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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

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

For the transition period from _____to _____

Commission file number: 0-32405

SEAGEN INC.

(Exact name of registrant as specified in its charter)

Delaware	**91-1874389**
(State or other Jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

21823 30th Drive SE, Bothell, WA 98021
(Address of principal executive offices, including zip code)
Registrant's telephone number, including area code: **(425) 527-4000**

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

Title of class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001	SGEN	The Nasdaq Stock Market LLC

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T 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	☐	Emerging growth company	☐
Non-accelerated filer	☐	Smaller reporting 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 voting and non-voting common equity held by non-affiliates of the registrant was approximately $21.1 billion as of the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing sale price on The Nasdaq Global Select Market reported for such date. Excludes an aggregate of 49,451,384 shares of the registrant's Common Stock held as of such date by officers, directors and stockholders that the registrant has concluded are or were affiliates of the registrant. Exclusion of such shares should not be construed to indicate that the holder of any such shares possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

There were 181,164,446 shares of the registrant's Common Stock issued and outstanding as of February 9, 2021.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference from the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in connection with the registrant's 2021 Annual Meeting of Stockholders.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains 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 are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "should," "could", "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements, except as required by law. Any or all of our forward-looking statements in this document may turn out to be incorrect. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading "Item 1A—Risk Factors." We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

RISK FACTOR SUMMARY

Investing in our securities involves a high degree of risk. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found under the heading "Item 1A—Risk Factors", below.

- Our success depends on our ability to effectively commercialize our products. If we and our collaborators are unable to effectively commercialize our products and to expand their utilization, our ability to generate significant revenue and our prospects for profitability will be adversely affected.
- Our success also depends on our ability to obtain regulatory approvals for our product candidates and for our current products in additional territories, as well as our ability to expand the labeled indications of use for our current products, and, if the requisite approvals are obtained, our ability to successfully launch and commercialize our products in their approved indications. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- Reports of adverse events or safety concerns involving our products or product candidates could delay or prevent us from obtaining or maintaining regulatory approvals or could negatively impact sales of our products or the prospects for our product candidates.
- Clinical trials are expensive and time consuming, may take longer than we expect or may not be completed at all, and their outcome is uncertain.
- The successful commercialization of our products and our product candidates will depend on a variety of factors, including the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies, and the acceptance of our products by the medical community and patients.
- Our product candidates are in various stages of development, and it is possible that none of our product candidates will ever become commercial products.
- Any failures or setbacks in our antibody-drug conjugate, or ADC, development program or our other platform technologies could negatively affect our business and financial position.
- We face intense competition and rapid technological change, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

- 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.
- Healthcare law and policy changes may have a material adverse effect on us.
- We are subject to various state and federal and foreign laws and regulations, including healthcare, data protection and privacy laws and regulations, that may impact our business and could subject us to significant fines and penalties or other negative consequences.
- We depend on collaborative relationships with other companies to assist in the development and commercialization of our products and some of our product candidates and for the development and commercialization of other product candidates utilizing or incorporating our technologies. If we are not able to locate suitable collaborators or if our collaborators do not perform as expected, this may negatively affect our ability to commercialize our products, develop and commercialize our product candidates and/or generate revenues through technology licensing, or may otherwise negatively affect our business.
- We currently rely on third-party manufacturers and other third parties for production of our drug products and our dependence on these manufacturers may impair the continued development and commercialization of our products and product candidates.
- If we are unable to enforce our intellectual property rights or if we fail to sustain and further procure additional intellectual property rights, we may not be able to successfully commercialize our products or any future products and competitors may be able to develop competing therapies.
- We have been and may in the future be subject to litigation, which could result in substantial damages and may divert management's time and attention from our business.
- We and our collaborators rely on license agreements for certain aspects of our products and product candidates and technologies such as our ADC technology. Failure to maintain these license agreements or to secure any required new licenses could prevent us from continuing to develop and commercialize our products and product candidates.
- If we are unable to manage our growth, our business, financial condition, results of operations and prospects may be adversely affected.
- Risks associated with our expanding operations in foreign countries could materially adversely affect our business.
- Our operating results are difficult to predict and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.
- We have a history of net losses. We expect to continue to incur net losses and may not achieve future sustained profitability for some time, if at all.
- Our stock price is volatile and our shares may suffer a decline in value.
- Our existing stockholders have significant control of our management and affairs.

PART I

Item 1. Business

Overview

Seagen is a biotechnology company that develops and commercializes targeted therapies to treat cancer. We are commercializing ADCETRIS®, or brentuximab vedotin, for the treatment of certain CD30-expressing lymphomas, PADCEV®, or enfortumab vedotin-ejfv, for the treatment of certain metastatic urothelial cancers, and TUKYSA®, or tucatinib, for treatment of certain metastatic HER2-positive breast cancers. We are also advancing a pipeline of novel therapies for solid tumors and blood-related cancers designed to address unmet medical needs and improve treatment outcomes for patients. Many of our programs, including ADCETRIS and PADCEV, are based on our antibody-drug conjugate, or ADC, technology that utilizes the targeting ability of monoclonal antibodies to deliver cell-killing agents directly to cancer cells. In October 2020, we changed our corporate name from Seattle Genetics, Inc. to Seagen Inc., reflecting the global expansion of our operations.

Our strategy is to become a leading global oncology company developing and marketing targeted therapies for cancer. Key elements of our strategy are to maximize the potential of our approved medicines through successful commercial execution, expand the number of patients eligible to receive our medicines by securing approvals of our commercial products in other countries, conduct clinical trials designed to support additional labels for our products, and develop new first-in-class or best-in-class medicines. We seek to commercialize our products either on our own as we expand our operations globally or through commercial partnerships. We are deploying our internal research, clinical, development, regulatory and manufacturing expertise to advance and expand our deep pipeline of drug candidates aimed at gaining new product approvals. We conduct internal research directed at identifying novel antigen targets, monoclonal antibodies and other targeting molecules, creating new antibody engineering techniques and developing new classes of stable linkers and cell-killing agents in support of our continued ADC innovation. In addition, we supplement these internal efforts by acquiring or in-licensing products, product candidates and technologies from biotechnology and pharmaceutical companies and academic institutions.

COVID-19

We are continuing to closely monitor the impact of the evolving effects of the COVID-19 pandemic on our business and are taking proactive efforts designed to protect the health and safety of our workforce, patients and healthcare professionals, and to continue our business operations and advance our goal of bringing important medicines to patients as rapidly as possible.

We continue to maintain measures designed to protect the health and safety of our workforce and to reduce the transmission of COVID-19, including a mandatory work-from-home policy for employees who can perform their jobs offsite. We are continuing essential research, manufacturing, and laboratory activities on site and maintain a number of additional precautionary measures designed to protect these onsite employees, such as temperature checks, screening protocols, masks, social distancing, contact tracing and making testing available. In the conduct of our business activities, we are also taking actions designed to protect the safety of patients and healthcare professionals. Among other actions, our field-based personnel have paused most in-person customer interactions in healthcare settings and have been using primarily electronic communications to support healthcare professionals and patients. They are engaging in limited in-person interactions where state and local laws and regulations allow, the institution or office is accepting in-person interactions and our field-based personnel are comfortable engaging in-person with healthcare providers. See also "—Human Capital Resources—COVID-19" below. We believe that the measures we have implemented are appropriate and are helping to reduce transmission of COVID-19, and we will continue to monitor conditions and related guidance from governmental authorities and adjust our activities as appropriate. For information regarding the impacts of the evolving effects of the COVID-19 pandemic on our ability and the ability of our collaborators to effectively market, sell and distribute our products and to develop our products and product candidates, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview—Outlook" in Part II Item 7 of this Annual Report on Form 10-K.

