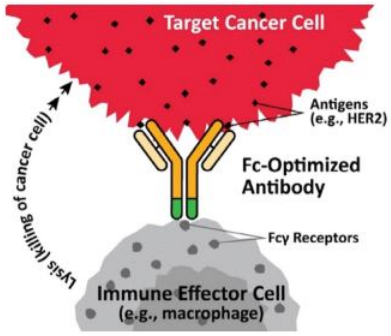
We have also advanced beyond our DART platform to establish a TRIDENT platform, which reflects the continuing evolution of our multi-specific antibody-based targeting expertise. Built on the DART module, the trivalent TRIDENT platform

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 antibody-dependent cellular cytotoxicity (ADCC).

ADCC



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

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

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

Our Collaborations

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

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

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patents intended to protect, for example, the composition of matter of our product candidates, their methods of use, the technology platforms used to generate them, related technologies and/or other aspects of the inventions that are important to our business. We also rely on trade secrets, confidentiality and invention assignment agreements and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

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

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

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

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

Pipeline Patent Protection

As of December 31, 2021, we held 88 patents in the United States with 46 patent applications pending and 814 patents in other countries of the world with 569 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 or Product Candidate	Expiration Date
margetuximab	2029
enoblituzumab	2031
retifanlimab	2036
tebotelimab	2036*
lorigerlimab	2036*
MGC018	2037*
MGD024	2039*

** pending*

Patent Term Extension and Reference Product Exclusivity

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

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

Trade Secrets

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

In-Licensed Intellectual Property

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

Manufacturing

We currently manufacture drug substance for most of our clinical trials at our manufacturing facilities located in Rockville, Maryland. We also rely on contract manufacturers, primarily Byondis, for production components of one of our ADC candidates. We have supplemented our drug substance manufacturing capacity through an arrangement with AGC Biologics, Inc. (AGC, formerly CMC Biologics, Inc.), a contract manufacturing organization, and commercially produced initial margetuximab commercial supply and inventory at AGC. In October 2021, the FDA approved the BLA supplement to add our commercial manufacturing site at 9704 Medical Center Drive in Rockville, Maryland as a licensed manufacturing site for margetuximab drug substance. We intend to commercially produce material for MARGENZA, as well as our and partner's product candidates when and if approved by the FDA. In addition, we currently rely on and will continue to rely on contract fill-finish service providers, primarily Ajinomoto Bio-Pharma Services and Baxter Healthcare Corporation, to fulfill our fill-finish needs for our current and future product candidates.

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

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

Commercialization

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

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

Competition

There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. These treatments consist both of small molecule drug products, as well as biologic therapeutics that work by using next-generation antibody technology platforms to address specific cancer targets. In

particular, MARGENZA is directed against HER2 and many companies have cancer therapeutics directed against HER2 that are either currently approved and on the market or may be in development, such as F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (Roche), particularly through its affiliate, Genentech, Inc., as well as Puma Biotechnology, Inc., Daiichi Sankyo Company, Limited and AstraZeneca plc. (AstraZeneca), Seagen Inc., Zymeworks, Inc., Shanghai Hengrui Pharmaceutical, and Byondis, many of which have significantly greater resources than we do. Market competition has limited the utilization of MARGENZA as a therapeutic, and these competitors as well as biosimilar trastuzumab competition may limit such utilization in the future.

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

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

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

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

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe effects, are more convenient or are less expensive than any products that we may develop, or the standards of care for cancer patients change while our clinical trials are ongoing. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of biosimilar products. Biosimilar products are expected to become available over the coming years. For example, trastuzumab biosimilars have been approved in the U.S. by the 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, pricing, reimbursement, 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 the 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 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 IND application is cleared and 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 the 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, the FDA may require post-market studies, known as Phase 4 studies, to be conducted as a condition of approval in order to gather additional information on the drug's effect in various populations and any side effects associated with long-term use. Depending on the risks posed by the drugs, other post-market requirements may be imposed. Only a small percentage of investigational drugs complete all three phases and obtain marketing approval.

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

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

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

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

The FDA regulates the content and format of prescription drug labeling, advertising, and promotion, including direct-to-consumer advertising and promotional Internet communications. The 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 the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA during which the FDA inspects manufacturing facilities to assess compliance with cGMPs. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs.

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

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

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

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

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

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

proposals to rescind or reduce the biologics exclusivity provisions of the ACA and it is uncertain whether or if any of those proposals may be approved, and if approved, how exclusivity for biologics would be affected.

Other Healthcare Laws and Compliance Requirements

We are be subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback and false claims laws. Anti-kickback laws generally prohibit a prescription drug manufacturer from soliciting, offering, receiving, or paying any remuneration to generate business, including the purchase or prescription of a particular drug. Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations,guidance or court decisions that apply the laws to particular industry practices. There is therefore a possibility that our practices might be challenged under such anti-kickback laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, any claims for payment for reimbursed drugs or services to third party payers (including Medicare and Medicaid) that are false or fraudulent. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and/or exclusion from federal health care programs (including Medicare and Medicaid).

Laws and regulations enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers with marketed products generally limit financial interactions between manufacturers and health care providers and/or require disclosure to the government and public of such interactions. State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our activities could be subject to the penalty provisions of the pertinent laws and regulations.

International Regulation

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

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

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

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

accelerated assessment, early dialogue and increased interaction with relevant regulatory committees to discuss development options, scientific advice at key development milestones, and proactive regulatory support from the EMA.

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

BioPharmaceutical Coverage, Pricing, and Reimbursement

In the United States and other countries, sales of any 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 marketplace that increases downward pressure on the prices of pharmaceutical products.

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

Employees

As of December 31, 2021, we had 427 full-time employees, 355 of whom were primarily engaged in research, development and manufacturing activities, and 77 of whom had an M.D. and/or Ph.D. Our employees are critically important to the achievement of our company’s mission and goals. We periodically conduct employee engagement surveys to understand our employees’ perspectives and endeavor to listen, change and improve on how we work together in response to these perspectives. We face significant competition for experienced and talented individuals in our area due to the growth of local companies. We monitor our compensation, benefits, and exit interview data and make changes as needed to enable the ongoing recruitment and selection of talented new employees, as well as to retain existing talent. We strive to offer our employees an intellectually challenging and diverse work environment, opportunities to expand their knowledge and skills, to receive feedback on performance, and for career advancement. Our Living Values, which focus on patients, honest and transparent communications, innovation, ethics, collaboration, our sense of urgency, getting results, and valuing diversity and striving for inclusion set the tone for how we work together.

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

Available Information

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

ITEM 1A. RISK FACTORS

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

Summary of Risk Factors Affecting Our Business

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

- We depend substantially on the success of the clinical development of our products and product candidates, through our own efforts or those of our collaborators, including MGC018. If we are unable to successfully complete clinical development, obtain additional regulatory approvals and commercialize our products and product candidates, or experience significant delays in doing so, our business will be materially harmed and we may not be able to generate sufficient revenues and cash flows to continue our operations.
- Clinical drug development involves a lengthy and expensive process, with a highly uncertain outcome. We expect to incur significant additional costs related to the development of MGC018 and our other product candidates and may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our other products and product candidates.
- We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. Our first commercial product, MARGENZA, launched in March 2021 and to date has not resulted in revenues sufficient for us to reach profitability. Accordingly, we may never achieve or sustain profitability.
- 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 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.
- The results of previous clinical trials may not be predictive of future results, and interim or top line data may be subject to change or qualification based the complete analysis of data. In addition, the results of our current or planned clinical trials may not satisfy the requirements of the U.S. Food and Drug Administration (FDA) or non-U.S. regulatory authorities for product approval.
- We use or may use novel technologies in the development of our product candidates and the FDA and other regulatory authorities have not approved or may not approve products that utilize these technologies.
- We may not be successful in our efforts to use and expand our technology platforms to build a pipeline of product candidates. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- MGC018, MARGENZA, or any other product candidate that we develop may fail to achieve or maintain market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- 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.

- 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.
- 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.
- The manufacture of MGC018, MARGENZA and our product candidates, for ourselves and our collaborators, is complex, and we may encounter difficulties in production. There can be no assurance that we will be able to effectively manufacture clinical quantities of our product candidates in the future. Further, we have limited experience in large-scale or commercial manufacturing, and there can be no assurance that we will be able to effectively manufacture commercial quantities of MARGENZA, or other products or product candidates, if and when approved.
- The current or future impact of the COVID-19 (or any variant thereof) pandemic may have significant negative impact on our clinical trials, preclinical studies, development, manufacturing and commercialization of our product and product candidates and other aspects of our business, staff, and operations. The extent to which the COVID-19 pandemic, both now and in the future, adversely affects our financial condition, results of operations, and liquidity, will depend on future developments, including but not limited to the measures taken by public and private entities in response to the pandemic, which remain highly uncertain and cannot be predicted.
- We have limited experience in launching and marketing our internally developed products. If we are unable to further develop marketing and sales capabilities or enter into agreements with third parties to market and sell our products, or our existing arrangements are not successful, we may not be able to generate substantial product sales revenue.
- We face significant competition and if our competitors continue to develop and market products that are more effective, safer or less expensive than our product and our product candidates, our current or future commercial opportunities may be negatively impacted.
- 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 health care items and services.
- Reimbursement decisions by third-party payors, including government payors, may have an adverse effect on pricing and market acceptance.
- 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.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish substantial rights.
- We contract with, and may in the future contract with, third parties for the distribution and commercialization of MARGENZA and our other product candidates. Failure of third-party contractors to successfully perform their obligations for commercialization, distribution, or other services could harm out ability to commercialize our product or product candidates.
- Our commercial success depends significantly on our ability to operate without infringing the valid patents and other proprietary rights of third parties.
- If we are unable to obtain and enforce patent protection for our products and our product candidates and related technology, our business could be materially harmed.
- 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 future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

- We are subject to securities litigation, which is expensive and could divert management attention and adversely impact our business.
- Failure to successfully develop and commercialize companion diagnostics with third party contractors for use with our product candidates could harm our ability to commercialize our product candidates.
- If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

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

We depend substantially on the success of the clinical development of our products and product candidates, through our own efforts or those of our collaborators, including MGC018. If we are unable to successfully complete clinical development, obtain additional regulatory approvals and commercialize our products and product candidates, or experience significant delays in doing so, our business will be materially harmed and we may not be able to generate sufficient revenues and cash flows to continue our operations.

Our business depends on the successful development, regulatory approval and commercialization of our products and product candidates, including MGC018. We have invested and will continue to invest a significant portion of our efforts and financial resources in the development of our product candidates, including MGC018. The success of our products and product candidates depends on many factors, including but not limited to:

- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies;
- safety and favorable efficacy and acceptable safety data from our clinical trials and other studies
- the sufficiency of our financial resources and ability to obtain additional funding for the development of our products and product candidates;
- receipt of regulatory approvals;
- the performance by clinical research organizations (CROs) or other third parties we may retain of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;
- ensuring we do not infringe, misappropriate or otherwise violate the valid patent, trade secret or other intellectual property rights of third parties;
- successfully launching our product candidates, including MGC018, if and when approved;
- maintaining commercial manufacturing capabilities, either by utilizing our current manufacturing facilities or making arrangements with third-party manufacturers;
- manufacturing or obtaining sufficient supplies of our products and product candidates that may be necessary for use in clinical trials for evaluation of our product candidates and commercialization of our products;
- obtaining favorable reimbursement from third-party payors for products and product candidates;
- competition with other products;
- post-marketing commitments to regulatory agencies following regulatory approval; and
- continued acceptable safety profile following regulatory approval.

Clinical drug development involves a lengthy and expensive process, with a highly uncertain outcome. We expect to incur significant additional costs related to the development of MGC018 and our other product candidates and may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our other products and product candidates.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and non-U.S. regulatory authorities, which regulations differ from country to country. We are not permitted to market our product candidates in the United States or in other countries until we receive

approval of a Biologics License Application (BLA) from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in drug development. For example, in November 2021, we announced the discontinuation of Cohort A of the MAHOGANY trial for margetuxumab in gastric cancer, based on a number of factors, including the prioritization of our other product candidates given the competition in this indication, and the FDA's approval of competing combination therapy with pembrolizumab. In addition, our collaborator Incyte submitted a BLA for retifanlimab in January 2021 and in July 2021, received a Complete Response Letter (CRL) from the FDA regarding its BLA. Incyte's announcement indicated that the FDA determined that additional data are needed to demonstrate the clinical benefit of retifanlimab for the submitted indication, and that Incyte is reviewing the CRL and will discuss next steps with the FDA. Obtaining approval of a BLA can be a lengthy, expensive and uncertain process. Further, in October 2021, Incyte withdrew its European application for marketing authorization of retifanlimab for the treatment of squamous carcinoma of the anal canal. In addition, failure to comply with FDA and non-U.S. regulatory requirements may, either before or after product approval, subject our company or our collaborators to administrative or judicially imposed sanctions, including:

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

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

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

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

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, or our collaborators, are either currently enrolling patients in clinical trials or anticipate initiating, continuing, or designing clinical trials for molecules that include MGC018, lorigerlimab, enoblituzumab, retifanlimab, tebotelimab, IMGC936 and MGD024 as monotherapies or in combination with other product candidates. In addition, Incyte is currently enrolling patients in clinical trials for retifanlimab, and other collaborators outside the United States are developing our product candidates. We anticipate in the future collaborators will initiate or continue clinical trials of one or more our product candidates. The continuation, modification, or commencement of existing or new clinical trials could be substantially delayed or prevented by several factors, including:

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

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

- delays in expected site initiation, patient recruitment and enrollment, for any reason, including as a result of public health crises such as the evolving COVID-19 pandemic;
- failure of patients to complete the clinical trial;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;
- lack of efficacy during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;
- economic and political instability in countries where our trial sites are located, including terrorist attacks, civil unrest and actual or threatened armed conflict;
- 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, the Investigational New Drug (IND) submission for MGD024 announced in November 2021 has not yet been accepted by the FDA while we address their comments on the submission. The trial start is on hold, pending alignment with the FDA. We believe we are able to address the FDA's comments and the MGD024 IND submission will be accepted for filing. A clinical hold received in the midst of conducting a trial may delay the progress of a clinical trial, or may require us to modify or discontinue such trial. Any failure or significant delay in completing clinical trials for our product candidates would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

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

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 or continued progress of the study or trial. 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, which may have an adverse effect on our ability to obtain or retain additional regulatory approval of MARGENZA and our product candidates in the U.S. or in other jurisdictions.

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

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

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

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

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

MGC018, MARGENZA, or any other product candidate that we develop may fail to achieve or maintain market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

MGC018, MARGENZA, or any other product candidate that we develop may fail to achieve or maintain market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success. For example, revenues from MARGENZA are unlikely to enable us to reach profitability.

If product candidates that we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidates that we develop will depend on a number of factors, including but not limited to:

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

A product's market acceptance depends significantly on the medical community's determination of clinical benefit and safety compared to alternative therapies available both now and in the future. For example. several new therapies for the treatment of HER2-positive breast cancer have recently been approved. Certain of these therapies may have or may be perceived to have greater efficacy benefits than MARGENZA in clinical trials. Competition from recently approved therapies has and may adversely impact the market acceptance of MARGENZA. In particular, final overall survival (OS) endpoint data from the SOPHIA trial analysis did not demonstrate a statistically significant advantage for MARGENZA over trastuzumab. This OS data may adversely affect the market acceptance of MARGENZA.

In addition, the potential market opportunities for our product candidates are difficult to precisely estimate. Our internal estimates of the potential market opportunities for MGC018 and our other product candidates include several key assumptions based on a variety of factors, which may include our industry knowledge, industry publications, third-party research reports, assessment of competition, and other surveys. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of these assumptions proves to be inaccurate, then the actual market for MGC018, our other product candidates could be smaller than our estimates of our potential market opportunity.

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

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

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

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

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

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

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 current Good Manufacturing Practices (cGMP) requirements, as set out in statute, regulations and interpreted through guidance. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. See "Other U.S. Post-Marketing Regulatory Requirements" above for additional information. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product or product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product or product candidates, including leading to significant delays in the availability of drug product for sale and our clinical trials or the termination or hold on a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions,

civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation or negatively impact a product's commercial success. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

The manufacture of MGC018, MARGENZA and our other product candidates, for ourselves and our collaborators, is complex, and we may encounter difficulties in production. There can be no assurance that we will be able to effectively manufacture clinical quantities of our product candidates in the future. Further, we have limited experience in large-scale or commercial manufacturing, and there can be no assurance that we will be able to effectively manufacture commercial quantities of MARGENZA, or other products or product candidates, if and when approved.

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

We also rely on third parties to manufacture certain components of our products or product candidates. See risk factor "**Risks Related to Our Dependence on Third Parties** - ***We contract with, and may in the future contract with, third parties for components of the manufacturing of MARGENZA and our other product candidates. Failure of third-party contractors to successfully perform their obligations could harm our ability to develop or commercialize our product or product candidates*****"** below.

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

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

Public health crises such as pandemics or similar outbreaks has, and may continue to have, a material impact our business. The COVID-19 pandemic and its variants continue to evolve, and to date have led to the implementation of various responses, including government-imposed quarantines, work and travel restrictions and other public health safety measures at the federal, state and local levels.

The continued spread of the COVID-19 pandemic has had, and may continue to have, a material impact on our clinical trials, preclinical studies, commercialization efforts, manufacturing and development of our product candidates and other aspects of our business, staff, and operations, which in turn may impact our financial condition, results of operations and liquidity. For instance, the COVID-19 pandemic impaired our ability to enroll patients in clinical trials, continue ongoing clinical trials or activate clinical trial sites, and MARGENZA commercialization, due to, for example, heightened exposure to COVID-19 if an outbreak occurs in a specific geography, the shifting of healthcare resources toward the pandemic or the closing of or limiting of access to clinical facilities, and reduced or eliminated in-person access to physicians and health care centers. Furthermore, patients may be unable or unwilling to enroll in our clinical trials or be unable to comply with clinical

trial protocols if COVID-19 related restrictions impede patient movement or interrupt healthcare services. Government-imposed quarantines and other restrictions may also require us to temporarily suspend activity at our clinical sites. The COVID-19 pandemic may also negatively affect the operations of third-party CROs that we rely upon to carry out our clinical trials, or the operations of other service providers, which could result in delays or disruptions in the supply of our product candidates or other aspects of our business or that of our collaborators. Any negative impact the COVID-19 pandemic has had, or will have, on patient enrollment or treatment or the timing and execution of our clinical trials could cause delays to our clinical trial activities, which could adversely affect our ability to seek and obtain regulatory approval for and to commercialize any approved product candidates, increase our operating expenses and have a material adverse effect on our business and financial results.

Further, the COVID-19 pandemic has increased the risk that a portion of the workforce, including ours, may suffer illness or otherwise be unable or unwilling to work due to close contact related precautions or due to choosing not to comply with vaccine mandates for healthcare workers. To date, we have seen limited business impact from COVID-19 related absences, but there can be no assurance that there will not be additional or significant employee COVID-19 related absences with negative business impact in the future. We have maintained an on-site workforce and implemented stay-at-home orders consistent with the requirements of the jurisdictions in which we operate, with arrangements such as remote work and flexible schedules for certain functions, as well as other measures intended to reduce the risks to our employees from the impact of the pandemic while maintaining our operations. Re-opening our offices could expose our employees to health risks, and us to associated liability, and could create additional risks and operational challenges that require us to make additional investments in the design, implementation and enforcement of new workplace health and safety protocols. We expect many employees to continue to work remotely or a hybrid of in-person and remote work, which presents risks, uncertainties and costs that could affect our performance, including operational and workplace culture challenges and uncertainty regarding office space needs. In addition, we implemented a company-wide vaccination requirement by the end of 2021, with certain exceptions. To date, we do not believe our vaccination requirement has resulted in workforce attrition nor will it result in material difficulty securing future labor needs. If employee attrition is significant, our business could be adversely affected.

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

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

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

In December 2020, the FDA approved MARGENZA, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. We launched MARGENZA in March 2021. In conjunction with Eversana Life Science Services, LLC (Eversana), we continue to build commercialization support in United States to commercialize MARGENZA in a manner we believe to be appropriate in light of the modest size of the market opportunity. We have limited internal commercialization capabilities, and any additional products or product candidates that we may develop or in-license, will require significant capital expenditures, management resources and time.

We have limited experience in commercializing our products. For example, we have limited experience in building and managing a commercial team, conducting a comprehensive market analysis, and reimbursement, or managing distributors and a field force for our products. We compete with many companies that currently have extensive and well-funded sales and marketing operations.

For commercialization of any or all of our product candidates, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to, or decide not to, further develop internal sales, marketing, and commercial distribution capabilities for any or all of our products, we will likely

pursue additional collaborative arrangements regarding the sales and marketing of our products. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our products ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our products.

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

We face significant competition and if our competitors continue to develop and market products that are more effective, safer or less expensive than our product and our product candidates, our current or future commercial opportunities may 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 potential treatments for cancer, including many major pharmaceutical and biotechnology companies. These treatments consist both of small molecule drug products, as well as biologic therapeutics that work by using next-generation antibody technology platforms to address specific cancer targets. In addition, several companies are developing therapeutics that work by targeting multiple specificities using a single recombinant molecule. See “Competition” above for additional information.

Our commercial opportunity for MARGENZA is limited, and the commercial opportunity for future product candidates including MGC018 may be reduced or limited 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. 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.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies, products or product candidates obsolete, less competitive or not economical.

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

The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any of our future approved products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs through lowering prescription drug prices, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including the Patient

Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), which became law in 2010. While it is difficult to assess the impact of the ACA in isolation, either in general or on our business specifically, it is widely thought that the ACA increases the likelihood of downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of, and the price we may charge for, any products we develop that receive regulatory approval. Further, the United State and foreign governments regularly consider additional reform measures that affect healthcare coverage and costs. Such reforms may include changes to the coverage and reimbursement of healthcare services and products. In particular, there have been executive, judicial and Congressional challenges to the ACA, which could have an impact on coverage and reimbursement for healthcare services covered by plans authorized by the ACA.

While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 (Tax Act) included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, on November 20, 2020, the Centers for Medicare & Medicaid Services (CMS) issued an interim final rule implementing former President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. However, it is unclear whether these or similar policy initiatives will be implemented in the future. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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

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

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

Market acceptance and sales of our products and product candidates, if approved for sale by the appropriate regulatory authorities, may depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will reimburse and establish payment levels and, in some cases, utilization management strategies, such as tiered formularies and prior authorization. We cannot be certain that reimbursement will be available for our products or any products that we develop . 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 to support a product's price, we may not be able to successfully commercialize any of our approved products.

There is uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage and reimbursement determination process is often time-consuming and costly. This process may require us to provide scientific and clinical information to support the coverage or reimbursement of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

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

Increasingly, third-party payors are requiring that biopharmaceutical manufacturers provide them with discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical products . There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific products and product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our products may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any approved product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Further, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Additionally, we or our collaborators may develop companion diagnostic tests for use with our product candidates where appropriate. We or our collaborators will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we may seek for our product candidates. While we have not yet developed any companion diagnostic tests for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates.

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

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

- decreased demand for our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- increased regulatory scrutiny;
- significant litigation costs;
- substantial monetary awards to or costly settlement with patients or other claimants;

- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

With respect to MGC018, MARGENZA and any of our other product candidates that are approved for commercial sale, we are, and will be, highly dependent upon physician and patient perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations.

As of December 31, 2021, we hold $20 million in product liability insurance coverage in the aggregate, with a per incident limit of $20 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage when we begin the commercialization of our product candidates. Insurance coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. A successful product liability claim or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operation.

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

We and our collaborators are subject to extensive ongoing obligations and continued regulatory review from applicable regulatory agencies with respect to any product obtaining regulatory approval, including MGC018 and MARGENZA, such as continued adverse event reporting requirements and post-marketing commitments, all of which may result in significant expense and limit our and our collaborators' ability to commercialize our current and any future approved products. For example, the FDA's approval of MARGENZA included a requirement that we provide to the FDA the data from the final overall survival endpoint from our SOPHIA study, which we reported in September 2021. Moreover, in connection with MARGENZA's approval, the labeling and advertising and promotion of MARGENZA are subject to additional regulatory requirements, which could entail significant expense and could negatively impact the potential commercialization of MARGENZA. To the extent other product candidates or those of our partners are approved by the FDA, we or our collaborators may be subject to similar post-marketing obligations.

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

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

- issuance of Form FDA 483 notices or Warning Letters by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties;
- criminal prosecutions;

- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing clinical trials;
- total or partial suspension of manufacturing;
- delays in commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us;
- refusals to permit drugs to be imported into or exported from the United States;
- restrictions on operations, including costly new manufacturing requirements; and
- product recalls or seizures.

The policies of the FDA and other regulatory agencies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of MGC018, our other product candidates or of MARGENZA in any additional indications or territories, or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we or our collaborators might not be permitted to market our current or any future approved products and our business would suffer.

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

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

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA, and other government employees and pause or stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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, and vaccination mandates. 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. Our first commercial product, MARGENZA, launched in March 2021 and to date has not resulted in revenues sufficient for us to reach profitability. Accordingly, we may never achieve or sustain profitability.

We have incurred significant losses since our inception. As of December 31, 2021, our accumulated deficit was approximately $974 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, manufacture product and product candidate inventory, prepare for and begin to commercialize any future approved products, and add infrastructure and personnel if needed 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 any of our product candidates.

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

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

We are advancing our product candidates through clinical development and have commercialized MARGENZA in collaboration with Eversana. Developing and commercializing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. In order to obtain such regulatory approval of product candidates, 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, 2021, combined with anticipated and potential collaboration payments and product revenues, will enable us to fund our operations through 2023. Such guidance does not reflect anticipated expenditures related to the potential late-stage development of MGC018 in mCRPC or further expansion of studies currently ongoing. Because development of our product candidates is uncertain, we are unable to estimate accurately the actual funds we will require to complete research, development and clinical testing to commercialize our product candidates.

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

- the number and characteristics of other product candidates and indications that we pursue;
- the scope, progress, timing, cost and results of research, preclinical development, and clinical trials, in particular, our planned potential registrational path trial for MCG018;
- the costs, timing and outcome of seeking and obtaining FDA and non-U.S. regulatory approvals;
- the costs associated with manufacturing our product candidates;
- the costs of establishing sales, marketing, and distribution capabilities;
- our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management, scientific, and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of our existing collaborations, and any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements.

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

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

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

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

Our ability to utilize our federal net operating losses (NOLs) and federal tax credits is currently limited, and may be limited further, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. The limitations apply if an ownership change, as defined by Section 382, occurs. Generally, an ownership change occurs when certain shareholders increase their aggregate ownership by more than 50 percentage points over their lowest ownership percentage in a testing period, which is typically three years or since the last ownership change. We are already subject to Section 382 limitations due to acquisitions we made in 2002 and 2008. As of December 31, 2021, we had federal and state NOL carryforwards of approximately $837 million and federal research and development tax credits of approximately $81 million available. Future changes in stock ownership may also trigger an ownership change and, consequently, another Section 382 limitation. Any limitation may result in expiration of a portion of the net operating loss or tax credit carryforwards before utilization which would reduce our gross deferred income tax assets and corresponding valuation allowance. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards and tax credit carryforwards to reduce United States federal income tax may be subject to limitations, which could potentially result in increased future cash tax liability to us.

Risks Related to Our Dependence on Third Parties

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

We have limited capabilities for drug development and have little to no internal capability for sales, marketing or distribution. We have entered into collaborations with other companies that we believe can provide such capabilities, including our agreements with, for example, Incyte Corporation, Zai Lab Limited, I-Mab Biopharma and Janssen Biotech, Inc. 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. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of our program collaborators.

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

For MGC018 and our other product candidates, we may in the future determine to collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for 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 products, product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for 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 MGC018 or our other product candidates, reduce or delay one or more of our other development programs, delay the commercialization of a product candidate or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop MGC018 or our other product candidates or bring them to market or continue to develop our technology platforms and our business may be materially and adversely affected.

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

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

We expect to continue to depend on independent clinical investigators and CROs to conduct our clinical trials, including future trials for MGC018 and other product candidates. 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 to successfully develop and commercialize companion diagnostics with third party contractors for use with our product candidates could harm our ability to commercialize our product candidates.

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

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

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

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

We contract with, and may in the future contract with, third parties for components of the manufacturing of MARGENZA and our other product candidates. Failure of third-party contractors to successfully perform their obligations could harm our ability to develop or commercialize our product or product candidates.

We currently have two cGMP manufacturing facilities located in Rockville, Maryland in 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 clinical trials of our and our collaborators' product candidates. We also manufacture commercial supply of MARGENZA. Although we believe we currently have capacity to produce most of the material required for our and our collaborators' clinical trials and for the commercial supply of MARGENZA, we may not be able to do so in the future, and may continue to rely on arrangements with third parties. We will continue to rely on third parties for bioconjugation to produce ADCs and for fill finish activities, neither of which our cGMP manufacturing facilities can currently accommodate.

We have entered into agreements with contract manufacturing organizations in the past to supplement our clinical supply and internal capacity as we commercialize MARGENZA and advance MGC018 and other product candidates in our pipeline. Current MARGENZA inventory was manufactured by a third party. In the future, we plan to manufacture MARGENZA utilizing our internal facility. In addition, in the future, we may use third parties for the manufacture of some or all components of our product candidates for clinical testing, including anti-body drug conjugates, as well as for commercial manufacture of some of our product candidates that receive marketing approval and that are not manufactured by us or one of our third party collaborators.. We may be unable to reach agreement with any of these contract manufacturers, or to identify and reach arrangements on satisfactory terms with other contract manufacturers, to manufacture any of our product candidates. Additionally, the facilities used by any contract manufacturer to manufacture any of our product candidates must be the subject of a satisfactory inspection before the FDA and other regulatory authorities approve a BLA or marketing authorization for the product candidate manufactured at that facility. We will depend on these third-party manufacturing partners for compliance

with the FDA's requirements for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA and other regulatory authorities' cGMP requirements, our product candidates will not be approved or, if already approved, may be subject to recalls.