Our Medicines

Our approved medicines include the following:

Product*	Therapeutic Area	U.S. Approved Indication
	**Hodgkin Lymphoma**	Previously untreated Stage III/IV classical Hodgkin lymphoma, or cHL, in combination with doxorubicin, vinblastine and dacarbazine cHL at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation, or auto-HSCT, consolidation cHL after failure of auto-HSCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates
	T-cell Lymphoma	Previously untreated sALCL or other CD30-expressing PTCL, including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin and prednisone sALCL after failure of at least one prior multi-agent chemotherapy regimen Primary cutaneous anaplastic large cell lymphoma, or pcALCL, or CD30-expressing mycosis fungoides who have received prior systemic therapy
	**Urothelial Cancer**	Locally advanced or metastatic urothelial cancer who have previously received a PD-1 or PD-L1 inhibitor and a platinum-containing chemotherapy before (neoadjuvant) or after (adjuvant) surgery in a locally advanced or metastatic setting.
	**Breast Cancer**	In combination with trastuzumab and capecitabine for the treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.

**ADCETRIS, PADCEV and TUKYSA are only indicated for adults.*

ADCETRIS®

ADCETRIS is an ADC targeting CD30, which is a protein located on the surface of cells and highly expressed in Hodgkin lymphoma, certain T-cell lymphomas as well as other cancers. ADCETRIS first received approval in an initial indication by the U.S. Food and Drug Administration, or FDA, in 2011 and has since been approved in a total of six indications to treat Hodgkin lymphoma and T-cell lymphomas in various settings including as frontline therapy.

Prior to the approval of ADCETRIS, the standard of care frontline therapy for patients with Hodgkin lymphoma and PTCL has seen limited improvement over the last few decades. Additionally, chemotherapy regimens have substantial associated toxicities and a significant number of lymphoma patients relapse and require additional treatments including other chemotherapy regimens and autologous stem cell transplant, or ASCT. Beyond our current labeled indications, we are evaluating ADCETRIS in several clinical trials to potentially broaden its use.

ADCETRIS is commercially available in more than 75 countries worldwide. We commercialize ADCETRIS in the U.S. and its territories and in Canada, and we collaborate with Takeda Pharmaceutical Company Limited, or Takeda, to develop and commercialize ADCETRIS on a global basis. Under this collaboration, Takeda has commercial rights in the rest of the world and pays us a royalty. Takeda has received regulatory approvals for ADCETRIS as monotherapy or in combination with agents in various settings for the treatment of patients with Hodgkin lymphoma or CD30-positive T-cell lymphomas in Europe and many countries throughout the rest of the world and is pursuing additional regulatory approvals.

PADCEV®

PADCEV is an ADC targeting Nectin-4, a protein expressed on the surface of cells and highly expressed in bladder cancer as well as other cancers. PADCEV was granted accelerated approval by the FDA in December 2019 for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a PD-1 or PD-L1 inhibitor and a platinum-containing chemotherapy before (neoadjuvant) or after (adjuvant) surgery in the locally advanced or metastatic setting. FDA approval of PADCEV was supported by data from a single-arm pivotal phase 2 clinical trial called EV-201. Continued approval may be contingent upon verification and description of clinical benefit in a required confirmatory trial. As discussed further below, Astellas and we plan to submit a supplemental BLA to the FDA based on the global phase 3 clinical trial called EV-301 as the confirmatory trial.

In the metastatic setting, several PD-1 and PD-L1 inhibitors have been approved for urothelial cancer in the past several years and are improving outcomes for some patients, yet the vast majority of patients do not benefit, or relapse, and require additional treatment options. Prior to the approval of PADCEV in the U.S. there were no approved agents in the post-platinum-based therapy and post-checkpoint inhibitor setting, representing an unmet medical need. We are conducting clinical trials in frontline metastatic disease, muscle invasive bladder cancer and in a range of other solid tumors. In addition, we are working on a development strategy in non-muscle invasive bladder cancer.

PADCEV, is being co-developed and jointly commercialized with Astellas Pharma, Inc., or Astellas. In the U.S., we and Astellas are jointly promoting PADCEV. In the U.S., we record net sales of PADCEV and are responsible for all distribution activities. We and Astellas each bear the costs of our own sales organizations in the U.S., equally share certain other costs associated with commercializing PADCEV in the U.S., and equally share in any profits realized in the U.S.

TUKYSA®

TUKYSA is an oral, small molecule tyrosine kinase inhibitor, or TKI, that is highly selective for HER2, a growth factor receptor overexpressed in many cancers. HER2 mediates cell growth, differentiation and survival. Tumors that over-express HER2 are generally more aggressive and historically have been associated with poor overall survival, compared with HER2-negative cancers. In April 2020, TUKYSA received approval from the FDA in combination with trastuzumab and capecitabine for the treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. FDA approval of TUKYSA was supported by data from the HER2CLIMB trial. We are conducting a broad clinical development program of TUKYSA including ongoing and planned trials in earlier lines of breast cancer and in other HER2-positive cancers.

The FDA reviewed the application for approval under the Oncology Center of Excellence's, or OCE's, Real Time Oncology Review, or RTOR, pilot program. We also participated in the Project Orbis initiative of the FDA OCE which provides a framework for concurrent submission and review of oncology products among international partners. Under this program we have received approval from the following countries participating in the FDA's Project Orbis initiative: U.S., Canada, Australia, Singapore, and Switzerland. In February 2021, the European Commission, or EC, granted marketing authorization for TUKYSA in combination with trastuzumab and capecitabine for the treatment of adult patients with HER2-positive locally advanced or metastatic breast cancer who have received at least two prior anti-HER2 treatment regimens. This approval is valid in all countries of the European Union as well as Norway, Liechtenstein, Iceland and Northern Ireland. We have also submitted a regulatory application to the U.K. Medicines and Healthcare Product Regulatory Authority, or MHRA.

We are commercializing TUKYSA in the U.S. and Canada and also expect to commercialize TUKYSA in Europe. In September 2020, we entered into a license and collaboration agreement with a subsidiary of Merck, or the TUKYSA Agreement, that granted exclusive rights to Merck & Co., Inc., or Merck, to commercialize TUKYSA in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. The collaboration is intended to accelerate global availability of TUKYSA.

Our Clinical Development Pipeline

The following table summarizes the key clinical trials of ADCETRIS, PADCEV, TUKYSA and our lead product candidates:

Product or Product Candidate	Tumor Type	Setting	Trial Name / Description	Development Status
ADCETRIS (brentuximab vedotin)	Diffuse large B-cell lymphoma	R/R	In combination with lenalidomide and rituximab	Phase 3*
	Hodgkin lymphoma	1L	In combination with nivolumab, doxorubicin and dacarbazine	Phase 2
	Hodgkin lymphoma or Peripheral T-cell lymphoma, unfit for chemotherapy	1L	Monotherapy	Phase 2
	Hodgkin lymphoma (pediatrics)	R/R	CheckMate 744: In combination with nivolumab[1]	Phase 2
	Peripheral T-cell lymphoma (< 10% CD30 expression)	1L	In combination with cyclophosphamide, doxorubicin and prednisone	Phase 2
	Metastatic solid tumors	R/R	In combination with pembrolizumab | post PD-1 inhibitor treatment	Phase 2
PADCEV (enfortumab vedotin-ejfv)[2]	Locally advanced or metastatic urothelial cancer	1L	EV-302: In combination with pembrolizumab vs chemotherapy alone	Phase 3*
		2L/3L	EV-301: Monotherapy | post PD(L)-1 and post platinum chemotherapy	Phase 3*
		2L	EV-201 Cohort 2: Monotherapy | post PD(L)-1, platinum naive and cisplatin ineligible	Phase 2*
		1L/2L	EV-103: Monotherapy and in combination with pembrolizumab	Phase 2*
	Muscle invasive bladder cancer	1L	EV-303/KEYNOTE-905: In combination with pembrolizumab | cisplatin-ineligible	Phase 3*
		1L	EV-304/KEYNOTE-B15: In combination with pembrolizumab | cisplatin-eligible	Phase 3*
		1L	EV-103: Monotherapy and in combination with pembrolizumab	Phase 2
	Locally advanced or metastatic solid tumors	R/R	EV-202: Monotherapy	Phase 2
TUKYSA (tucatinib)	HER2+ metastatic breast cancer	1L/2L	HER2CLIMB-02: In combination with T-DM1	Phase 3*
	High risk HER2+ breast cancer	ADJ	COMPASSHER2 RD[5]: In combination with T-DM1	Phase 3*
	HER2+ metastatic breast cancer		HER2CLIMB-04: In combination with trastuzumab deruxtecan	Phase 2
	HER2+ metastatic colorectal cancer	R/R	MOUNTAINEER: In combination with trastuzumab	Phase 2*
	HER2+ gastroesophogeal cancer	2L	MOUNTAINEER-02: In combination trastuzumab, ramucirumab and chemotherapy	Phase 2*
	Metastatic solid tumors HER2 alterations		In combination trastuzumab with or without fulvestrant	Phase 2
	HER2+ gastric cancer	1L	In combination with trastuzumab and oxaliplatin	Phase 1
Tisotumab Vedotin[3]	Recurrent/metastatic cervical cancer	2L/3L	innovaTV 301: Monotherapy	Phase 3*
		2L/3L	innovaTV 204: Monotherapy	Phase 2*
		1L/2L	innovaTV 205: In combination with other ant-cancer agents	Phase 1/2
	Locally advanced solid tumors		innovaTV 206: (Japan only)	Phase 2
	Metastatic solid tumors	R/R	innovaTV 207: Monotherapy	Phase 2
	Platinum-resistant ovarian cancer	2L	innovaTV 208: Monotherapy	Phase 2
Padiratuzumab Vedotin[4]	Metastatic triple-negative breast cancer	1L	In combination with pembrolizumab	Phase 2
	Metastatic solid tumors	R/R	Monotherapy	Phase 2
	Metastatic breast cancer (HR+/HER2-)	R/R	In combination with trastuzumab	Phase 2

1L: front/first-line 2L:second-line R/R:relapsed or refractory ADJ = adjuvant
* indicates registrational intent

1. Clinical collaboration with Bristol-Myers Squibb
2. 50:50 co-development and commercial collaboration with Astellas
3. 50:50 co-development and commercial collaboration with Genmab
4. 50:50 co-development and commercial collaboration with Merck
5. Conducted in collaboration with Alliance for Clinical Trials in Oncology and National Cancer Institute (NCI)

Clinical Development Status

ADCETRIS (brentuximab vedotin)

Beyond our current labeled indications, we are evaluating ADCETRIS as monotherapy and in combination with other agents in ongoing trials which include several potential registration-enabling trials. In addition to our corporate-sponsored trials there are numerous investigator-sponsored trials of ADCETRIS in the United States. The investigator-sponsored trials include the use of ADCETRIS in a number of malignant hematologic indications and in solid tumors.

As previously reported, the phase 3 ECHELON-1 trial achieved its primary endpoint with the combination of ADCETRIS plus AVD (Adriamycin [doxorubicin], vinblastine and dacarbazine) resulting in a statistically significant improvement in modified PFS compared to the control arm of ABVD, which includes bleomycin, in patients with Stage III and IV frontline classical Hodgkin lymphoma. Also previously reported, the phase 3 ECHELON-2 trial met its primary endpoint with the combination of ADCETRIS plus CHP (cyclophosphamide, Adriamycin [doxorubicin], vincristine, prednisone) resulting in a statistically significant improvement in PFS versus the control arm of CHOP in patients with CD30-expressing PTCL. In December 2020, five-year updates from the ECHELON-1 and ECHELON-2 clinical trials were presented at the 62nd American Society of Hematology annual meeting in December 2020. The five-year update of the ECHELON-1 clinical trial shows treatment with ADCETRIS in combination with AVD chemotherapy results in superior long-term outcomes when compared to ABVD. Additionally, the ECHELON-2 clinical trial continues to demonstrate significant durable improvement in progression-free survival and overall survival of ADCETRIS plus CHP when compared to CHOP.

PADCEV (enfortumab vedotin-ejfv)

In collaboration with Astellas we are conducting or planning to conduct clinical trials across the spectrum of bladder cancer including ongoing trials in frontline metastatic urothelial cancer and muscle invasive bladder cancer. We are planning a development strategy for non-muscle invasive bladder cancer as well. In addition, we are conducting a trial in a range of other solid tumors.

In September 2020, we announced that the global phase 3 clinical trial called EV-301, which compared PADCEV to chemotherapy in adult patients with locally advanced or metastatic urothelial cancer who were previously treated with platinum-based chemotherapy and a PD-1/L1 inhibitor, met its primary endpoint of overall survival, or OS, compared to chemotherapy. For patients in the PADCEV arm of the trial, rash, fatigue, and decreased neutrophil count were the most frequent Grade 3 or greater treatment-related adverse events occurring in more than 5 percent of patients. Astellas and we plan to submit a supplemental BLA based on the EV-301 results to the FDA as the confirmatory trial following PADCEV's accelerated approval in December 2019. EV-301 is also intended to support global regulatory submissions.

In October 2020, we announced positive topline results from the second cohort of patients in the pivotal phase 2 EV-201 trial. The cohort is evaluating PADCEV for patients with locally advanced or metastatic urothelial cancer who have been previously treated with a PD-1/L1 inhibitor and have not received a platinum-containing chemotherapy and are ineligible for cisplatin. We plan to submit a supplemental BLA to the FDA based on the results which is intended to support an indication in this setting.

PADCEV is also being investigated in frontline metastatic urothelial cancer and earlier stages of bladder cancer. We and Astellas are conducting a phase 1b/2 clinical trial, called EV-103, that is a multi-cohort, open-label trial of PADCEV alone or in combination with the anti-PD-1 therapy pembrolizumab. The trial is evaluating safety, tolerability and activity in locally advanced and first- and second-line metastatic urothelial cancer, and was expanded to include muscle invasive bladder cancer, or MIBC. In February 2020, updated results from the trial in patients with previously untreated locally advanced or metastatic urothelial cancer who were ineligible for treatment with cisplatin-based chemotherapy were presented at the 2020 Genitourinary Cancers Symposium.

In February 2020, based on the positive initial results of the EV-103 trial, the FDA granted Breakthrough Therapy designation for PADCEV in combination with pembrolizumab for the treatment of patients with unresectable locally advanced or metastatic urothelial cancer who are unable to receive cisplatin-based chemotherapy in the first-line setting. In April 2020, we announced that based on discussions with the FDA, data from the randomized cohort K in the EV-103 trial, along with other data from the EV-103 trial, could potentially support registration under the FDA's accelerated approval pathway. The primary outcome measures are objective response rate and duration of response. We expect to complete enrollment in cohort K by the end of 2021.

In addition to the potential accelerated approval pathway based on the EV-103 trial, we are conducting a global, registrational phase 3 trial, called EV-302, in frontline metastatic urothelial cancer in collaboration with Astellas and a subsidiary of Merck & Co., Inc., or Merck. We, Astellas and Merck are jointly funding EV-302 and the trial is being led by us. EV-302 is an open-label, randomized phase 3 clinical trial evaluating the combination of PADCEV and pembrolizumab versus chemotherapy alone in patients with previously untreated locally advanced or metastatic urothelial cancer. The trial includes metastatic urothelial cancer patients who are either eligible or ineligible for cisplatin-based chemotherapy. The trial has dual primary endpoints of progression-free survival and overall survival and is intended to support global regulatory submissions and potentially serve as a confirmatory trial if accelerated approval is granted based on EV-103.

In April 2020, we and Astellas entered into an agreement with Merck to evaluate PADCEV in MIBC. Merck has amended its ongoing phase 3 KEYNOTE-905/EV-303 registrational trial in cisplatin-ineligible patients with MIBC to include an arm evaluating PADCEV in combination with pembrolizumab. In October 2020, we and Astellas entered into an agreement with Merck to evaluate PADCEV in combination with pembrolizumab in a phase 3 trial, called KEYNOTE-B15/EV-304, to be conducted by Merck in cisplatin-eligible patients with MIBC which was initiated in the first quarter of 2021.

In January 2020, we and Astellas also initiated a phase 2 clinical trial, called EV-202, to evaluate PADCEV monotherapy in solid tumors that have high-levels of Nectin-4 expression, including non-small cell lung, head and neck, gastric/esophageal and breast cancers. In March 2020, the first patient was dosed in the trial.

Since the launch of PADCEV we have continued to monitor product safety in clinical trials and in the post marketing setting. Nectin-4, which PADCEV targets, is expressed in the skin, and rash is a common adverse event associated with PADCEV use, but is generally mild and reversible. Severe rashes, however, do occur and are described in the current U.S. prescribing information. Severe cutaneous adverse reactions including fatal cases of Stevens Johnson Syndrome and toxic epidermal necrolysis have occurred in patients treated with PADCEV in the post marketing setting and during clinical trials. We have communicated the occurrence of these rare events via a letter together with updated recommendations to health care providers who may treat patients with urothelial cancer. We are working with the FDA regarding updates to the U.S. prescribing information to reflect these events. The overall benefit-risk balance remains favorable for the use of PADCEV in its approved indication.

TUKYSA (tucatinib)

We are conducting a broad clinical development program of TUKYSA including ongoing and planned trials in earlier lines of breast cancer and in other HER2-positive cancers.

In October 2019, we initiated a phase 3 randomized trial, called HER2CLIMB-02, evaluating TUKYSA versus placebo, each in combination with T-DM1, for patients with unresectable locally advanced or metastatic HER2-positive breast cancer, including those with brain metastases, who have had prior treatment with a taxane and trastuzumab.

We are supporting a U.S. cooperative group that is conducting a phase 3 randomized trial, called CompassHER2 RD, which is evaluating TUKYSA in combination with T-DM1 in the adjuvant setting for patients with high-risk, HER2-positive breast cancer.

We are also conducting a phase 2 trial, called HER2CLIMB-04, evaluating TUKYSA in combination with trastuzumab deruxtecan in previously treated locally-advanced or metastatic HER2-positive breast cancer.

We are conducting a phase 2 trial, called MOUNTAINEER, evaluating TUKYSA in combination with trastuzumab in patients with HER2-positive, RAS wild-type metastatic colorectal cancer after treatment with first- and second-line standard-of-care therapies. Initial results from 23 patients were presented at the ESMO 2019 Congress that demonstrated encouraging antitumor activity. We believe the trial could potentially support an application for accelerated approval in the U.S.

We are conducting a phase 2/3 trial, called MOUNTAINEER-02, in combination with trastuzumab, ramucirumab and paclitaxel in second-line HER2-positive metastatic gastroesophageal cancer. We have also initiated a phase 1b trial evaluating TUKYSA in combination with trastuzumab and oxaliplatin based chemotherapy in first-line HER2-positive unresectable or metastatic colorectal, gastric, esophageal and gallbladder cancers.

Tisotumab Vedotin

In collaboration with Genmab we are developing tisotumab vedotin for metastatic cervical cancer and are evaluating it for other solid tumors.

We and Genmab are conducting a pivotal phase 2 trial, called innovaTV 204, evaluating single-agent tisotumab vedotin for patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment. In September 2020, data from the innovaTV 204 trial were presented at the European Society for Medical Oncology, or ESMO, Virtual Congress 2020. Results from the trial showed a 24 percent confirmed objective response rate, or ORR, by independent central review with a median duration of response, or DOR, of 8.3 months. The most common treatment-related adverse events (greater than or equal to 20 percent) included alopecia, epistaxis (nose bleeds), nausea, conjunctivitis, fatigue and dry eye. In February 2021, we submitted a BLA to the FDA seeking accelerated approval for recurrent or metastatic cervical cancer who have relapsed or progressed on or after prior treatment.

In January 2021, we and Genmab initiated a phase 3 clinical trial, called innovaTV 301, to evaluate tisotumab vedotin compared to chemotherapy in patients with recurrent or metastatic cervical cancer who have received one or two prior lines of therapy. innovaTV 301 is intended to support global regulatory applications for potential approvals in regions where innovaTV 204 does not support approval and to potentially serve as a confirmatory trial in the U.S. if we are able to obtain accelerated approval based on the tisotumab vedotin BLA submission.

We are also conducting a phase 2 clinical trial, called innovaTV 205, evaluating tisotumab vedotin as monotherapy and in combination with certain other anti-cancer agents for first-line treatment of patients with recurrent or advanced cervical cancer. Additionally, we are conducting a phase 2 clinical trial, called innovaTV 207, for patients with relapsed, locally advanced or metastatic solid tumors and a phase 2 clinical trial, called innovaTV 208, for patients with platinum-resistant ovarian cancer.

Ladiratuzumab Vedotin

We are developing ladiratuzumab vedotin, or LV, an ADC targeting LIV-1, which is currently being evaluated in phase 1 and phase 2 clinical trials both as monotherapy and in combination with other agents for patients with metastatic breast cancer and select solid tumors with high LIV-1 expression. In September 2020, we and a subsidiary of Merck entered into a license and collaboration agreement, or the LV Agreement, under which the companies will jointly develop and share future costs and profits worldwide for LV.

Other clinical and early-stage product candidates

We are advancing a pipeline of early-stage clinical candidates as well as multiple preclinical and research-stage programs that employ our proprietary technologies. We advanced several product candidates into clinical development in 2020 and we plan to submit additional IND applications to the FDA in 2021.

Our Antibody-Drug Conjugate (ADC) Technology

ADCETRIS, PADCEV and many product candidates in our clinical-stage pipeline utilize our ADC technology. ADCs are monoclonal antibodies that are linked to cytotoxic, or cell-killing, agents. Our ADCs utilize monoclonal antibodies that internalize within target cells after binding to a specified cell-surface receptor. Enzymes present inside the cell catalyze the release of the cytotoxic agent from the monoclonal antibody, which then results in the desired activity, specific killing of the target cell.

A key component of our ADCs are the linkers that attach the cell-killing agent to the monoclonal antibody. The drug linkers are designed to deliver the cytotoxic agent to tumors by virtue of the monoclonal antibody binding to the intended cell surface receptor on the target cell. The cytotoxic agent is released when the ADC internalizes within the target cell, resulting in cell killing. This targeted delivery of the cell-killing agent is intended to maximize delivery of the cytotoxic agent to targeted cells while minimizing toxicity to normal tissues. Our most advanced ADCs, including ADCETRIS, PADCEV, tisotumab vedotin and LV, use our proprietary auristatin-based ADC technology. Auristatins are microtubule disrupting agents. In contrast to natural products that are often more difficult to produce and link to antibodies, the cytotoxic drugs used in our ADCs are synthetically produced and are readily scalable for manufacturing. This technology is also the basis of our ADC collaborations. We own or hold exclusive or partially-exclusive licenses to multiple issued patents and patent applications covering our ADC technology. We continue to evaluate new linkers, antibody formats and cell-killing agents for use in our ADC programs.

Our Sugar-Engineered Antibody (SEA) Technology

Our proprietary SEA technology is a method to selectively reduce fucose incorporation in monoclonal antibodies as they are produced in cell line-based manufacturing. Our preclinical data show that this results in increased binding to innate immune effector cells and enhanced potency in antibody dependent cellular cytotoxicity, or ADCC, in tumor cells. We believe this enhancement in ADCC activity may provide improved anti-tumor activity. Our SEA technology is a novel approach to modify the activity of monoclonal antibodies that is complementary to our ADC technology.