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

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

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

Commercialization collaborations will be important to our business. If we are unable to maintain commercialization collaborations, or if commercialization collaborations are not successful, our business could be adversely affected.

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

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

- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further commercialization of MARGNEZA or applicable product candidates.

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

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

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

Risks Related to Cybersecurity

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

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

Risks Related to Our Intellectual Property

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

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

Patents that we may ultimately be found to infringe could be issued to third parties. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial

condition and results of operations. Moreover, our failure to maintain a license to any technology that we require may also materially harm our business, financial condition, and results of operations. Furthermore, we would be exposed to a threat of litigation.

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

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, opposition or other proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

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

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

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

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

Issued patents may be challenged, narrowed, invalidated or circumvented. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by biotechnology companies. The legal systems of certain countries

do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the enforceability and scope of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives.

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

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

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

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

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

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

- we or our collaborators may initiate litigation or other proceedings against third parties to enforce our patent rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;

- third parties may initiate opposition, reexamination or inter partes review proceedings challenging the validity or scope of our patent rights, requiring us or our collaborators and/or licensors to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents currently identified as being owned by or licensed to us;
- the USPTO may initiate an interference between patents or patent applications owned by or licensed to us and those of our competitors, requiring us or our collaborators and/or licensors to participate in an interference proceeding to determine the priority of invention, which could jeopardize our patent rights; or
- third parties may seek approval to market biosimilar versions of our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

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

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

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable.

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

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

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

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to

the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

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

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

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

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

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

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially,

Risks Related to Legal Compliance Matters

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

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

We 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.

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

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

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

Additionally, the intent standard under the federal anti-kickback statute and the criminal healthcare fraud statutes (discussed below) was amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified

case law that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil false claims act.

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal anti-kickback statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, under the Sunshine Act provisions of the ACA, covered manufacturers of drugs, devices, biological and medical supplies for which payment is available under a federal health care program (with certain exceptions) are subject to annual federal reporting and disclosure requirements with regard to payments or other transfers of value made to physicians defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals as well as information regarding certain ownership and investment interests held by physicians and their immediate family members.

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

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

We and our collaborators may also be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business, as well as foreign jurisdictions. In the United States, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and its implementing regulations, impose requirements on “covered entities,” including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective “business associates” that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors relating to the privacy, security and transmission of individually identifiable health information. We are subject to other state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For example, the General Data Protection Regulation (EU) 2016/679 (GDPR) which went into effect on May 25, 2018, imposes privacy and security obligations on any entity that collects and/or processes health data from individuals located in the European Union. Under the GDPR, fines of up to 20 million Euros or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance. In addition, on June 28, 2018, California enacted the California Consumer Privacy Act (CCPA), which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent state privacy legislation in the United States, which could increase our potential liability and adversely affect our business. As well as complicating our compliance efforts, non-compliance with these laws could result in penalties or significant legal liability.

Further, in order to distribute products commercially in the United States, we or our collaborators must also comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers, and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to

adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, track, and report gifts, compensation and other remuneration made to physicians and other healthcare providers, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit certain other sales and marketing practices.

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

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

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 other personnel will also be critical to our success. For example, we have experienced increased employee turnover, consistent with high numbers of employee resignations across the broader American economy, and we may continue to experience employee turnover in the future that may have an adverse effect on our business strategy. New hires require significant training and, in most cases, take significant time before they achieve full productivity. New employees may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals. In addition, the foregoing may be exacerbated by employees unwilling to work due to choosing not to comply with vaccine mandates for healthcare workers or for government contractors. 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. Such competition may increase due to the recent move by companies to offer a remote or hybrid work environment. 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, motivate existing employees, or maintain our corporate culture in a hybrid or remote work environment and in the midst of higher turnover, our ability to pursue our growth strategy will be limited.

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

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

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

As of December 31, 2021, we had 427 full-time employees. As our development and commercialization plans and strategies develop, we may choose to expand our employee base for managerial, operational, manufacturing, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Any such growth could require significant capital expenditures and may divert financial resources from other projects, such as the commercialization of MARGENZA and the development of existing and additional product candidates. If our management is unable to effectively manage such growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize MARGENZA, our product candidates and compete effectively with others in our industry will depend, in part, on our ability to effectively manage any such growth.

Risks Relating to Our Common Stock

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

The market price of our common stock has been and may continue to be volatile. Companies that have experienced volatility in the market price of their common stock are often subject to securities class action litigation. For example, on September 13, 2019, a securities class action complaint was filed against us, and certain of our officers and/or directors in the U.S. District Court for the District of Maryland. On September 29, 2021, the District Court issued an Order dismissing the case, with prejudice. On October 28, 2021 the Lead Plaintiff filed a Notice of Appeal, and on January 18, 2022 the Lead Plaintiff filed its opening brief. The case is now pending in the Fourth Circuit. This or any future securities litigation brought by private parties or government enforcement agencies could result in substantial costs and diversion of management’s attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities.

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

- results and timing of our clinical trials and clinical trials of our competitors’ products;
- failure or discontinuation of any of our development programs;
- issues in manufacturing our product candidates or future approved products;
- regulatory developments or enforcement in the United States and foreign countries with respect to our product candidates or our competitors’ products;
- competition from existing products or new products that may emerge;

- developments or disputes concerning patents or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- changes in estimates or recommendations by securities analysts, if any cover our common stock;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concern over our product candidates or any future approved products;
- threatened or actual litigation;
- future or anticipated sales of our common stock;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key personnel;
- changes in the structure of health care payment systems in the United States or overseas;
- failure of any of MARGENZA or our product candidates, if approved, to achieve commercial success;
- economic and other external factors or other disasters or crises;
- period-to-period fluctuations in our financial condition and results of operations, including the timing of receipt of any milestone or other payments under commercialization or licensing agreements;
- general market conditions and market conditions for biopharmaceutical stocks;
- overall fluctuations in U.S. equity markets; and
- impact of the COVID-19 pandemic as well as mandatory and voluntary actions taken to mitigate the evolving public health impact of the pandemic.

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

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

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

- allow the authorized number of directors to be changed only by resolution of our board of directors;
- establish a classified board of directors, providing that not all members of the board of directors be elected at one time;
- authorize our board of directors to issue without stockholder approval blank check preferred stock that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors;

- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;
- establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings;
- limit who may call stockholder meetings; and
- require the approval of the holders of 75% of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our restated certificate of incorporation and restated bylaws.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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

ITEM 3. LEGAL PROCEEDINGS

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

See note 11, Commitments and Contingencies, to the consolidated financial statements for more information.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

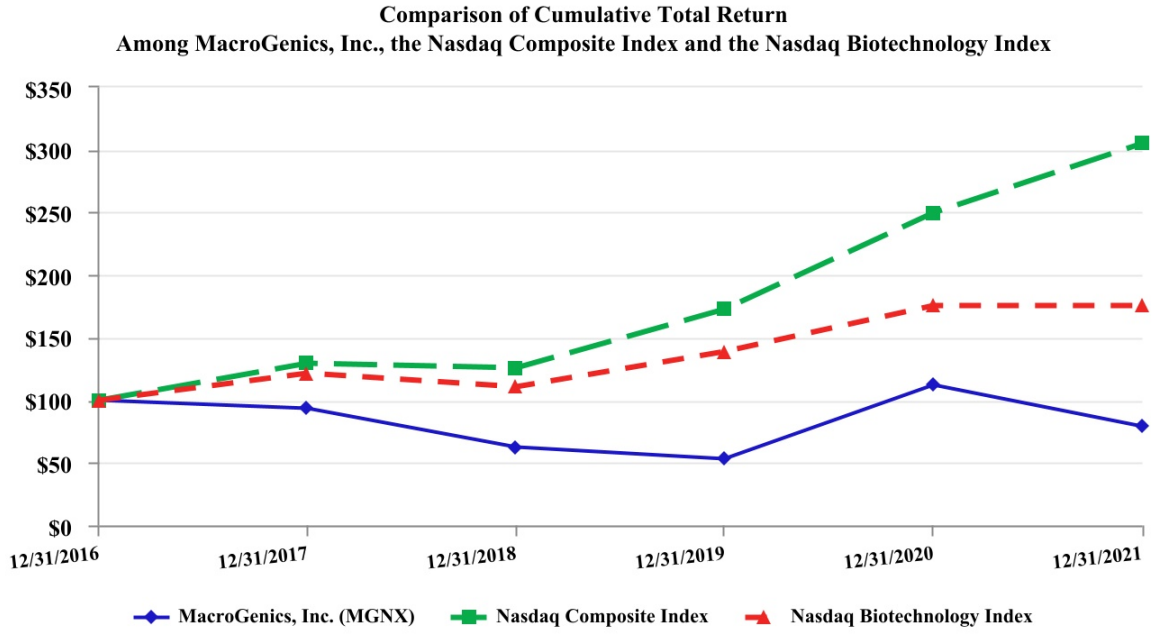
ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on the Nasdaq Global Select Market under the symbol "MGNX". As of February 22, 2022, we had 61,324,258 shares of common stock outstanding held by approximately 62 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, 2016 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. RESERVED

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, 2020 compared to the year ended December 31, 2019, 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, 2020 filed with the SEC on February 25, 2021.

Overview

We are a biopharmaceutical company focused on developing and commercializing innovative antibody-based therapeutics for the treatment of cancer. We have a pipeline of product candidates being evaluated in clinical trials sponsored by us or our collaborators. These product candidates include six immuno-oncology programs, some of which were created primarily using our proprietary, antibody-based technology platforms. We believe our product candidates have the potential, if approved for marketing by regulatory authorities, to have a meaningful effect on treating patients' unmet medical needs as monotherapy or, in some cases, in combination with other therapeutic agents. In March 2021, we and our commercialization partner commenced U.S. marketing of MARGENZA (margetuximab-cmkb), a human epidermal growth factor receptor 2 (HER2) receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

We 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 only began generating revenues from the sale of products in 2021. 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, 2021, combined with anticipated and potential collaboration payments and product revenues, should enable us to fund our operations through 2023. Our guidance does not reflect expenditures relating to the potential late-stage development of MGC018 in metastatic castration-resistant prostate cancer (mCRPC) or further expansion of studies currently ongoing.

Through December 31, 2021, we had an accumulated deficit of $973.9 million. We expect that over the next several years this deficit will increase as we increase our expenditures in research and development in connection with our ongoing activities with several clinical trials.

COVID-19 Pandemic

The COVID-19 pandemic has negatively impacted the global economy, created significant financial market volatility, disrupted global supply chains, and resulted in a significant number of infections and deaths worldwide. In addition, several national, state and local governments have placed restrictions on people from gathering in groups or interacting within a certain physical distance.

To date, although there has been some negative impact on our business and operations, including, for example, slowed clinical trial enrollment, we have been able to mitigate against more severe impacts of the COVID-19 pandemic on our business and operations. However, the COVID-19 pandemic could have a more significant negative impact on our business in the future depending on the depth of the effects and the duration of the crisis. In response to the COVID-19 pandemic, we have been focused on keeping our employees safe, continuing patients on trials, and maintaining our manufacturing capabilities and research efforts. The COVID-19 pandemic and its variants are evolving and we continue to monitor our business very closely to try and mitigate any potential impacts. We expect the pandemic to continue to have some near-term impact on the initiation of new studies, commercialization activities, and on clinical trial enrollment. Significant delays in the timing of our clinical trials and in regulatory reviews could adversely affect our ability to commercialize the product candidates in our pipeline. We are classified as a government contractor because of our contract with National Institute of Allergy and Infectious Diseases (NIAID), and our government contract includes provisions to comply with Executive Order 14042. The contract terms include the requirement that all our employees that may be on site at the same location as any employee supporting the government contract be fully vaccinated against COVID-19, unless legally entitled to an accommodation due to a disability or religious

belief, practice or observance. In anticipation of deadlines associated with the contract terms and Executive Order 14042, we implemented a company-wide vaccination requirement by the end of 2021, with certain exceptions. To date, we do not believe our vaccination requirement has resulted in workforce attrition nor will it result in material difficulty securing future labor needs. If attrition is significant, our business could be adversely affected.

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

Collaborations

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

- *Incyte.* In 2017, we entered into an exclusive global collaboration and license agreement with Incyte Corporation (Incyte) for retifanlimab (also known as INCMGA0012), an investigational monoclonal antibody that inhibits programmed cell death protein 1 (PD-1) (Incyte License Agreement). Incyte has obtained exclusive worldwide rights for the development and commercialization of retifanlimab in all indications, while we retain the right to develop our pipeline assets in combination with retifanlimab. Incyte paid us an upfront payment of $150.0 million under the terms of the agreement. In July 2021, Incyte announced that the U.S. Food and Drug Administration (FDA) had issued a Complete Response Letter (CRL) regarding its Biologics License Application (BLA) for retifanlimab as a potential treatment for adult patients with locally advanced or metastatic squamous cell carcinoma of the anal canal. Incyte’s announcement indicated that the FDA determined that additional data were needed to demonstrate the clinical benefit of retifanlimab for the submitted indication, and that Incyte was reviewing the CRL and would discuss next steps with the FDA. Incyte subsequently withdrew its European application for marketing authorization of retifanlimab for the treatment of squamous carcinoma of the anal canal. Incyte has stated it is pursuing development of retifanlimab in potentially registration-enabling studies beyond squamous cell carcinoma of the anal canal, including in patients with MSI-high endometrial cancer, Merkel cell carcinoma and non-small cell lung cancer. Incyte is also pursing development of retifanlimab in combination with multiple product candidates from its pipeline.

  Under the terms of the Incyte License Agreement, Incyte leads global development of retifanlimab. Assuming successful development and commercialization of retifanlimab by Incyte, we could receive total development and regulatory milestones of up to approximately $420.0 million and up to $330.0 million in commercial milestones. We received $70.0 million of the total development milestones through December 31, 2021. If retifanlimab is approved and commercialized, we would be eligible to receive tiered royalties of 15% to 24% on any global net sales and we have the option to co-promote retifanlimab with Incyte. We retain the right to develop our pipeline assets in combination with retifanlimab, with Incyte commercializing retifanlimab and us commercializing our asset(s), if any such potential combinations are approved. We also have an agreement with Incyte under which we are to perform development and manufacturing services for Incyte's clinical needs of retifanlimab (Incyte Clinical Supply Agreement) and another agreement under which we are entitled to manufacture a portion of Incyte’s global commercial supply of retifanlimab (Incyte Commercial Supply Agreement).

- *Zai Lab*. In 2018, we entered into a collaboration and license agreement with Zai Lab Limited (Zai Lab) under which Zai Lab obtained regional development and commercialization rights in mainland China, Hong Kong, Macau and Taiwan (Zai Lab’s territory) for (i) margetuximab, an immune-optimized anti-HER2 monoclonal antibody, (ii) tebotelimab, 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 (2018 Zai Lab Agreement). Zai Lab will lead clinical development in its territory.

  Under the terms of the 2018 Zai Lab Agreement, Zai Lab paid us an upfront payment of $25.0 million less foreign withholding tax of $2.5 million. Assuming successful development and commercialization of margetuximab, tebotelimab and the TRIDENT molecule, we could receive up to $140.0 million in development and regulatory

milestones, of which we have already received $4.0 million ($3.6 million net of foreign withholding tax). Subsequent to December 31, 2021, we earned $5.0 million upon Zai Lab's achievement of a regulatory milestone. In addition, Zai Lab would pay us tiered royalties at percentage rates of mid-teens to 20% for net sales of margetuximab in Zai Lab's territory, mid-teens for net sales of tebotelimab in Zai Lab's territory and 10% for net sales of the TRIDENT molecule in Zai Lab's territory, which may be subject to adjustment in specified circumstances.

In 2019, we entered into two agreements under which we are to perform manufacturing services for Zai Lab's clinical needs of margetuximab and tebotelimab (Zai Lab Clinical Supply Agreements).

In June 2021, we entered into a collaboration and license agreement with Zai Lab US LLC (collectively with Zai Lab Limited referred herein as Zai Lab) involving collaboration programs and license-only programs (collectively, the Programs) encompassing four separate immuno-oncology molecules (2021 Zai Lab Agreement). The first program covers a lead research molecule that incorporates our DART platform and binds CD3 and an undisclosed target that is expressed in multiple solid tumors (Lead Program). The second program covers a target to be designated by us. For these programs, Zai Lab receives commercial rights in Greater China, Japan, and Korea while we receive commercial rights in all other territories. Under the Lead Program, Zai Lab received an option upon reaching a predefined clinical milestone to convert the regional arrangement into a global 50/50 profit share. If Zai Lab elects such option, Zai Lab is to pay us $85.0 million plus any research costs incurred by both parties as of the option election date. Zai Lab also obtained exclusive, global licenses from us to develop, manufacture and commercialize two additional molecules (license-only programs). Zai Lab granted us a worldwide, royalty-free, co-exclusive license to conduct the development activities allocated to us.

Under the terms of the 2021 Zai Lab Agreement, the Lead Program includes joint research and development services by both us and Zai Lab. For the other programs, Zai Lab can separately negotiate and agree with us to perform research and development services in the future.

In connection with the execution of the 2021 Zai Lab Agreement, Zai Lab paid us an upfront payment of $25.0 million. Additionally, as part of the consideration for the rights granted to Zai Lab under the 2021 Zai Lab Agreement, we and Zai Lab entered into a separate stock purchase agreement (Stock Purchase Agreement) whereby Zai Lab paid us approximately $30.0 million to purchase 958,467 newly issued shares of our common stock, par value $0.01, at a fixed price of $31.30 which represented a $10.4 million premium over the share price on the Stock Purchase Agreement date.

Assuming successful development and commercialization of the Programs under the 2021 Zai Lab Agreement, we could receive up to $1.4 billion in development, regulatory and commercial milestones. In addition, Zai Lab would pay us tiered royalties at percentage rates of low double-digit teens on annual net sales of certain specified products and of mid-single digits to low double-digit teens on annual net sales of other specified products in Zai's territory, subject to specified royalty reduction pursuant to the 2021 Zai Lab Agreement. Per the terms of the 2021 Zai Lab Agreement, we may also receive reimbursements from Zai Lab for certain research and development costs incurred by us.

- *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 License 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 us.

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

  In October 2021, we entered into an agreement under which we are to perform development and manufacturing services for I-Mab's clinical needs of enoblituzumab.

- *Janssen.* In December 2020, we entered into a research collaboration and global license agreement to develop a preclinical bispecific molecule with Janssen Biotech, Inc. (Janssen). The research collaboration will incorporate our proprietary DART platform to enable simultaneous targeting of two undisclosed targets in a therapeutic area outside oncology. Under the terms of the agreement, Janssen paid us an upfront payment of $20.0 million and will

be responsible for funding all expenses. We will also be eligible to receive up to $312.0 million in potential milestone payments and tiered royalties of up to 10% on worldwide product sales.

Financial Operations Overview

Revenue

Our revenue consists primarily of collaboration revenue, including amounts recognized relating to upfront nonrefundable payments for licenses or options to obtain future licenses, amounts earned by performing development and manufacturing services, research and development funding and milestone payments earned under our collaboration and license agreements with our strategic collaborators. In addition, we have earned revenues through several grants and/or contracts with the U.S. government and other research institutions on behalf of the U.S. government, primarily with respect to research and development activities related to infectious disease product candidates. During 2021 we launched MARGENZA and began generating revenue from product sales. However, revenues from MARGENZA are unlikely to enable us to reach profitability.

Cost of Product Sales

Cost of product sales relates to sales of MARGENZA. These costs include material, manufacturing and shipping costs, as well as royalties payable on net sales of MARGENZA and inventory reserves. All product costs incurred prior to FDA approval of MARGENZA in December 2020 were expensed as research and development expense. We expect cost of product sales to continue to be positively impacted as we sell through inventory that was expensed prior to FDA approval of MARGENZA. We are currently unable to estimate how long it will be until we begin selling product manufactured post FDA approval.

Research and Development Expense

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

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

It is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates, or if, when or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical trials and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

Selling, General and Administrative Expense

Selling, general and administrative expense consists 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. Selling, general and administrative expense also includes costs incurred under the arrangement with our commercialization partner, Eversana Life Science Services, LLC, and other legal and professional fees.

Other Income

Other income consists of realized and unrealized gains and losses on equity securities and interest income earned on our cash, cash equivalents and marketable securities.

Critical Accounting 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. We did not make any material changes to these assumptions during the year ended December 31, 2021, and do not expect any material changes in the near term to the underlying assumptions. If we were to adjust our assumptions, the results of any material revisions would be reflected in the consolidated financial statements prospectively from the date of the change in estimate. Management considers an accounting estimate to be critical if:

- it requires a significant level of estimation uncertainty; and
- changes in the estimate are reasonably likely to have a material effect on our financial condition or results of operations.

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.

Inventory

When we believe regulatory approval is probable and expect future economic benefit from the sales of a product candidate to be realized, we capitalize manufacturing costs (whether internally produced or through third-party contract manufacturing organizations) as inventory. Prior to receiving our first approval from the FDA in December 2020, we expensed all costs incurred related to the manufacture of MARGENZA as research and development expense because of the inherent risks associated with the development of a product candidate, the uncertainty about the regulatory approval process and the lack of history for us of regulatory approval of drug candidates. Subsequent to FDA approval in December 2020, we began capitalizing our third-party contract manufacturing MARGENZA inventory costs.

Revenue Recognition

We recognize revenue under Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customer*s, (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.

Collaborative and other agreements

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

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

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

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

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

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

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

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

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

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

Product Revenue, Net

We entered into a limited number of arrangements with specialty distributors in the United States to distribute MARGENZA. The delivery of our product represents a single performance obligation for these transactions and we record net product revenue when control is transferred to the customer, generally upon receipt by the customer. The transaction price for net product revenue represents the amount we expect to receive, which is net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns, and other deductions. Accruals are established for these deductions, and actual amounts incurred are offset against applicable accruals. Customer discounts are recorded as reductions of accounts receivable on the consolidated balance sheets. Allowance for product returns, provider chargebacks, government and other rebates and service fees are recorded as a component of accrued expenses and other current liabilities on the consolidated balance sheets.Sales deductions are based on management's estimates that consider payor mix in target markets and experience to-date. These estimates involve a substantial degree of judgment, in particular, for government-mandated rebates and chargebacks, such as for the Medicaid and 340B programs.

Cost of product sales

Cost of product sales relates to sales of MARGENZA. These costs include material, manufacturing and shipping costs, as well as royalties payable on net sales of MARGENZA and inventory reserves. All product costs incurred prior to FDA approval of MARGENZA in December 2020 were expensed as research and development expense. We expect cost of product sales to continue to be positively impacted as we sell through inventory that was expensed prior to FDA approval of

MARGENZA. We are currently unable to estimate how long it will be until we begin selling product manufactured post FDA approval.

Research and Development Expense, Including Clinical Trial Accruals/Expenses

Research and development expense consists of costs we incur for our own research and development activities and costs incurred by our collaborators under cost sharing arrangements. Research and development costs consist of salaries and benefits, including related stock-based compensation, laboratory supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities on our behalf, such as CROs, and the cost of acquiring and manufacturing clinical trial materials, including costs incurred under agreements with 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 expense, 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 expense 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.

Recent Accounting Pronouncements

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

Results of Operations

Revenue

The following represents a comparison of our revenue for the years ended December 31, 2021 and 2020 (dollars in millions):

	Year Ended December 31,		Increase/(Decrease)		
	2021	**2020**			
Revenue from collaborative and other agreements	$ 63.3	$ 97.8	$ (34.5)	(35)	%
Product revenue, net	12.3	—	12.3		N/A
Revenue from government agreements	1.8	7.1	(5.3)	(75)	%
Total revenue	**$ 77.4**	**$ 104.9**	**$ (27.5)**	**(26)**	**%**

The decrease of $34.5 million in revenue from collaborative and other agreements for the year ended December 31, 2021 compared to the year ended December 31, 2020 was primarily due to:

- a decrease of $25.0 million in development milestones recognized under the Incyte License Agreement;
- a decrease of $18.5 million recognized under the Janssen research collaboration and global license agreement;
- recognition of a $12.0 million payment from Boehringer Ingelheim International GmbH (BII) for retention of rights to two DART molecules during 2020;
- a decrease of $8.6 million recognized under the 2018 Zai Lab Agreement; and

- a decrease of approximately $7.1 million in revenue recognized under the Incyte Clinical Supply Agreement due to decreased development activity.

These decreases were partially offset by:

- recognition of $20.3 million in revenue from the 2021 Zai Lab Agreement executed in June 2021;
- an increase of $9.2 million in revenue recognized under the I-Mab License Agreement; and
- an increase of $6.4 million in revenue recognized under the Incyte Commercial Supply Agreement which was executed in late 2020.

The decrease of $5.3 million in revenue from government agreements for the year ended December 31, 2021 compared to the year ended December 31, 2020 was primarily due to decreased development costs related to the second DART molecule.

Revenue from product sales is recorded net of applicable provisions for rebates, chargebacks and discounts, distribution-related fees and other sales-related deductions. The table below includes a reconciliation of the accounts associated with these deductions (in millions):

	Rebates and chargebacks	Distribution fees, product returns and other	Total
Balance as of December 31, 2020	$ —	$ —	$ —
Provision related to current year sales	1.7	0.8	2.5
Payments/credits for current year sales	(1.3)	(0.4)	(1.7)
Balance as of December 31, 2021	$ 0.4	$ 0.4	$ 0.8

Cost of Product Sales

Cost of product sales for the year ended December 31, 2021 consisted primarily of reserves for unsaleable inventory, as well as product royalties. Product sold during the year ended December 31, 2021 consisted of drug product that was previously charged to research and development expense prior to FDA approval of MARGENZA, which favorably impacted our gross margin for the year ended December 31, 2021. No similar cost of product sales was recognized during the year ended December 31, 2020, as there were no sales of MARGENZA during those periods.

Research and Development Expense

The following represents a comparison of our research and development expense for the years ended December 31, 2021 and 2020 (dollars in millions):

	Year Ended December 31,		Increase/(Decrease)	
	2021	2020		
Margetuximab	$ 41.5	$ 49.5	$ (8.0)	(16) %
MGC018	31.3	12.8	18.5	145 %
Flotetuzumab	28.8	26.6	2.2	8 %
Tebotelimab	19.5	23.5	(4.0)	(17) %
Enoblituzumab	19.1	14.2	4.9	35 %
Retifanlimab	14.5	22.7	(8.2)	(36) %
Lorigerlimab (formerly MGD019)	13.4	8.6	4.8	56 %
IMGC936	5.7	4.3	1.4	33 %
DART molecules under HIV government contract	5.1	7.0	(1.9)	(27) %
MGD024	3.7	0.1	3.6	N/A
Other programs (a)	32.0	23.9	8.1	34 %
Total research and development expense	**$ 214.6**	**$ 193.2**	**$ 21.4**	**11 %**

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

Research and development expense for the year ended December 31, 2021 increased by $21.4 million compared to the year ended December 31, 2020. This increase was primarily attributable to:

- increased MGC018 development, manufacturing and clinical trial costs related to our Phase 1/2 dose expansion study;
- increased development of discovery projects and preclinical molecules;
- increased clinical trial enrollment costs related to enoblituzumab;
- increased clinical trial costs related to our lorigerlimab Phase 1 dose expansion study; and
- costs related to IND preparation and clinical trial initiation for MGD024.

These increases were partially offset by:

- decreased development and manufacturing costs related to retifanlimab due to timing of manufacturing activities for Incyte under the Incyte supply agreements;
- decreased clinical trial and BLA support costs for margetuximab; and
- decreased development and manufacturing costs related to tebotelimab.

Selling, General and Administrative Expense

The following represents a comparison of our general and administrative expenses for the years ended December 31, 2021 and 2020 (dollars in millions):

	Year Ended December 31,		Increase/(Decrease)	
	2021	2020		
Selling, general and administrative expenses	$ 63.0	$ 42.7	$ 20.3	48 %

Selling, general and administrative expenses increased for the year ended December 31, 2021 by $20.3 million compared to 2020 primarily due to due to costs related to the launch of MARGENZA, as well as increased labor-related costs and legal expenses.

Other Income

The decrease of $0.6 million in other income for the year ended December 31, 2021 compared to the year ended December 31, 2020 is primarily due to decreased investment income.

Liquidity and Capital Resources

Cash Flows

The following table represents a summary of our cash flows for the years ended December 31, 2021 and 2020 (dollars in millions):

	Year Ended December 31,		Increase/(Decrease)	
	2021	2020		
Net cash provided by (used in):				
Operating activities	$ (143.8)	$ (111.9)	$ (31.9)	(29) %
Investing activities	(36.6)	(7.8)	(28.8)	(369) %
Financing activities	122.8	174.3	(51.5)	(30) %
Net increase (decrease) in cash and cash equivalents	**$ (57.6)**	**$ 54.6**	**$ (112.2)**	**205 %**

Operating Activities

Net cash 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, 2021 benefiting from the $25.0 million upfront payment under the 2021 Zai Lab Agreement, $15.0 million milestone payment received from Incyte, and $4.5 million milestone payment

from I-Mab. The year ended December 31, 2020 benefited from the $40.0 million in milestone payments received from Incyte, the $20.0 million upfront payment from Janssen, and the $12.0 million received from BII.

Investing Activities

Net cash used in investing activities during the years ended December 31, 2021 and 2020 is primarily due to purchases of marketable securities, partially offset by maturities of marketable securities.

Financing Activities

Net cash provided by financing activities for the years ended December 31, 2021 and 2020 reflects net cash proceeds from our securities offerings of approximately $117.8 million and $170.5 million, respectively, and cash from stock option exercises and the purchase of shares under our employee stock purchase plan. Net cash provided by financing activities for the year ended December 31, 2021 also reflects approximately $19.6 million from Zai Lab under the Stock Purchase Agreement.