A key feature of our SEA technology is that no genetic modification of the antibody-producing cell line is necessary and standard cell culture conditions can be used while maintaining the underlying manufacturing processes, yields and product quality. We believe the SEA approach may be simpler and more cost-effective to implement as compared to existing technologies for enhancing antibody effector function, most of which require development of new cell lines.

We have several product candidates that are being evaluated in phase 1 clinical trials that utilize our SEA technology including SEA-CD40, SEA-TGT, SEA-BCMA and SEA-CD70. These agents are targeted at a variety of cancer types.

Other Technologies

In addition, we utilize other technologies designed to maximize antitumor activity and reduce toxicity of antibody-based therapies. Genetic engineering enables us to produce antibodies that are optimized for their intended uses. For ADCs, we screen and select antibodies that bind to antigens that are differentially expressed on tumor cells versus vital normal tissues, rapidly internalized within target cells and have potent anti-tumor activity in preclinical models. For our SEA technology we produce antibodies that demonstrate potent anti-tumor activities by virtue of ADCC, or through additional immune stimulatory mechanisms that are triggered by the enhanced binding potency to innate immune cells. Our ADCs utilize native or engineered conjugation sites to optimize drug attachment. In some cases, we evaluate the use of our monoclonal antibodies and ADCs in combination with conventional chemotherapy and other anticancer agents, which may result in increased antitumor activity.

Research Programs

In addition to our pipeline of current product candidates and technologies, we have internal research programs directed toward developing new classes of potent anti-tumor and immune stimulatory agents and new ADC linkers, the identification of novel drug targets and monoclonal antibodies, and advancing our antibody engineering initiatives.

New Tumor Cell-Killing Agents. We continue to identify and study new agents with anti-tumor mechanisms of action that will provide pipeline diversity and complement the auristatins that we currently use in our ADC technology. We also seek to develop new drugs that are designed to activate the host immune system by targeting key immune stimulatory pathways that can mediate innate or adaptive anti-tumor immune responses.

New Drug Linkers. We are conducting research with the intent to develop new ADC linkers that are designed to provide the appropriate stability in the bloodstream and drug release characteristics to effectively target cancer cells and improved cancer cell selectivity and tolerability.

Novel Monoclonal Antibodies and Antigen Targets. We are actively engaged in internal efforts to identify and develop monoclonal antibodies, and other therapeutic molecules, to target tumor antigens and important tumor or immune pathways. For ADCs, we focus on drug targets that are highly expressed on the surface of cancer cells that have the appropriate expression, distribution and internalization properties that make them desirable as monoclonal antibody or ADC targets. We may then create and screen panels of cancer-reactive monoclonal antibodies in our laboratories to identify those with the desired specificity and optimized drug delivery properties. Additionally, we identify targets that play key roles in anti-tumor innate or adaptive immune responses and identify antibodies and other therapeutic molecules to stimulate an anti-tumor immune response. We supplement these internal efforts by evaluating opportunities to in-license targets and antibodies from academic groups and other biotechnology and pharmaceutical companies, such as our ongoing collaborations with Astellas and Genmab.

Antibody Engineering. We have substantial internal expertise in antibody engineering including humanization, binding affinity optimization, enhancement of immunological function by blocking fucosylation, as well as engineering antibodies to improve drug linkage sites for use with our ADC technology. By modifying the number and type of drug-linkage sites found on our antibodies, we believe that we can improve ADC drug properties and the cost-effectiveness of our manufacturing processes for conjugation of ADCs.

Corporate Collaborations

We enter into collaborations with pharmaceutical and biotechnology companies to advance the development and commercialization of our product candidates and to supplement our internal pipeline. We seek collaborations that will allow us to retain significant future participation in product sales through either profit-sharing or royalties paid on net sales. We also have licensed our technologies to collaborators to be developed with their own antibodies. These collaborations benefit us in many ways, including generating cash flow and revenues that partially offset expenditures on our internal research and development programs, expanding our knowledge base regarding ADCs across multiple targets and antibodies provided by our collaborators and providing us with future pipeline opportunities through co-development or opt-in rights to new product candidates.

Takeda ADCETRIS Collaboration

We have an agreement with Takeda for the global co-development of ADCETRIS and the commercialization of ADCETRIS by Takeda in its territory. We have commercial rights for ADCETRIS in the U.S. and its territories and in Canada. Takeda has commercial rights in the rest of the world. Under the collaboration, we and Takeda can each conduct development activities and equally co-fund the cost of certain mutually agreed development activities. Costs associated with co-development activities are included in research and development expense.

As of December 31, 2020, we had achieved milestone payments totaling $157.5 million related to regulatory and commercial progress by Takeda. As of December 31, 2020, total future potential development and regulatory milestone payments to us under this collaboration could total $77.0 million. In addition, we recognize royalty revenues, where royalties are based on a percentage of Takeda's net sales of ADCETRIS in its licensed territories, with percentages ranging from the mid-teens to the mid-twenties based on annual net sales tiers, and sales-based milestones. Takeda bears a portion of third-party royalty costs owed on its sales of ADCETRIS, which is included in royalty revenues.

Either party may terminate the collaboration agreement if the other party materially breaches the agreement and such breach remains uncured. Takeda may terminate the collaboration agreement for any reason upon prior written notice to us and we may terminate the collaboration agreement in certain circumstances. The collaboration agreement can also be terminated by mutual written consent of the parties. If neither party terminates the collaboration agreement, then the agreement automatically terminates on the expiration of all payment obligations.

Astellas PADCEV Collaboration

We have a collaboration agreement with Agensys, Inc., which subsequently became an affiliate of Astellas, to jointly research, develop and commercialize ADCs for the treatment of several types of cancer. The collaboration encompasses combinations of our ADC technology with fully-human antibodies developed by Astellas to proprietary cancer targets. Under this collaboration, we and Astellas are co-funding all development costs for PADCEV.

In 2018, we and Astellas entered into a joint commercialization agreement to govern the global commercialization of PADCEV:

- In the U.S., we and Astellas jointly promote PADCEV. We record sales of PADCEV in the U.S. and are responsible for all U.S. distribution activities. The companies each bear the costs of their own sales organizations in the U.S., equally share certain other costs associated with commercializing PADCEV in the U.S., and equally share in any profits realized in the U.S.
- Outside the U.S., we have commercialization rights in all countries in North and South America, and Astellas has commercialization rights in the rest of the world, including Europe, Asia, Australia and Africa. The agreement is intended to provide that we and Astellas will effectively equally share in costs incurred and any profits realized in all of these markets. Cost and profit sharing in Canada, the United Kingdom, Germany, France, Spain and Italy will be based on product sales and costs of commercialization. In the remaining markets, the commercializing party will bear costs and will pay the other party a royalty rate applied to net sales of the product based on a rate intended to approximate an equal profit share for both parties.

Astellas or its affiliates are responsible for overseeing the manufacturing supply chain for PADCEV for development and commercial use. However, we are responsible for packaging and labeling in countries in which we sell PADCEV. In addition, we are responsible for establishing a second source supply chain, whether through internal or third party sources.

Either party may terminate the collaboration agreement if the other party becomes insolvent or the other party materially breaches the agreement and such breach remains uncured. Subject to certain restrictions, either party may terminate the collaboration agreement for any reason upon prior written notice to the other party. The collaboration agreement can also be terminated by mutual written consent of the parties. If neither party exercises its option to terminate the collaboration agreement, then the agreement will automatically terminate on the later of the expiration of all payment obligations pursuant to the collaboration agreement, or the day upon which we and Astellas cease to develop and commercialize products under the agreement.

Either party may terminate the joint commercialization agreement if the other party becomes insolvent. The joint commercialization agreement expires on a country-by-country basis upon complete cessation of the commercialization, launch and selling of PADCEV in that country.