Our multiple product candidates currently under development will require significant additional research and development efforts that include extensive preclinical studies and clinical testing, and regulatory approval prior to commercial use. As a biotechnology company, we have primarily funded our operations with proceeds from the sale of our common stock in equity offerings, revenue from our multiple collaboration agreements, and contracts and grants from NIAID. Management regularly reviews our available liquidity relative to our operating budget and forecast to monitor the sufficiency of our working capital, and anticipates continuing to draw upon available sources of capital, including equity and debt instruments, to support our product development activities. There can be no assurances that new sources of capital will be available to us on commercially acceptable terms, if at all. Also, any future collaborations, strategic alliances and marketing, distribution or licensing arrangements may require us to give up some or all rights to a product or technology at less than its full potential value. If we are unable to enter into new arrangements or to perform under current or future agreements or obtain additional capital, we will assess our capital resources and may be required to delay, reduce the scope of, or eliminate one or more of our product research and development programs or clinical studies, and/or downsize our organization. Although it is difficult to predict our funding requirements, we anticipate that our cash, cash equivalents and marketable securities as of December 31, 2021, as well as anticipated and potential collaboration payments, and product revenues should enable us to fund our operations through 2023, assuming our programs and collaborations advance as currently contemplated.

Material Cash Requirements

Our short-term and long-term material cash requirements consist of operational and capital expenditures, some of which contain contractual obligations. Our primary uses of cash relate to paying salaries and benefits, administering clinical trials, marketing our product, and providing the technology and facilities necessary to support our operations. The most significant contractual obligations are the operating leases at our facilities in Maryland and California. Our future minimum lease payments as of December 31, 2021 totaled $6.9 million related to short-term lease liabilities, and $25.5 million related to long-term lease liabilities. See Note 6, Leases, in the Notes to the Financial Statements in this Annual Report on Form 10-K for additional information about our lease liabilities. We also have short-term commitments for ongoing capital improvement projects totaling approximately $1.7 million as of December 31, 2021. We expect to fund these requirements with current cash, cash equivalents and marketable securities as well as anticipated and potential collaboration payments, and product revenues.

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, 2021, we had cash, cash equivalents and marketable securities of $243.6 million. Our primary exposure to market risk is related to changes in interest rates. Due to the short-term maturities of our cash equivalents and marketable securities and the low risk profile of our marketable securities, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities. We have the ability to hold our marketable securities until maturity, and we therefore do not expect a change in market interest rates to affect our operating results or cash flows to any significant degree.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, including our principal executive and principal financial officers, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2021. 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, 2021, and has concluded that there was no change that occurred during the quarterly period ended December 31, 2021 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, 2021. 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, 2021, 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, 2021 has been audited by Ernst & Young, LLP, an independent registered public accounting firm, as stated in their report which is included herein on page 68.

ITEM 9B. OTHER INFORMATION

On February 22, 2022, Eric Risser, the Company’s current Senior Vice President, Business Development and Portfolio Management and Chief Business Officer, was promoted to the position of Chief Operating Officer. Mr. Risser will continue to receive compensation in connection with such appointment pursuant to his current Employment Agreement with the Company, dated March 8, 2016. Mr. Risser’s biography is included in the Company’s definitive proxy statement on Schedule 14A, filed

with the Securities and Exchange Commission on April 2, 2021, in the section titled “Executive Officers” and is incorporated herein by reference.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

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, 2021, 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, 2021, 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, 2021 and 2020, 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, 2021, and the related notes and our report dated February 24, 2022, 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

Tysons, Virginia
February 24, 2022

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 2022 annual meeting of stockholders (the 2022 Proxy Statement).

ITEM 11. EXECUTIVE COMPENSATION

We incorporate herein by reference the relevant information concerning executive compensation to be included in the 2022 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 2022 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 2022 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 2022 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 24, 2022
/s/ James Karrels James Karrels	Senior Vice President, Chief Financial Officer and Secretary (Principal Financial Officer)	February 24, 2022
/s/ Lynn Cilinski Lynn Cilinski	Vice President, Controller and Treasurer (Principal Accounting Officer)	February 24, 2022
/s/ Paulo Costa Paulo Costa	Director	February 24, 2022
/s/ Karen Ferrante, M.D. Karen Ferrante, M.D.	Director	February 24, 2022
/s/ Edward Hurwitz Edward Hurwitz	Director	February 24, 2022
/s/ Scott Jackson Scott Jackson	Director	February 24, 2022
/s/ Federica O'Brien Federica O'Brien	Director	February 24, 2022
/s/ Jay Siegel, M.D. Jay Siegel, M.D.	Director	February 24, 2022
/s/ David Stump, M.D. David Stump, M.D.	Director	February 24, 2022

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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, 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, 2021, 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 24, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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

Collaboration and Licensing Agreement with Zai Lab

Description of the Matter

As discussed in Note 10 of the consolidated financial statements, in June 2021, the Company entered into a collaboration and license agreement with Zai Lab US LLC ("Zai Agreement"). As part of the consideration for the rights granted to Zai Lab US LLC under the Zai Agreement, the Company and Zai Lab US LLC entered into a separate stock purchase agreement ("Stock Purchase Agreement"). The Zai Agreement and Stock Purchase Agreement are referred to collectively as the Agreements. The Agreements resulted in the recognition of $20.3 million of revenue from collaborative and other agreements and $16.1 million of deferred revenue for the year ended December 31, 2021, respectively.

Accounting for the Zai Agreement required the Company to make significant judgments, including but not limited to the identification of performance obligations and the estimation of the standalone selling price of each identified performance obligation. The standalone selling price of the performance obligation was not directly observable; therefore, the Company estimated the standalone selling price using an adjusted market assessment approach, representing the estimated amount that the Company believes the market is willing to pay for the product or service. The estimate was based on consideration of observable inputs, such as, values of other preclinical collaboration arrangements adjusted for the Company's estimate of the probability of success for each program under the agreement. Changes to these assumptions can have a material effect on the allocation of the transaction price to the performance obligations as well as the amount and timing of revenue recognized. As a result, auditing the identification of performance obligations and estimates of standalone selling price for performance obligations required especially complex auditor judgment.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls over the Company's collaboration revenue process. For example, we tested controls over management's process to determine the significant assumptions described above with respect to the identification of the performance obligations and the related estimation of the standalone selling price of each performance obligation.

To audit the Company's revenue recognition related to the Zai Agreement, we performed audit procedures that included, among others, inspecting the executed Agreements and accounting assessment and evaluating whether the promised services and performance obligations were properly identified. In addition, we evaluated management's estimates of the standalone selling price of the identified performance obligations. For example, we evaluated the market values of other preclinical collaboration arrangements and the probability of success assumptions used by the Company in developing the estimates of standalone selling price by comparing the significant assumptions described above to current industry trends using available information from other guideline companies within the same industry and other relevant factors. We also performed a sensitivity analysis of the significant assumptions to evaluate the impact that the change in the estimated standalone selling price of certain performance obligations resulting from changes in the significant assumptions would have on the allocation of transaction price to each performance obligation, as well as revenue recognized during the period.

/s/ Ernst & Young LLP

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

Tysons, Virginia
February 24, 2022

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

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 123,469	$ 181,131
Marketable securities	120,147	91,400
Accounts receivable	10,386	23,081
Inventory, net	4,388	—
Prepaid expenses and other current assets	21,170	16,982
Total current assets	279,560	312,594
Property, equipment and software, net	37,676	42,225
Other non current assets	18,009	23,924
Total assets	$ 335,245	$ 378,743
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 15,500	$ 8,031
Accrued expenses and other current liabilities	33,755	34,198
Deferred revenue	20,646	4,456
Lease liabilities	4,677	3,988
Total current liabilities	74,578	50,673
Deferred revenue, net of current portion	—	6,926
Lease liabilities, net of current portion	20,791	25,260
Other non current liabilities	258	—
Total liabilities	95,627	82,859
Stockholders' equity:		
Common stock, 0.01 par value -- 125,000,000 shares authorized, 61,307,428 and 56,244,771 shares outstanding at December 31, 2021 and December 31, 2020, respectively	613	562
Additional paid-in capital	1,213,002	1,067,150
Accumulated other comprehensive income (loss)	(61)	(7)
Accumulated deficit	(973,936)	(771,821)
Total stockholders' equity	239,618	295,884
Total liabilities and stockholders' equity	$ 335,245	$ 378,743

See accompanying notes.

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

	Year Ended December 31,		
	2021	**2020**	**2019**
Revenues:			
Revenue from collaborative and other agreements	$ 63,294	$ 97,764	$ 62,024
Product revenue, net	12,349	—	—
Revenue from government agreements	1,804	7,119	2,164
Total revenues	77,447	104,883	64,188
Costs and expenses:			
Cost of product sales	2,651	—	—
Research and development	214,577	193,201	195,309
Selling, general and administrative	63,014	42,742	46,064
Total costs and expenses	280,242	235,943	241,373
Loss from operations	(202,795)	(131,060)	(177,185)
Other income	680	1,321	25,374
Net loss	(202,115)	(129,739)	(151,811)
Other comprehensive income:			
Unrealized gain (loss) on investments	(54)	(23)	19
Comprehensive loss	$ (202,169)	$ (129,762)	$ (151,792)
Basic and diluted net loss per common share	$ (3.37)	$ (2.47)	$ (3.16)
Basic and diluted weighted average common shares outstanding	59,944,717	52,442,389	48,082,728

See accompanying notes.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2018	42,353,301	$ 424	$ 732,727	$ (490,271)	$ (3)	$ 242,877
Share-based compensation	—	—	19,571	—	—	19,571
Issuance of common stock, net of offering costs	6,325,000	63	118,594	—	—	118,657
Stock plan related activity	280,462	3	1,312	—	—	1,315
Unrealized gain on investments	—	—	—	—	19	19
Net loss	—	—	—	(151,811)	—	(151,811)
Balance, December 31, 2019	48,958,763	490	872,204	(642,082)	16	230,628
Share-based compensation	—	—	20,676	—	—	20,676
Issuance of common stock, net of offering costs	6,612,815	66	170,390	—	—	170,456
Stock plan related activity	673,193	6	3,880	—	—	3,886
Unrealized loss on investments	—	—	—	—	(23)	(23)
Net loss	—	—	—	(129,739)	—	(129,739)
Balance, December 31, 2020	56,244,771	562	1,067,150	(771,821)	(7)	295,884
Share-based compensation	—	—	23,126	—	—	23,126
Issuance of common stock, net of offering costs	4,580,653	46	117,772	—	—	117,818
Stock plan related activity	482,004	5	4,954	—	—	4,959
Unrealized loss on investments	—	—	—	—	(54)	(54)
Net loss	—	—	—	(202,115)	—	(202,115)
Balance, December 31, 2021	61,307,428	$ 613	$ 1,213,002	$ (973,936)	$ (61)	$ 239,618

See accompanying notes.

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

	Year Ended December 31,		
	2021	**2020**	**2019**
Operating activities			
Net loss	$ (202,115)	$ (129,739)	$ (151,811)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	11,258	11,957	12,306
Amortization of premiums and discounts on marketable securities	1,607	(260)	(1,461)
Share-based compensation	23,126	20,676	19,571
Other non-cash items	2,035	—	—
Changes in operating assets and liabilities:			
Accounts receivable	12,696	(10,337)	16,839
Inventory	(6,424)	—	—
Prepaid expenses and other current assets	(4,188)	(5,697)	(4,878)
Other non current assets	5,915	581	(1,578)
Accounts payable	7,125	3,723	787
Accrued expenses and other current liabilities	(607)	6,994	(6,057)
Lease liabilities	(3,780)	(1,324)	2,881
Deferred revenue	9,264	(8,472)	(20,869)
Other non current liabilities	258	—	—
Net cash used in operating activities	(143,830)	(111,898)	(134,270)
Cash flows from investing activities			
Purchases of marketable securities	(231,208)	(223,745)	(264,399)
Proceeds from sales and maturities of marketable securities	200,800	221,866	189,330
Purchases of property, equipment and software	(6,201)	(5,906)	(4,289)
Net cash used in investing activities	(36,609)	(7,785)	(79,358)
Cash flows from financing activities			
Proceeds from issuance of common stock, net of offering costs	117,818	170,456	118,657
Proceeds from stock option exercises and ESPP purchases	4,959	3,886	1,315
Net cash provided by financing activities	122,777	174,342	119,972
Net change in cash and cash equivalents	(57,662)	54,659	(93,656)
Cash and cash equivalents at beginning of period	181,131	126,472	220,128
Cash and cash equivalents at end of period	$ 123,469	$ 181,131	$ 126,472
Non-cash operating and investing activities			
Right-of-use assets modified in exchange for operating lease obligation	$ —	$ —	$ 6,408
Property and equipment included in accounts payable or accruals	$ 508	$ 66	$ 66

See accompanying notes.

1. Organization and Nature of Operations

MacroGenics, Inc. (the Company) is incorporated in the state of Delaware. The Company is a biopharmaceutical company focused on developing and commercializing innovative antibody-based therapeutics designed to modulate the human immune response for the treatment of cancer. The Company has a pipeline of product candidates being evaluated in clinical trials sponsored by MacroGenics or its collaborators. These product candidates include six immuno-oncology programs, some of which were created primarily using the Company's proprietary, antibody-based technology platforms. The Company believes our product candidates have the potential, if approved for marketing by regulatory authorities, to have a meaningful effect on treating patients' unmet medical needs as monotherapy or, in some cases, in combination with other therapeutic agents. In March 2021, the Company and its commercialization partner commenced U.S. marketing of MARGENZA (margetuximab-cmkb), a human epidermal growth factor receptor 2 (HER2) receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

Liquidity

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

As a biotechnology company, the Company has primarily funded its operations with proceeds from the sale of its common stock in equity offerings, revenue from its multiple collaboration agreements, and contracts and grants from the National Institute of Allergy and Infectious Diseases (NIAID). Management regularly reviews the Company's available liquidity relative to its operating budget and forecast to monitor the sufficiency of the Company's working capital. Based on the Company's most recent cash flow forecast, the Company believes its current resources are sufficient to fund its operating plans for a minimum of twelve months from the date that this Annual Report was filed. In the longer term, the Company plans to meet its operating requirements by generating revenue from current and future strategic collaborations or other arrangements, as well as MARGENZA product sales. The Company anticipates continuing to draw upon available sources of capital, including equity and debt instruments, to support its product development activities. If the Company is unable to enter into new arrangements or to perform under current or future agreements or obtain additional capital, the Company will assess its capital resources and may be required to delay, reduce the scope of, or eliminate one or more of its product research and development programs or clinical studies, and/or downsize its organization.

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

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

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

Use of Estimates

The preparation of the financial statements in accordance with generally accepted accounting principles (GAAP) requires the Company to make estimates and judgments in certain circumstances that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. In preparing these consolidated financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. On an ongoing basis, the Company evaluates its estimates, including those related to revenue recognition, fair values of assets, inventory, 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. Although actual results could differ from these estimates, management does not believe that such differences would be material.

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. Classification of marketable securities between current and non-current is dependent upon the maturity date at the balance sheet date taking into consideration the Company's ability and intent to hold the investment to maturity. 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, along with interest income and amortization of premiums and discounts.

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, 2021 or 2020, 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. There were no transfers between levels during the periods presented.

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

	Fair Value Measurement at December 31, 2021		
	Total	Level 1	Level 2
Assets:			
Money market funds	$ 17,202	$ 17,202	$ —
U.S Treasury securities	81,132	81,132	—
Government-sponsored enterprises	7,734	—	7,734
Corporate debt securities	37,280	—	37,280
Total assets measured at fair value [(a)]	$ 143,348	$ 98,334	$ 45,014

	Fair Value Measurement at December 31, 2020		
	Total	Level 1	Level 2
Assets:			
Money market funds	$ 49,004	$ 49,004	$ —
U.S Treasury securities	60,623	60,623	—
Corporate debt securities	33,776	—	33,776
Total assets measured at fair value [(b)]	$ 143,403	$ 109,627	$ 33,776

(a) Total assets measured at fair value at December 31, 2021 includes approximately $23.2 million reported as cash and cash equivalents and $120.1 million reported as marketable securities on the balance sheet.

(b) Total assets measured at fair value at December 31, 2020 includes approximately $52.0 million reported as cash and cash equivalents and $91.4 million reported as marketable securities on the balance sheet.

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, MARGENZA net product sales and contracts and research grants received from U.S. government agencies. The following table includes those counterparties that represent more than 10% of total revenue earned in the periods indicated:

	Year Ended December 31,		
	2021	2020	2019
Incyte Corporation (Incyte)	31%	47%	35%
Janssen Biotech, Inc. (Janssen)	*	19%	—%
Zai Lab Limited (Zai Lab)	30%	11%	29%
Les Laboratoires Servier and Institut de Recherches Servier (Servier)	—%	*	18%
I-Mab Biopharma (I-Mab)	16%	*	*

* Amount is less than 10% for the period indicated.

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

	December 31,	
	2021	2020
Janssen	*	87%
Zai Lab	23%	*
I-Mab	12%	—%
McKesson Plasma & Biologics and McKesson Specialty Care Distribution LLC	18%	—%
ASD Healthcare and Oncology Supply	18%	—%

* Balance is less than 10% as of the date indicated.

Inventory

When the Company believes regulatory approval is probable and expects future economic benefit from the sales of a product candidate to be realized, the Company capitalizes manufacturing costs (whether internally produced or through third-party contract manufacturing organizations) as inventory. Prior to receiving its first approval from the U.S. Food and Drug Administration (FDA) in December 2020, the Company expensed all costs incurred related to the manufacture of MARGENZA as research and development expense because of the inherent risks associated with the development of a product candidate, the uncertainty about the regulatory approval process and the lack of history for the Company of regulatory approval of drug candidates. Subsequent to FDA approval in December 2020, the Company began capitalizing its MARGENZA third-party contract manufacturing inventory costs.

Inventory is composed of raw materials, work-in-process, and finished goods, which are goods that are available for sale. The Company values its inventories at the lower of cost or estimated net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials and third-party contract manufacturing costs, on a first-in, first-out basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess, obsolete or unsaleable inventories to their estimated realizable value in the period in which the impairment is first identified. Such write downs, should they occur, are recorded within the cost of product sales in the statement of operations.

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, 2021, and 2020, the Company determined that there were no impaired assets.

Revenue recognition

The Company recognizes revenue under ASC Topic 606, *Revenue from Contracts with Customer*s (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.

Collaborative and other agreements

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

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

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

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

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

The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

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

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

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

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

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties who are both active participants in the activities and are both exposed to significant risks and rewards dependent on the commercial success of such activities. Such arrangements generally are within the scope of ASC 808, *Collaborative Arrangements* (ASC 808). While ASC 808 defines collaborative arrangements and provides guidance on income statement presentation, classification, and disclosures related to such arrangements, it does not address recognition and measurement matters, such as (1) determining the appropriate unit of accounting or (2) when the recognition criteria are met. Therefore, the accounting for these arrangements is either based on an analogy to other accounting literature or an accounting policy election by the Company. The Company accounts for certain components of the collaboration agreement that are reflective of a vendor-customer relationship (e.g., licensing arrangement) based on 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 10, Collaboration and Other Agreements.

Product revenue, net

The Company entered into a limited number of arrangements with specialty distributors in the United States to distribute MARGENZA. These arrangements are considered to be contracts with customers and are in the scope of ASC 606. The Company has written contracts with each of its customers that have a single performance obligation - to deliver products upon receipt of a customer order - and these obligations are satisfied when delivery occurs and the customer receives the product. The specialty distributors subsequently resell the Company's product to healthcare providers. Product revenue is recorded net of applicable reserves for variable consideration, including discounts and other allowances. Shipping and handling costs for product shipments occur prior to the customer obtaining control of the goods and are recorded in cost of sales. For the year ended December 31, 2021, the shipping costs incurred were immaterial.

Reserves for Variable Consideration. Revenue from product sales is recorded at the net sales price, which includes estimates of variable consideration. Components of variable consideration typically include discounts, product returns, provider chargebacks and discounts and government rebates. Variable consideration is estimated following the expected value method in accordance with ASC 606 and includes such factors as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Estimates of the variable consideration were not deemed constrained during the year ended December 31, 2021.

Customer Discounts and Service Fees. The Company may provide customers with discounts which are explicitly stated in the contracts. These discounts are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, these contracts may include written service arrangements whereby the Company pays fees to customers who provide services such as sales order management, data, contract administration and distribution services, at rates which the Company believes to be consistent with fair market value. The Company has determined such services received to date are not distinct from the Company's sale of products to its customers and, therefore, these payments have been recorded as a reduction of revenue within the statement of operations.

Product Returns. Consistent with industry practice, the Company offers the specialty distributors product return rights pursuant to written contracts and/or Company returned goods policies. The Company estimates the amount of its product sales that may be returned by its customers and records an estimated liability and a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product returns using industry benchmarking as well as other information available, such as visibility into the inventory remaining in the distribution channel, since the Company does not have its own returns experience. The Company's estimates of product returns may be adjusted in the future based on actual returns experience, known or expected changes in the marketplace, or other factors.

Provider Chargebacks and Discounts. Chargebacks for fees and discounts to healthcare providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to customers who directly purchase the product from the Company. In such cases, customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. The reserve for chargebacks is established in the same period that the related revenue is recognized, resulting in a reduction of product revenue. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by customers, and the Company generally issues credits for such amounts within a few weeks of the customer's notification to the Company of the resale. Chargebacks consist of credits the Company expects to issue for units that remain in the distribution channel at each reporting period end that the Company expects will be sold to qualified healthcare providers and chargebacks that customers have claimed, but for which the Company has not yet issued a credit.

Government Rebates. The Company is subject to discount and/or rebate obligations under state Medicaid programs, Medicare and contractual agreements with and statutory obligations to certain Federal and State entities. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimates of future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel at the end of each reporting period.

Customer discounts are recorded as a reduction of accounts receivable on the consolidated balance sheets. Allowance for product returns, provider chargebacks, government and other rebates and service fees are recorded as a component of accrued expenses and other current liabilities on the consolidated balance sheets.

Cost of Product Sales

Cost of product sales relates to sales of MARGENZA. These costs include material, manufacturing and shipping costs, as well as royalties payable on net sales of MARGENZA and inventory reserves. All product costs incurred prior to FDA

approval of MARGENZA in December 2020 were expensed as research and development expense. The Company expects cost of product sales to continue to be positively impacted as the Company sells through inventory that was expensed prior to FDA approval of MARGENZA. The Company is currently unable to estimate how long it will be until it begins selling product manufactured post FDA approval.

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

Leases

The Company determines whether an arrangement is or contains a lease at the inception of an arrangement under ASC 842, *Leases*. For leases where the Company is the lessee, right-of-use (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.

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,		
	2021	2020	2019
Stock options and RSUs	8,395,421	7,467,603	7,159,494

Recently Adopted Accounting Standards

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

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

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

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* (ASU 2019-12). ASU 2019-12 is part of the FASB’s overall simplification initiative and seeks to simplify the accounting for income taxes by updating certain guidance and removing certain exceptions. The updated guidance is effective for fiscal years beginning after December 15, 2020 and interim periods within those fiscal years. The adoption of this standard as of January 1, 2021 had no impact on the Company's consolidated financial statements and related disclosures.

Accounting Standards Issued But Not Yet Adopted

The Company considers the applicability and impact of all ASUs. ASUs were assessed and determined to be either not applicable or are expected to have minimal impact on the Company's consolidated financial statements.

3. Marketable Securities

Available-for-sale marketable securities as of December 31, 2021 and 2020 were as follows (in thousands):

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 81,184	$ —	$ (52)	$ 81,132
Government-sponsored enterprises	7,739	—	(5)	7,734
Corporate debt securities	31,285	—	(4)	31,281
Total	$ 120,208	$ —	$ (61)	$ 120,147

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

All of the Company's available-for-sale securities held at December 31, 2021 and 2020 had contractual maturities of less than one year. All of the Company's available-for-sale marketable debt securities in an unrealized loss position as of December 31, 2021 and 2020 were in a loss position for less than twelve months. Unrealized losses on available-for-sale debt securities as of December 31, 2021 and 2020 were not significant and were primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. Accordingly, no allowance for credit losses related to the Company's available-for-sale debt securities was recorded for the years ended December 31, 2021 and 2020. The Company does not intend to sell these investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity. The Company recorded interest income of $2.0 million, $0.8 million and $3.4 million during the years ended December 31, 2021, 2020 and 2019, respectively, which is included in other income on the consolidated statements of operations and comprehensive loss.

4. Inventory, Net

All of the Company's inventory relates to the manufacturing of MARGENZA. The following table sets forth the Company's inventory, net of reserves (in thousands):

	December 31, 2021
Work in process	$ 3,929
Finished goods	459
Total inventory, net	$ 4,388

Prior to FDA approval of MARGENZA in December 2020, the cost of materials and expenses associated with the manufacturing of MARGENZA were recorded as research and development expense. Subsequent to FDA approval, the Company began capitalizing inventory costs related to the manufacture of MARGENZA. The inventory balance as of December 31, 2021 is net of a reserve of $2.0 million for unsaleable inventory which is reflected in cost of product sales for the year ended December 31, 2021.

	Inventory Reserves (in thousands)			
	Balance at Beginning of Year	Additions Charged to Expenses	Deductions	Balance at End of Year
Year Ended December 31, 2021	$ —	$ (2,035)	$ —	$ (2,035)

5. Property, Equipment and Software

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

	December 31,	
	2021	2020
Computer equipment	$ 2,890	$ 2,663
Software	9,453	8,242
Furniture and office equipment	713	713
Motor vehicles	50	50
Lab equipment	45,693	41,202
Leasehold improvements	51,056	48,884
Construction in progress	630	2,022
Property, equipment and software	110,485	103,776
Less accumulated depreciation and amortization	(72,809)	(61,551)
Property, equipment and software, net	$ 37,676	$ 42,225

Depreciation and amortization expense related to property, equipment and software for the years ended December 31, 2021, 2020 and 2019 was $11.3 million, $12.0 million and $12.3 million, respectively.

6. Leases

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

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

	December 31,	
	2021	2020
Weighted-average remaining lease term (in years)	5.1	5.9
Weighted-average discount rate	9.7 %	9.7 %

During the years ended December 31, 2021 and 2020, the Company made cash payments for operating leases of $6.7 million and $5.9 million, respectively. As of December 31, 2021 and 2020, the Company's ROU assets were valued at $16.6 million and $19.3 million, respectively, and are included in other non current assets on the consolidated balance sheet.

The components of lease cost for the years ended December 31, 2021 and 2020 were as follows (in thousands):

	December 31,	
	2021	2020
Operating lease cost	$ 5,613	$ 5,410
Variable lease cost	960	1,083
Sublease income	(814)	(770)
Net lease cost	$ 5,759	$ 5,723

As of December 31, 2021, the maturities of the Company's operating lease liabilities were as follows (in thousands):

2022	6,940
2023	6,796
2024	5,856
2025	5,084
2026	4,210
Thereafter	3,554
Total lease payments	32,440
Less: imputed interest	(6,972)
Total lease liabilities	$ 25,468

7. 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 $0.01 per share. There were no shares of undesignated preferred stock issued or outstanding as of December 31, 2021 or 2020.

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

In November 2020, the Company entered into a sales agreement (Sales Agreement) with an agent to sell, from time to time, shares of its common stock having an aggregate sales price of up to $100.0 million through an ATM Offering. The shares that were sold under the Sales Agreement were issued and sold pursuant to the Company's shelf registration statement on Form S-3 that was filed with the SEC on November 4, 2020. During the year ended December 31, 2021, the Company sold 3,622,186 shares of common stock at a weighted average price per share of $27.60, resulting in net proceeds of approximately $98.2 million, net of underwriting discounts and commissions and other offering expenses.

In April 2021, the Company entered into Amendment No. 1 to the Sales Agreement which increases the amount of the Company’s common stock that can be sold by the Company through its agent under the ATM Offering, from an aggregate offering price of up to $100.0 million to an aggregate offering price of up to $300.0 million. During the year ended December 31, 2021, the Company did not sell any shares of common stock related to Amendment No. 1 to the Sales Agreement.

As part of the consideration for the rights granted to Zai Lab US LLC under the collaboration and license agreement described more fully in Note 10, Collaboration and Other Agreements, the Company and Zai Lab US LLC entered into a separate stock purchase agreement (Stock Purchase Agreement). Under this Stock Purchase Agreement, Zai Lab US LLC paid the Company approximately $30.0 million to purchase 958,467 newly issued shares of the Company's common stock, par value $0.01, at a fixed price of $31.30 which represented a $10.4 million premium over the share price on the Stock Purchase Agreement date.

8. 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, 2021,

employees purchased 34,922 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, 2021, under the 2003 Plan, there were options to purchase an aggregate of 187,543 shares of common stock outstanding at a weighted average exercise price of $2.96 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, 2021, the maximum number of shares of common stock authorized to be issued by the Company under the 2013 Plan was increased to 13,856,781. 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, 2021, under the 2013 Plan, there were options to purchase an aggregate of 8,186,378 shares of common stock outstanding at a weighted average exercise price of $21.90 per share.

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

	Year Ended December 31,		
	2021	**2020**	**2019**
Research and development	$ 11,337	$ 10,833	$ 10,023
Selling, general and administrative	11,789	9,843	9,548
Total stock-based compensation expense	$ 23,126	$ 20,676	$ 19,571

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,		
	2021	**2020**	**2019**
Expected dividend yield	0%	0%	0%
Expected volatility	86.2% -87.4%	67.3% - 109%	74% - 76%
Risk-free interest rate	0.64% - 1.55%	0.4% - 1.8%	1.4% - 2.6%
Expected term	6.25 years	6.25 years	6.25 years

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

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

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

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

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

The following table summarizes stock option activity for 2021:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2020	7,258,353	$ 21.48	6.8	
Granted	1,941,671	20.83		
Exercised	(332,767)	17.55		
Forfeited or expired	(493,336)	21.05		
Outstanding, December 31, 2021	8,373,921	$ 21.47	6.6	$ 7,841
As of December 31, 2021:				
Exercisable	5,546,382	$ 22.61	5.6	$ 4,764
Vested and expected to vest	8,010,695	$ 21.58	6.5	$ 7,468

During 2021, 2020 and 2019 the Company issued 332,767, 504,445 and 219,045 net shares of common stock, respectively, in conjunction with stock option exercises. The Company received cash proceeds from the exercise of stock options of approximately $5.8 million, $5.3 million and $0.7 million during 2021, 2020 and 2019, respectively.