Either party may also opt out of co-development and profit-sharing under the collaboration agreement in return for receiving milestones and royalties from the continuing party. In addition, either party may opt out of co-development and profit-sharing for PADCEV on a country-by-country basis, in return for receiving royalties pursuant to the collaboration agreement from the continuing party with respect to that country.

Merck TUKYSA Collaboration

In September 2020, we entered into the TUKYSA Agreement with Merck. Under the TUKYSA Agreement, we granted Merck exclusive rights to commercialize TUKYSA in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. Merck is responsible for marketing applications for approval in its territory, supported by the positive results from the HER2CLIMB clinical trial. We retained commercial rights in, and will record sales in, the U.S., Canada and Europe. Merck also agreed to co-fund a portion of the TUKYSA global development plan, which encompasses several ongoing and planned trials across HER2-positive cancers. We will continue to lead ongoing TUKYSA global development operational execution. Merck will solely fund and conduct country-specific clinical trials necessary to support anticipated regulatory applications in its territories. Under the TUKYSA Agreement, we are responsible for supplying Merck with TUKYSA for the purpose of clinical development and commercialization. We received an upfront cash payment from Merck of $125.0 million and also received $85.0 million in prepaid research and development funding to be applied to Merck's global development cost sharing obligations. We are eligible to receive progress-dependent milestone payments of up to $65.0 million, and are entitled to receive tiered royalties on sales of TUKYSA by Merck that begin in the low twenty percent range and escalate based sales volume by Merck in its territory. We owe Array Biopharma Inc., or Array, an affiliate of Pfizer, a portion of any non-royalty payments received from sublicensing TUKYSA rights, as well as a low double-digit royalty based on net sales of TUKYSA by us, and will owe a single-digit royalty based on net sales of TUKYSA by Merck in its territories.

Genmab Tisotumab Vedotin Collaboration

We have a collaboration agreement with Genmab to develop and commercialize ADCs targeting tissue factor, under which we previously exercised a co-development option for tisotumab vedotin. Under this collaboration, we and Genmab are co-funding all development costs for tisotumab vedotin. In February 2021, we submitted a BLA for tisotumab vedotin to the FDA seeking accelerated approval for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

In October 2020, we and Genmab entered into a joint commercialization agreement to govern the global commercialization of tisotumab vedotin:

- In the U.S., we and Genmab will co-promote tisotumab vedotin. We will record sales of tisotumab vedotin in the U.S. and will be responsible for leading U.S. distribution activities. The companies will each hire and maintain 50% of the sales representatives and medical science liaisons, equally share those and certain other costs associated with commercializing tisotumab vedotin in the U.S., and equally share in any profits realized in the U.S.
- Outside the U.S., we have commercialization rights in the rest of the world except for Japan, where Genmab has commercialization rights. In Europe, China, and Japan, we and Genmab will equally share 50% of the costs associated with commercializing tisotumab vedotin as well as any profits realized in these markets. In markets outside the U.S. other than Europe, China, and Japan, aside from certain costs enumerated in the agreement, we will be solely responsible for all costs associated with commercializing tisotumab vedotin, and will pay Genmab a royalty based on a percentage of aggregate net sales ranging from the mid-teens to mid-twenties.

We currently rely on Genmab for the supply of tisotumab vedotin. However, in connection with the joint commercialization agreement, we will be responsible for overseeing the clinical and any commercial manufacturing of tisotumab vedotin following a transition period. Either party may terminate the collaboration agreement or the joint commercialization agreement if the other party becomes insolvent or materially breaches the applicable agreement and such breach remains uncured. In addition, either party may terminate the collaboration agreement if such party's patent rights subject to the agreement are challenged by the other party or its sublicensees. Either party may also opt out of co-development and profit-sharing under the collaboration agreement in return for receiving milestones and royalties from the continuing party. The opt out provisions of the collaboration agreement may also be applied to the joint commercialization agreement. In addition, Genmab may elect to opt out of co-promotion of tisotumab vedotin in the United States by providing us with prior written notice.

Merck LV Collaboration

In September 2020, we entered into the LV Agreement with Merck. Under the terms of the LV Agreement, we granted Merck a co-exclusive worldwide development and commercialization license for LV and agreed to jointly develop and commercialize LV on a worldwide basis. We received an upfront cash payment of $600.0 million, and we are eligible to receive up to $850.0 million in milestone payments upon the initiation of certain clinical trials and regulatory approval in certain major markets, and up to an additional $1.75 billion in milestone payments upon the achievement of specified annual global net sales thresholds. Each company is responsible for 50% of global costs to develop and commercialize LV and will receive 50% of potential future profits. We will lead regulatory and distribution activities, and will record sales, in the United States and Canada. Merck will lead regulatory activities in Europe, and we will lead distribution activities and record sales in Europe. We and Merck will co-commercialize LV in the United States and Europe. Merck will lead regulatory, promotion and distribution activities, and will record sales, in countries outside of the United States, Canada and Europe.

The LV Agreement will remain in effect, unless earlier terminated, until LV is no longer being developed or commercialized under the LV Agreement. The LV Agreement also contains customary provisions for termination by Merck for convenience, and by either party, including in the event of breach of the LV Agreement, subject to cure, or upon a challenge of such party's licensed patents or upon the other party's bankruptcy, subject, in each case, to customary reversion rights.

In connection with the LV Agreement, we entered into a stock purchase agreement with Merck in September 2020, referred to as the Purchase Agreement, pursuant to which we agreed to issue and sell, and Merck agreed to purchase 5,000,000 newly-issued shares of our common stock, at a purchase price of $200 per share, for an aggregate purchase price of $1.0 billion. We closed the transactions contemplated by the Purchase Agreement on October 27, 2020 following the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

ADC License Agreements

We have license agreements for our ADC technology with a number of biotechnology and pharmaceutical companies. Under these agreements, which we have entered into in the ordinary course of business, we have granted research and commercial licenses to use our technology, most often in conjunction with the licensee's technology. In certain agreements, we also have agreed to conduct limited development activities and to provide other materials, supplies, and services to our licensees during a specified term of the agreement. We typically receive upfront cash payments and progress- and sales-dependent milestones for the achievement by our licensees of certain events, and annual maintenance fees and support fees for research and development services and materials provided under the agreements. We also are entitled to receive royalties on net sales of any resulting products incorporating our ADC technology. Our licensees are solely responsible for research, product development, manufacturing and commercialization of any product candidates under these agreements, which includes the achievement of the potential milestones.

In 2019, Genentech received accelerated approval from the FDA for Polivy™ (polatuzumab vedotin-piic), an ADC that uses our technology, to treat patients with relapsed or refractory diffuse large B-cell lymphoma. In August 2020, GlaxoSmithKline plc, or GSK, received accelerated approval from the FDA and conditional marketing authorization from the EC for Blenrep™ (belantamab mafodotin-blmf), an ADC developed by GSK that uses our technology, for treatment of patients with relapsed or refractory multiple myeloma who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor and an immunomodulatory agent. Under our ADC license agreements with Genentech and GSK, these events triggered milestone payments to us and we are also entitled receive royalties on net sales of Polivy and Blenrep worldwide. The product candidates being developed under our other ADC license agreements are at various stages of clinical and preclinical development. Our ability to generate meaningful future revenues from our other ADC license agreements will largely depend on products that incorporate our technologies entering late-stage clinical development, and receiving marketing approval from the FDA and subsequently being commercialized, if any.

In-license Agreements

We have in-licensed antibodies, targets and enabling technologies from pharmaceutical and biotechnology companies and academic institutions for use in our pipeline programs and ADC technology, including the following:

- Bristol-Myers Squibb License. In 1998, we obtained rights to some of our technologies and product candidates, portions of which are exclusive, through a license agreement with BMS. Through this license, we secured rights to use various targeting technologies. Under the terms of the license agreement, we are required to pay royalties in the low single digits on net sales of products, including ADCETRIS, which incorporate various technologies owned by BMS. Our obligation to pay royalties on ADCETRIS under the agreement expires in August 2021. The term of the license agreement expires on a country-by-country and product-by-product basis upon the later of the expiration of the last valid claim covering the applicable product within that country or either ten or twelve years depending on the particular patents applicable to the product after the first commercial sale of the applicable product within that country. We and BMS each have the right to terminate the license agreement prior to its expiration for insolvency or material breach, subject to cure and dispute resolution provisions. In addition, the license agreement will terminate automatically in the event that we fail to maintain certain required insurance.