The weighted-average grant-date fair value of options granted during 2021, 2020 and 2019 was $15.20, $10.68 and $13.98 per share, respectively. The total intrinsic value of options exercised during 2021, 2020 and 2019 was approximately $3.3 million, $4.3 million and $2.9 million, respectively. The total fair value of stock options which vested during 2021, 2020 and 2019 was $20.2 million, $16.7 million and $17.7 million, respectively. As of December 31, 2021, the total unrecognized compensation expense related to non-vested stock options, net of related forfeiture estimates, was $31.1 million, which the Company expects to recognize over a weighted-average period of approximately 2.5 years.

Restricted Stock Units

During 2019, the Company awarded RSUs under the 2013 Plan to all employees with at least six months of service as of the date of grant except executive officers. Each RSU entitled the holder to receive one share of the Company's common stock when the RSU vested. The RSUs vested in two equal installments on the first and second anniversary of the grant date and have all vested as of December 31, 2021. The Company also grants RSUs to employees from time to time as a component of their compensation. Compensation expense related to RSUs is recognized on a straight-line basis.

The following table summarizes RSU activity for 2021:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding, December 31, 2020	209,250	$ 15.92
Granted	16,500	26.27
Vested	(184,100)	15.66
Forfeited or expired	(20,150)	16.04
Outstanding, December 31, 2021	21,500	$ 25.97

At December 31, 2021, there was $0.4 million of total unrecognized compensation cost related to unvested RSUs, which the Company expects to recognize over a remaining weighted-average period of 2.3 years.

9. Income Taxes

For the years ended December 31, 2021, 2020 and 2019 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,	
	2021	2020
Deferred income tax assets:		
Federal U.S. net operating loss carryforward	$ 175,802	$ 136,086
State net operating loss carryforward	49,965	37,465
Research and development credit, net	60,514	50,271
Orphan drug credit, net	24,858	23,409
Operating lease liabilities	7,008	8,048
Deferred revenue	1,245	3,132
Other	16,727	14,285
Gross deferred income tax assets	336,119	272,696
Valuation allowance	(327,595)	(263,403)
Net deferred income tax assets	8,524	9,293
Deferred income tax liabilities:		
Depreciation	(1,688)	(2,123)
Operating lease ROU assets	(4,576)	(5,316)
Prepaid expenditures	(2,260)	(1,854)
Gross deferred income tax liabilities	(8,524)	(9,293)
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, 2021, the Company has U.S. federal and state net operating loss (NOL) carryforwards of approximately $837.0 million. Of these NOLs, $238.0 million will expire in various years beginning in 2025 through 2037. $599.0 million of NOLs were generated post December 31, 2017 and carryforward indefinitely. In addition, the Company has U.S. federal tax credits of $81.0 million which will expire in various years beginning in 2022 through 2041.

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, 2021, $13.5 million of the Company's U.S. Federal NOLs are limited for use over the years 2022 – 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 $824.0 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,		
	2021	2020	2019
United States federal tax at statutory rate	$ (42,445)	$ (27,245)	$ (31,880)
State taxes (net of federal benefit)	(12,806)	(8,100)	(9,524)
Deferred income tax adjustments	473	344	2,004
Research credit, net	(10,243)	(14,691)	(5,830)
Orphan drug credit, net	(1,449)	(528)	(301)
Other permanent items	1,199	1,156	1,206
Equity-based compensation	1,079	554	1,889
Change in valuation allowance	64,192	48,510	42,436
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,		
	2021	2020	2019
Beginning balance	$ 6,126	$ 4,950	$ 4,318
Increases for current year tax positions	965	839	637
Increases/(decreases) for prior year tax positions	106	337	(5)
Ending balance	$ 7,197	$ 6,126	$ 4,950

As of December 31, 2021 and 2020, of the total gross unrecognized tax benefits, approximately $7.2 million and $6.1 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, 2021, 2020 and 2019, 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 2002 forward remain open to examination due to the carryover of unused income tax credits, and from 2004 forward due to the carryover of unused net operating losses.

10. Collaboration and Other Agreements

Incyte

Incyte License Agreement

In 2017, the Company entered into an exclusive global collaboration and license agreement with Incyte for retifanlimab, an investigational monoclonal antibody that inhibits programmed cell death protein 1 (PD-1) (Incyte License Agreement). Incyte has obtained exclusive worldwide rights for the development and commercialization of retifanlimab in all indications, while the Company retains the right to develop its pipeline assets in combination with retifanlimab. Under the terms of the Incyte License Agreement, Incyte paid the Company an upfront payment of $150.0 million in 2017. In July 2021, Incyte announced that the FDA had issued a Complete Response Letter (CRL) regarding its Biologics License Application (BLA) for retifanlimab as a potential treatment for adult patients with locally advanced or metastatic squamous cell carcinoma of the anal canal. Incyte’s announcement indicated that the FDA determined that additional data are needed to demonstrate the clinical benefit of retifanlimab for the submitted indication, and that Incyte was reviewing the CRL and would discuss next steps with the FDA. Incyte subsequently withdrew its European application for marketing authorization of retifanlimab for the treatment of squamous carcinoma of the anal canal. Incyte has stated it is pursuing development of retifanlimab in potentially registration-enabling studies beyond squamous cell carcinoma of the anal canal, including in patients with MSI-high endometrial cancer,

Merkel cell carcinoma and non-small cell lung cancer. Incyte is also pursuing development of retifanlimab in combination with multiple product candidates from its pipeline.

Under the terms of the Incyte License Agreement, Incyte will lead global development of retifanlimab. Assuming successful development and commercialization by Incyte, the Company could receive up to approximately $420.0 million in development and regulatory milestones, and up to $330.0 million in commercial milestones. From the inception of the Incyte License Agreement through December 31, 2021, the Company has recognized $70.0 million in development milestones under Incyte License Agreement. If retifanlimab is approved and commercialized, the Company would be eligible to receive tiered royalties of 15% to 24% on any global net sales. The Company retains the right to develop its pipeline assets in combination with retifanlimab, with Incyte commercializing retifanlimab and the Company commercializing its asset(s), if any such potential combinations are approved. In addition, the Company retains the right to manufacture a portion of both companies' global commercial supply needs of retifanlimab, subject to the separate commercial supply agreement.

The Company evaluated the Incyte License Agreement under the provisions of ASC 606 and identified the following two performance obligations under the agreement: (i) the license of retifanlimab and (ii) the performance of certain clinical activities through a brief technology transfer period. The Company determined that the license and clinical activities are separate performance obligations because they are capable of being distinct, and are distinct in the context of the contract. The license has standalone functionality as it is sublicensable, Incyte has significant capabilities in performing clinical trials, and Incyte is capable of performing these activities without the Company's involvement; the Company performed the activities during the transfer period as a matter of convenience. The Company determined that the transaction price of the Incyte License 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. From 2018 through December 31, 2021, it became probable that a significant reversal of cumulative revenue would not occur for development milestones totaling $70.0 million related to clinical and regulatory activities related to the further advancement of retifanlimab, including Incyte's initiation of a Phase 3 clinical trial. Therefore the associated consideration was added to the estimated transaction price and was recognized as revenue.

The Company recognized the $150.0 million allocated to the license when it satisfied its performance obligation and transferred the license to Incyte in 2017. The $4.0 million allocated to the clinical activities was recognized ratably as services were performed during 2017 and 2018. The Company recognized revenue of $15.0 million, $40.0 million and $0.1 million under the Incyte Agreement during the years ended December 31, 2021, 2020 and 2019, respectively. All of the revenue recognized during the years ended December 31, 2021 and 2020 was related to development milestones.

Incyte Clinical Supply Agreement

In 2018, the Company entered into an agreement with Incyte under which the Company is to perform development and manufacturing services for Incyte's clinical needs of retifanlimab (Incyte Clinical Supply Agreement). The Company evaluated this agreement under ASC 606 and identified one performance obligation under the agreement: to perform services related to the development and manufacturing of the clinical supply of retifanlimab. The transaction price is based on the costs incurred to develop and manufacture drug product and drug substance, and is recognized over time as the services are provided, as the performance by the Company does not create an asset with an alternative use and the Company has an enforceable right to payment for the performance completed to date. The transaction price is being recognized using the input method reflecting the costs incurred (including resources consumed and labor hours expended) related to the manufacturing services. During the years ended December 31, 2021, 2020 and 2019, the Company recognized revenue of $1.5 million, $8.6 million and $22.1 million, respectively, for services performed under this agreement.

Incyte Commercial Supply Agreement

In 2020, the Company entered into an agreement with Incyte pursuant to which the Company is entitled to manufacture a portion of the global commercial supply needs for retifanlimab (Incyte Commercial Supply Agreement). Unless

terminated earlier, the term of the Incyte Commercial Supply Agreement will expire upon the expiration of Incyte's obligation to pay royalties under the Incyte License Agreement. The Company evaluated this agreement under ASC 606 and identified one performance obligation under the agreement: to perform services related to manufacturing the commercial supply of retifanlimab. The transaction price is based on a fixed price per batch of bulk drug substance to be manufactured and is recognized over time as the services are provided, as the performance by the Company does not create an asset with an alternative use and the Company has an enforceable right to payment for the performance completed to date. The transaction price is being recognized using the input method reflecting the costs incurred (including resources consumed and labor costs incurred) related to the manufacturing services. During the years ended December 31, 2021 and 2020, the Company recognized revenue of $7.8 million and $1.4 million, respectively, for services performed under this agreement.

Zai Lab Limited

2018 Zai Lab Agreement

In 2018, the Company entered into a collaboration and license agreement with Zai Lab Limited (Zai Lab) under which Zai Lab obtained regional development and commercialization rights in mainland China, Hong Kong, Macau and Taiwan (Zai Lab's territory) for (i) margetuximab, an immune-optimized anti-HER2 monoclonal antibody, (ii) tebotelimab, 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 (2018 Zai Lab Agreement). Zai Lab will lead clinical development of these molecules in its territory.

Under the terms of the 2018 Zai Lab Agreement, Zai Lab paid the Company an upfront payment of $25.0 million ($22.5 million after netting value-added tax withholdings of $2.5 million). Assuming successful development and commercialization of margetuximab, tebotelimab and the TRIDENT molecule, the Company could receive up to $140.0 million in development and regulatory milestones, $4.0 million of which ($3.6 million after netting value-added tax withholdings of $0.4 million) was earned during the year ended December 31, 2020. Subsequent to December 31, 2021, the Company earned $5.0 million upon Zai Lab's achievement of a regulatory milestone. In addition, Zai Lab would pay the Company tiered royalties at percentage rates of mid-teens to 20% for net sales of margetuximab in Zai Lab's territory, mid-teens for net sales of tebotelimab in Zai Lab's territory and 10% for net sales of the TRIDENT molecule in Zai Lab's territory, which may be subject to adjustment in specified circumstances.

The Company evaluated the 2018 Zai Lab Agreement under the provisions of ASC 606 and identified the following material promises under the arrangement for each of the two product candidates, margetuximab and tebotelimab: (i) an exclusive license to develop and commercialize the product candidate in Zai Lab's territory and (ii) certain research and development activities. The Company determined that each license and the related research and development activities were not distinct from one another, as the license has limited value without the performance of the research and development activities. As such, the Company determined that these promises should be combined into a single performance obligation for each product candidate. Activities related to margetuximab and tebotelimab are separate performance obligations from each other because they are capable of being distinct, and are distinct in the context of the contract. The Company evaluated the promises related to the TRIDENT molecule and determined they were immaterial in context of the contract, therefore there is no performance obligation related to that molecule. The Company determined that the net $22.5 million upfront payment from Zai Lab constituted the entirety of the consideration to be included in the transaction price as of the outset of the arrangement, and the transaction price was allocated to the two performance obligations based on their relative standalone selling price. The standalone selling price of the performance obligations was determined using the adjusted market assessment approach considering similar collaboration and license agreements. The potential development and regulatory milestone payments are fully constrained until the Company concludes that achievement of the milestone is probable, and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price. Any consideration related to royalties will be recognized if and when the related sales occur, as they were determined to relate predominantly to the license granted to Zai Lab and, therefore, have also been excluded from the transaction price. The Company re-assesses the transaction price in each reporting period and when events whose outcomes are resolved or other changes in circumstances occur.

Due to the relatively short-term nature of the recognition period, the revenue associated with the tebotelimab performance obligation was recognized on a straight-line basis as the Company performed research and development activities under the agreement. The fixed consideration related to the margetuximab performance obligation was also recognized on a straight-line basis as the Company performed research and development activities under the agreement due to the short-term nature of the recognition period. Straight-line recognition is materially consistent with the pattern of performance of the research and development activities of each product candidate. The variable consideration related to the margetuximab performance obligation was recognized upon certain regulatory achievements during 2020. During the year ended

December 31, 2020, the Company recognized revenue of $8.6 million related to the 2018 Zai Lab Agreement. No revenue was recognized under the 2018 Zai Lab Agreement during the year ended December 31, 2021.

Zai Lab Clinical Supply Agreements

During 2019, the Company entered into two agreements under which the Company is to perform manufacturing services for Zai Lab's clinical needs of margetuximab and tebotelimab (Zai Lab Clinical Supply Agreements). The Company evaluated the agreements under ASC 606 and determined that they should be accounted for as a single contract and identified two performance obligations within the contract: to perform services related to manufacturing the clinical supply of each of margetuximab and tebotelimab. The transaction price is based on the costs incurred to manufacture drug product and drug substance, and is recognized over time as the services are provided, as the performance by the Company does not create an asset with an alternative use and the Company has an enforceable right to payment for the performance completed to date. The transaction price is being recognized using the input method reflecting the costs incurred (including resources consumed and labor hours expended) related to the manufacturing service. During the years ended December 31, 2021 and 2020, the Company recognized revenue of $2.8 million and $2.7 million, respectively, related to the Zai Lab Clinical Supply Agreements.

2021 Zai Lab Agreement

In June 2021, the Company entered into a collaboration and license agreement with Zai Lab US LLC (collectively with Zai Lab Limited referred herein as Zai Lab) involving collaboration programs and license-only programs (collectively, the Programs) encompassing four separate immuno-oncology molecules (2021 Zai Lab Agreement). The first program covers a lead research molecule that incorporates the Company's DART platform and binds CD3 and an undisclosed target that is expressed in multiple solid tumors (Lead Program). The second program covers a target to be designated by the Company. For these programs, Zai Lab receives commercial rights in Greater China, Japan, and Korea while the Company receives commercial rights in all other territories. Under the Lead Program, Zai Lab received an option upon reaching a predefined clinical milestone to convert the regional arrangement into a global 50/50 profit share. If Zai Lab elects such option, Zai Lab is to pay the Company $85.0 million plus any research costs incurred by both parties as of the option election date. Zai Lab also obtained exclusive, global licenses from the Company to develop, manufacture and commercialize two additional molecules. Zai Lab granted the Company a worldwide, royalty-free, co-exclusive license to conduct the development activities allocated to the Company.

Under the terms of the 2021 Zai Lab Agreement, the Lead Program includes joint research and development services by both the Company and Zai Lab. For the other programs, Zai Lab can separately negotiate and agree with the Company to perform research and development services in the future.

In connection with the execution of the 2021 Zai Lab Agreement, Zai Lab paid the Company an upfront payment of $25.0 million. Additionally, as part of the consideration for the rights granted to Zai Lab under the 2021 Zai Lab Agreement, the Company and Zai Lab entered into the Stock Purchase Agreement whereby Zai Lab paid the Company approximately $30.0 million to purchase shares of the Company's common stock at a fixed price of $31.30 which represented a $10.4 million premium over the share price on the Stock Purchase Agreement date.

Assuming successful development and commercialization of the Programs, the Company could receive up to approximately $800.0 million in development and regulatory milestones and $600.0 million in commercial milestones. In addition, Zai Lab would pay the Company tiered royalties at percentage rates of low double digit teens on annual net sales of certain specified products and of mid-single digits to low double digit teens on annual net sales of other specified products in Zai Lab's territory, which may be subject to specified royalty reduction pursuant to the 2021 Zai Lab Agreement. Per the terms of the 2021 Zai Lab Agreement, the Company may also receive reimbursements from Zai Lab for certain research and development costs incurred by the Company.

The Company evaluated the 2021 Zai Lab Agreement under the provisions of ASC 606 and identified the following material promises: (i) exclusive licenses to develop, manufacture and commercialize the products in Zai Lab's territory for each Program and (ii) certain research and development activities for the Lead Program. The Company determined that for the Lead Program, the license is not distinct from the related research and development activities, considering the early stage of development of the molecule and the Company's significant expertise in this area and as such, the research and development services are expected to significantly modify and customize the license. Therefore, for the Lead Program, the license and the services were combined into a single performance obligation. Since the other programs each represent distinct intellectual property and there are no other services included in the 2021 Zai Lab Agreement related to these licenses, each license is considered to be a distinct performance obligation. As such, there are four performance obligations included in the 2021 Zai Lab Agreement.

The Company concluded that the estimated transaction price is $40.4 million, consisting of the $25.0 million upfront payment, the $10.4 million premium related to the purchase of the Company's common stock, and the $5.0 million estimated reimbursement by Zai Lab for research and development activities for the Lead Program. The potential milestone payments were deemed to be 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 will re-assess the transaction price in each reporting period and when events whose outcomes are resolved or other changes in circumstances occur.

The transaction price of $40.4 million was then allocated to the four performance obligations based on their relative standalone selling price. The standalone selling price of the performance obligations was not directly observable; therefore, the Company estimated the standalone selling price using an adjusted market assessment approach, representing the amount that the Company believes a market participant is willing to pay for the product or service. The estimate was based on consideration of observable inputs, such as, values of other preclinical collaboration arrangements adjusted for the Company's estimate of the probability of success for each Program.

Revenue related to the Lead Program license and related research and development services performance obligation is being recognized over time as the research and development activities are performed. The Company will utilize 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. The Company recognized revenue allocated to the other programs at a point in time upon transfer of the licenses to Zai Lab in June 2021. During the year ended December 31, 2021, the Company recognized revenue of $20.3 million under the 2021 Zai Lab Agreement. As of December 31, 2021, there was $16.1 million in deferred revenue under the agreements, all of which is current.

Janssen Biotech, Inc.

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

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

The Company recognized the $20.0 million allocated to the license when it satisfied its performance obligation and transferred the license to Janssen in December 2020. The $2.2 million allocated to the research and development activities is being recognized over the Company's involvement in the research term, which is estimated to be less than two years. During the year ended December 31, 2021, the Company recognized revenue of $1.5 million for research and development activities performed under the Janssen Agreement.

I-Mab Biopharma

I-Mab License Agreement

In 2019, the Company entered into a collaboration and license agreement with I-Mab Biopharma (I-Mab) to develop and commercialize enoblituzumab, an immune-optimized, anti-B7-H3 monoclonal antibody that incorporates the Company's proprietary Fc Optimization technology platform (I-Mab License 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 License 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, of which $5.0 million has been earned from the inception of the I-Mab License Agreement through December 31, 2021. In addition, I-Mab would pay the Company tiered royalties ranging from mid-teens to 20% on annual net sales in I-Mab's territory.

The Company evaluated the I-Mab License Agreement under the provisions of ASC 606 and identified the following material promises under the arrangement: (i) an exclusive license to develop and commercialize enoblituzumab in I-Mab's territories, (ii) perform certain research and development activities and (iii) conduct a chronic toxicology study. The Company determined that the license and the related research and development activities were not distinct from one another, as the license has limited value without the performance of the research and development activities. As such, the Company determined that the license and related research and development activities should be combined into a single performance obligation. The Company determined that the $15.0 million upfront payment from I-Mab constituted the entirety of the consideration to be included in the transaction price as of the outset of the arrangement for the license and related research and development activities. The Company has also determined that the chronic toxicology study is distinct from the other promises and has estimated the variable consideration of that performance obligation to be approximately $1.0 million. I-Mab paid the Company for the cost of this study as the costs were incurred during 2019 and 2020, and I-Mab received a one-time credit of eighty percent of the total amount of such costs against the milestone achieved during 2021. The Company reassessed the transaction price as it became probable that a significant reversal of cumulative revenue would not occur for a $5.0 million milestone ($4.5 million after netting a one-time credit as described above) related to development progress of enoblituzumab, therefore the associated consideration was added to the estimated transaction price and was recognized as revenue. 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 License Agreement is being recognized using a cost-based input method according to costs incurred to date compared to estimated total costs. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligations. During the years ended December 31, 2021 and 2020, the Company recognized revenue of $11.5 million and $2.2 million, respectively, related to the I-Mab License Agreement. At December 31, 2021, $4.5 million in revenue was deferred under the I-Mab License Agreement, all of which was current. At December 31, 2020, $11.4 million in revenue was deferred under the I-Mab License Agreement, $4.5 million of which was current and $6.9 million of which was non-current.

I-Mab Clinical Supply Agreement

In October 2021, the Company entered into an agreement under which the Company is to perform development and manufacturing services for I-Mab's clinical needs of enoblituzumab (I-Mab 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 enoblituzumab. The transaction price is based on the costs incurred to develop and manufacture drug product and drug substance, and is recognized over time as the services are provided, as the performance by the Company does not create an asset with an alternative use and the Company has an enforceable right to payment for the performance completed to date. The transaction price will be recognized using the input

method reflecting the costs incurred (including resources consumed and labor hours expended) related to the manufacturing services. During the year ended December 31, 2021, the Company recognized revenue of $1.3 million for research and development activities performed under the I-Mab Clinical Supply Agreement.

Provention Bio, Inc.

In 2018, the Company entered into a license agreement with Provention Bio, Inc. (Provention) pursuant to which the Company granted Provention exclusive global rights for the purpose of developing and commercializing MGD010 (renamed PRV-3279), a CD32B x CD79B DART molecule being developed for the treatment of autoimmune indications (Provention License Agreement). As partial consideration for the Provention License Agreement, Provention granted the Company a warrant to purchase shares of Provention's common stock at an exercise price of $2.50 per share. If Provention successfully develops, obtains regulatory approval for, and commercializes PRV-3279, the Company will be eligible to receive up to $65.0 million in development and regulatory milestones and up to $225.0 million in commercial milestones. As of December 31, 2021, the Company has not recognized any milestone revenue under this agreement. If commercialized, the Company would be eligible to receive single-digit royalties on net sales of the product. The license agreement may be terminated by either party upon a material breach or bankruptcy of the other party, by Provention without cause upon prior notice to the Company, and by the Company in the event that Provention challenges the validity of any licensed patent under the agreement, but only with respect to the challenged patent.

Also, in 2018, the Company entered into an asset purchase agreement with Provention pursuant to which Provention acquired the Company's interest in teplizumab (renamed PRV-031), a monoclonal antibody being developed for the treatment of type 1 diabetes (Asset Purchase Agreement). As partial consideration for the Asset Purchase Agreement, Provention granted the Company a warrant to purchase shares of Provention's common stock at an exercise price of $2.50 per share. If Provention successfully develops, obtains regulatory approval for, and commercializes PRV-031, the Company will be eligible to receive up to $170.0 million in regulatory milestones and up to $225.0 million in commercial milestones. As of December 31, 2021, the Company has not recognized any milestone revenue under this agreement. If commercialized, the Company would be eligible to receive single-digit royalties on net sales of the product. Provention has also agreed to pay third-party obligations, including low single-digit royalties, a portion of which is creditable against royalties payable to the Company, aggregate milestone payments of up to approximately $1.3 million and other consideration, for certain third-party intellectual property under agreements Provention is assuming pursuant to the Asset Purchase Agreement. Further, Provention is required to pay the Company a low double-digit percentage of certain consideration to the extent it is received in connection with a future grant of rights to PRV-031 by Provention to a third party.

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

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

Boehringer Ingelheim International GmbH

In 2010, the Company entered into a collaboration and license agreement with Boehringer Ingelheim International GmbH (BII) to discover, develop and commercialize multiple DART molecules that were to be evaluated during a five-year period that ended in 2015 (Boehringer Agreement). Under the terms of the agreement, the Company granted BII an exclusive, worldwide, royalty-bearing, license under its intellectual property to research, develop, and market DART molecules generated

under the agreement. During the evaluation period, BII selected two product candidates to develop (BII DARTs). Under the terms of the Boehringer Agreement, BII paid the Company an upfront payment of $15.0 million which was fully recognized prior to December 31, 2015. The variable consideration under this agreement included potential future development and sales milestones and royalties on net sales in the event that the BII DARTs are commercialized.

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

NIAID Contract

The Company entered into a contract with NIAID, effective as of September 15, 2015, to perform product development and to advance up to two DART molecules, including MGD014 (NIAID Contract). Under the NIAID 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.

Since the inception of the NIAID Contract, NIAID has exercised the two options contemplated in the original contract and executed modifications such that the total funded contract value as of December 31, 2021 is $25.1 million. In addition, the most recent modification changed the period of performance under the NIAID Contract to end in July 2023. The Company recognized revenue of $1.8 million, $7.1 million and $2.2 million under the NIAID contract during the years ended December 31, 2021, 2020 and 2019, respectively.

11. 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 (District Court) by Todd Hill naming the Company, its Chief Executive Officer, Dr. Koenig, and its Chief Financial Officer, Mr. Karrels, as defendants for allegedly making false and materially misleading statements regarding the Company’s SOPHIA trial. On August 17, 2020, the Employees’ Retirement System of the City of Baton Rouge and Parish of East Baton Rouge was appointed as Lead Plaintiff, and on October 16, 2020, the Lead Plaintiff filed an amended complaint. The amended complaint asserts a putative class period stemming from February 6, 2019 to June 4, 2019. The Company filed a Motion to Dismiss on November 30, 2020. On September 29, 2021, the District Court issued an Order dismissing the case, with prejudice. On October 28, 2021 the Lead Plaintiff filed a Notice of Appeal, and on January 18, 2022, the Lead Plaintiff filed its opening brief. The appeal is now pending in the Fourth Circuit. 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.

12. 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 $1.6 million for the year ended December 31, 2021 and $1.4 million for each of the years ended December 31, 2020 and December 31, 2019.

13. Subsequent Event

In January 2022, the Company entered into an agreement with Incyte under which Incyte reserved capacity at one of the Company’s GMP manufacturing facilities where the Company will manufacture certain bulk drug substance for Incyte. This agreement is unrelated to the Incyte agreements described in Note 10, Collaboration and Other Agreements. Under the terms of the agreement, Incyte will pay the Company an upfront fee of $10.0 million.

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 3.1 to the Company's Current Report on Form 8-K (File No. 001-36112) filed on April 2, 2021)
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 (incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K filed on February 25, 2021)
4.3†	Investor Agreement by and between Johnson and Johnson Innovation-JJDC, Inc. and the Company, dated December 19, 2014 (incorporated by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K filed on March 3, 2015)
10.1	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
10.2†	Global Collaboration and License Agreement by and between the Company and Incyte Corporation, dated October 24, 2017 (incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K filed on February 27, 2018)
10.3+	Company 2003 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
10.4+	Form of Incentive Stock Option Agreement under 2003 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on September 4, 2013)
10.5+	Company 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
10.6+	Form of Incentive Stock Option Agreement under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
10.7+	Form of Nonstatutory Stock Option Agreement under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
10.8+	Form of Restricted Stock Units Grant Notice under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 6, 2015)
10.9+	2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-8 (File No. 333-214386) filed by the Company on November 2, 2016)
10.10+	Employment Agreement between the Company and Scott Koenig, M.D., Ph.D. (incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K filed by the Company on February 29, 2016)
10.11+	Employment Agreement between the Company and James Karrels (incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K filed by the Company on February 29, 2016)
10.12+	Employment Agreement between the Company and Ezio Bonvini, M.D. (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on May 4, 2016)
10.13+	Employment Agreement between the Company and Eric Risser (incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K filed on February 28, 2017)
10.14+	Employment Agreement between the Company and Stephen Eck, M.D. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on April 29, 2021)
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)

10.16#	Commercial Supply Agreement by and between Incyte Corporation and the Company, dated October 13, 2020 (incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K filed on February 25, 2021)
10.17#	Product Commercialization Agreement by and between the Company and Eversana Life Science Services, LLC, dated November 13, 2020 (incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K filed on February 25, 2021)
10.18#	Collaboration and License Agreement by and between the Company and Zai Lab US LLC, dated June 15, 2021 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on July 29, 2021)
10.19	Stock Purchase Agreement by and between the Company and Zai Lab Limited, dated June 14, 2021 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on July 29, 2021)
23.1*	Consent of Ernst & Young, LLP, Independent Registered Public Accounting Firm
31.1*	Rule 13a-14(a) Certification of Principal Executive Officer
31.2*	Rule 13a-14(a) Certification of Principal Financial Officer
32.1**	Section 1350 Certification of Principal Executive Officer
32.2**	Section 1350 Certification of Principal Financial Officer
101.INS	XBRL Instance Document
101.SCH	XBRL Schema Document
101.CAL	XBRL Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Labels Linkbase Document
101.PRE	XBRL Presentation Linkbase Document
104	Cover Page Interactive Data (formatted as Inline XBRL and contained in Exhibit 101 filed herewith)

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment granted by the SEC.

Portions of this document (indicated by "[***]" have been omitted because they are not material and are the type that MacroGenics, Inc. treats as private and confidential.

+ Indicates management contract or compensatory plan.

* Filed herewith.

** Furnished herewith.

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, Form S-8 No. 333-230292, Form S-8 No. 333-237127, and Form S-8 No. 333-253502) 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., and
4. Registration Statement (Form S-3 No. 333-249851) of MacroGenics, Inc.;

of our reports dated February 24, 2022, 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, 2021.

/s/ Ernst & Young LLP

Tysons, Virginia
February 24, 2022

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, 2021 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 24, 2022

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, 2021 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 24, 2022

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, 2021 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 24, 2022

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, 2021 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 24, 2022