- University of Miami License. In 1999, we entered into an exclusive license agreement with the University of Miami, Florida, covering an anti-CD30 monoclonal antibody that is the basis for the antibody component of ADCETRIS. Under the terms of this license, we made an upfront payment and progress-dependent milestone payments. We are required to pay annual maintenance fees and royalties in the low single digits on net sales of products, including ADCETRIS, incorporating technology licensed from the University of Miami. The term of the license agreement expires ten years after the first commercial sale of ADCETRIS or on August 21, 2021, upon which we will have in perpetuity a fully paid-up, royalty free, nonexclusive, sublicensable license. We and the University of Miami each have the right to terminate the license agreement prior to its expiration for insolvency or material breach, subject to cure provisions.
- Array BioPharma, Inc. We are a party to a license agreement with Array, which was acquired by Pfizer in July 2019. Pursuant to the license agreement, Array has granted us an exclusive license to develop, manufacture and commercialize TUKYSA. We will pay Array a portion of any non-royalty payments received from sublicensing TUKSYA rights, including non-royalty payments received from Merck pursuant to the TUKYSA Agreement. Array is also entitled to receive a low double-digit royalty based on net sales of TUKYSA by us and a single-digit royalty based on any net sales of TUKYSA by our sublicensees, including Merck. The term of the license agreement expires on a country-by-country basis upon the later of the expiration of the last valid claim covering TUKYSA within that country or 10 years after the first commercial sale of TUKYSA within that country. We and Array each have the right to terminate the license agreement prior to its expiration for insolvency or material breach, subject to cure and dispute resolution provisions.
- Other Licenses. Under the terms of in-license agreements related to our pipeline programs, we would potentially owe development, regulatory, and sales-based milestones, and royalties on net sales of certain approved products.

Patents and Proprietary Technology

Our owned and licensed patents and patent applications are directed to ADCETRIS, PADCEV, TUKYSA, our product candidates, monoclonal antibodies, our ADC and SEA technologies and other antibody-based and/or enabling technologies. We commonly seek patent claims directed to compositions of matter, including antibodies, ADCs, and drug-linkers containing highly potent cell-killing agents, as well as methods of using such compositions. When appropriate, we also seek claims to related technologies, such as methods of using certain sugar analogs utilized in our SEA technology. For each of our products and product candidates, we have filed or expect to file multiple patent applications. We maintain patents and prosecute applications worldwide for technologies that we have out-licensed, such as our ADC technology. Similarly, for partnered products and product candidates, such as ADCETRIS, PADCEV, TUKYSA, tisotumab vedotin and LV, we seek to work closely with our development partners to coordinate patent efforts, including patent application filings, prosecution, term extension, defense and enforcement. As our products and product candidates advance through research and development, we seek to diligently identify and protect new inventions, such as combination therapies, improvements to methods of manufacturing, and methods of treatment. We also work closely with our scientific personnel to identify and protect new inventions that could eventually add to our development pipeline.

We own or have rights to the following patents relating to our products and our pipeline (in addition to certain patents covering our early-stage product candidates):

- For ADCETRIS and our related ADC technology, we own twelve patents in the United States and Europe that will expire between 2021 and 2031.
- For PADCEV and our related ADC technology, we own, co-own or have licensed rights to thirteen patents in the United States and Europe that will expire between 2022 and 2031. Of these patents, we own or co-own eleven patents and have licensed rights to two patents.
- For TUKYSA, we have licensed rights to nine patents in the United States and Europe that will expire between 2024 and 2033.

- For tisotumab vedotin and our related ADC technology, we own, co-own or have licensed rights to eleven patents in the United States and Europe that will expire between 2022 and 2036. Of these patents, we own or co-own five patents and have licensed rights to six patents.
- For LV and our related ADC technology, we own, co-own or have licensed rights to nine patents in the United States and Europe that will expire between 2022 and 2032. Of these patents, we own or co-own eight patents and have licensed rights to one patent.

The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage as determined by the patent office or courts in the country, and the availability of legal remedies in the country. The list above does not identify all patents that may be related to our products and product candidates. For example, in addition to the listed patents, we have patents on platform technologies (that relate to certain general classes of products or methods), as well as patents that relate to methods of using, manufacturing or administering a product or product candidate, that may confer additional patent protection. We also have pending patent applications that may give rise to new patents related to one or more of these agents.

The information in the above list is based on our current assessment of patents that we own, co-own or control or have licensed. The information is subject to revision, for example, in the event of changes in the law or legal rulings affecting our patents or if we become aware of new information. Significant legal issues remain unresolved as to the extent and scope of available patent protection for biotechnology products and processes in the U.S. and other important markets outside the U.S. We expect that litigation will likely be necessary to determine the term, validity, enforceability, and/or scope of certain of our patents and other proprietary rights. An adverse decision or ruling with respect to one or more of our patents could result in the loss of patent protection for a product and, in turn, the introduction of competitor products or follow-on biologics to the market earlier than anticipated, and could force us to either obtain third-party licenses at a material cost or cease using a technology or commercializing a product.

Patents expire, on a country by country basis, at various times depending on various factors, including the filing date of the corresponding patent application(s), the availability of patent term extension and supplemental protection certificates and requirements for terminal disclaimers. Although we believe our owned and licensed patents and patent applications provide us with a competitive advantage, the patent positions of biotechnology and pharmaceutical companies can be uncertain and involve complex legal and factual questions. We and our corporate collaborators may not be able to develop patentable products or processes or obtain patents from pending patent applications. Even if patent claims are allowed, the claims may not issue. In the event of issuance, the patents may not be sufficient to protect the proprietary technology owned by or licensed to us or our corporate collaborators. Our or our collaborators' current patents, or patents that issue on pending applications, may be challenged, invalidated, infringed or circumvented. In addition, changes to patent laws in the United States or in other countries may limit our ability to defend or enforce our patents, or may apply retroactively to affect the term and/or scope of our patents. Our patents have been and may in the future be challenged by third parties in post-issuance administrative proceedings or in litigation as invalid, not infringed or unenforceable under U.S. or foreign laws, or they may be infringed by third parties. As a result, we are or may be from time to time involved in the defense and enforcement of our patent or other intellectual property rights in a court of law and administrative tribunals, such as in U.S. Patent and Trademark Office inter partes review or reexamination proceedings, foreign opposition proceedings or related legal and administrative proceedings in the United States and elsewhere. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings or litigation may be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our proprietary technologies without a license from us or our collaborators. Our and our collaborators' patents may also be circumvented, which may allow third parties to use similar technologies without a license from us or our collaborators.

Our commercial success depends significantly on our ability to operate without infringing patents and proprietary rights of third parties. Organizations such as pharmaceutical and biotechnology companies, universities and research institutions may have filed patent applications or may have been granted patents that cover technologies similar to the technologies owned or licensed to us or to our collaborators. In addition, we are monitoring the progress of multiple pending patent applications of other organizations that, if granted, may require us to license or challenge their validity or enforceability in order to continue commercializing ADCETRIS, PADCEV, or TUKYSA or to commercialize our product candidates. Our challenges to patents of other organizations may not be successful, which may affect our ability to commercialize ADCETRIS, PADCEV, TUKYSA or our product candidates. We cannot determine with certainty whether patents or patent applications of other parties may materially affect our or our collaborators' ability to make, use or sell ADCETRIS, PADCEV, TUKYSA or any other products or product candidates.

We require our scientific personnel to maintain laboratory notebooks and other research records in accordance with our policies, which are designed to strengthen and support our intellectual property protection. In addition to our patented intellectual property, we also rely on trade secrets and other proprietary information, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a proprietary information and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. These agreements provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of their relationship with us except in limited circumstances. These agreements also provide that we will own all inventions conceived or reduced to practice by the individual in the course of rendering services to us. Our policy and agreements and those of our collaborators may not sufficiently protect our confidential information, or third parties may independently develop equivalent information.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, pre-market approval, manufacture, marketing and distribution of biopharmaceutical products. These agencies and other regulatory agencies regulate research and development activities and the testing, approval, manufacture, quality control, safety, efficacy, labeling, storage, distribution, import, export, recordkeeping, pricing, advertising and promotion of products and product candidates. Failure to comply with applicable FDA or other requirements may result in Warning Letters, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market. The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. We must obtain approval of our product candidates from the FDA before we can begin marketing them in the United States. Similar approvals are also required in other countries.

Product development and approval within this regulatory framework is uncertain, can take many years and requires the expenditure of substantial resources. The necessary steps before a new biopharmaceutical product may be sold in the United States ordinarily include:

- preclinical *in vitro* and *in vivo* tests, some of which must comply with Good Laboratory Practices, or GLP;
- submission to the FDA of an IND which must become effective before clinical trials may commence, and which must be updated periodically as new information is obtained and at least annually with a report on development;
- development of a drug formulation and manufacture of the drug for clinical trials, and commercial sale, if approved;
- completion of adequate and well controlled human clinical trials to establish the safety and efficacy of the product candidate for its intended use;
- submission to the FDA of a BLA or NDA which must be accompanied by a substantial user fee unless the fee is waived;

- FDA pre-approval inspection of manufacturing facilities for current Good Manufacturing Practices, or GMP, compliance and FDA inspection of select clinical trial sites and/or trial sponsors for Good Clinical Practice, or GCP, compliance; and
- FDA review and approval of the BLA or NDA, which includes the product prescribing information, prior to any commercial sale.

Clinical Trials Regulation in the U.S.

The results of preclinical tests (which include laboratory evaluation as well as preclinical GLP studies to evaluate toxicity) for a particular product candidate, together with related manufacturing information and analytical data, and a clinical protocol are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30 day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. New clinical trial protocols can be submitted to the existing IND during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP regulations and regulations for informed consent and privacy of individually-identifiable information.

Clinical trials generally are conducted in three sequential phases that may overlap or in some instances, be skipped. In phase 1, the initial introduction of the product into humans, the product candidate is tested to assess safety, metabolism, pharmacokinetics and pharmacological actions associated with increasing doses. Phase 2 usually involves trials in a limited patient population to evaluate the efficacy of the potential product for specific, targeted indications, determine dosage tolerance and optimum dosage and further identify possible adverse reactions and safety risks. Phase 3 and pivotal trials are undertaken to evaluate further clinical efficacy and safety often in comparison to standard therapies within a broader patient population, generally at geographically dispersed clinical sites. Phase 4, or post-marketing, trials may be required as a condition of commercial approval by the FDA and may also be voluntarily initiated by us or our collaborators. Phase 1, phase 2 or phase 3 testing may not be completed successfully within any specific period of time, if at all, with respect to any of our product candidates. Similarly, suggestions of safety, tolerability or efficacy in earlier stage trials do not necessarily predict findings of safety and efficacy in subsequent trials. Furthermore, the FDA, an IRB or we may suspend a clinical trial at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical trials are subject to central registration and results reporting requirements, such as on www.clinicaltrials.gov.

Approval Process in the U.S.

The results of preclinical studies, pharmaceutical development and clinical trials, together with information on a product's chemistry, manufacturing, and controls, are submitted to the FDA, in the form of a BLA or NDA, for approval of the manufacture, marketing and commercial shipment of the pharmaceutical product. Data from clinical trials are not always conclusive and the FDA and other regulatory agencies may interpret data differently than we or our collaborators interpret data. The FDA may also convene an Advisory Committee of external advisors to answer questions regarding the approvability and labeling of an application. The FDA is not obligated to follow the Advisory Committee's recommendation. The submission of a BLA or NDA is required to be accompanied by a substantial user fee, with few exceptions or waivers. The user fee is administered under the Prescription Drug User Fee Act, or PDUFA, which sets goals for the timeliness of the FDA's review. A standard review period is twelve months from submission of an original application, while priority review is eight months from submission of an original application. The testing and approval process is likely to require substantial time, effort and resources, and there can be no assurance that any approval will be granted on a timely basis, if at all. The FDA may deny review of an application by refusing to file the application or not approve an application by issuance of a complete response letter if applicable regulatory criteria are not satisfied, require additional testing or information, or require post-market testing and surveillance to monitor the safety or efficacy of the product. Approval may occur with significant Risk Evaluation and Mitigation Strategies, or REMS, that limit the clinical use in the prescribing information, distribution or promotion of a product.

Drug or biologic products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval from the FDA upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA requires, as a condition for accelerated approval, pre-approval of promotional materials.

Once an approval is issued, the FDA may require safety-related labeling changes or withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require further testing of an approved product, including phase 4 clinical trials, and surveillance programs to monitor the safety of the approved product, and the FDA has the power to prevent or limit further marketing of the approved product based on the results of these post-marketing programs or other information.

Post-Approval Regulations in the U.S.

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including manufacture, labeling, distribution, advertising, promotion, recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion, and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA.

Manufacturers and 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 and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form FDA 483 and Warning Letters that could cause us to modify certain activities. A Form FDA 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidance. Failure to adequately and promptly correct the observations(s) can result in further regulatory enforcement action. In addition to Form FDA 483 notices and Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, not approve our products, require us to recall a product from distribution or withdraw approval of the BLA or NDA for that product. Failure to comply with ongoing regulatory obligations can result in delay of approval or Warning Letters, product seizures, criminal penalties, and withdrawal of approved products, among other enforcement remedies.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet, and off-label promotion. While physicians may prescribe products for off-label uses, manufacturers may only promote products for the approved indications and in accordance with the provisions of the approved label. The FDA has very broad enforcement authority under the Federal Food, Drug and Cosmetic Act, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing entities to correct deviations from FDA standards, and state and federal civil and criminal investigations and prosecutions.

FDA Regulation of Companion Diagnostics

Certain of our products and product candidates may rely upon in vitro companion diagnostics for use in selecting the patients that we believe will respond to our therapeutics. If safe and effective use of a therapeutic product depends on an in vitro diagnostic, the FDA generally will require approval or clearance of a reproducible, validated diagnostic test to be used with our therapeutic product at the same time that FDA approves the therapeutic product. The review of these in vitro companion diagnostics in conjunction with the review of our cancer treatments involves coordination of review by the FDA's Center for Drug Evaluation and Research and by the FDA's Center for Devices and Radiological Health. The FDA's premarket approval, or PMA, process is costly, lengthy, and uncertain. The receipt and timing of PMA approval may have a significant effect on the receipt and timing of any future commercial approvals for our products and product candidates. Human diagnostic products are subject to pervasive and ongoing regulatory obligations, including the submission of medical device reports, adherence to the Quality Systems Regulation, recordkeeping and product labeling, as enforced by the FDA and comparable state authorities.

The FDA's approval of ADCETRIS in the frontline PTCL indication included a post-marketing commitment to develop a clinically validated in-vitro diagnostic device for the selection of patients with CD30-expressing PTCL, not including sALCL, for treatment with ADCETRIS in this indication. We and Takeda have a collaboration with Ventana Medical Systems, Inc., or Ventana, under which Ventana is working to develop, manufacture and commercialize a companion diagnostic test to measure CD30 expression levels in tissue specimens. If Ventana develops an in-vitro diagnostic device that we are able to clinically validate, the FDA or another regulatory authority may revise our label for the frontline PTCL indication or in connection with any future approvals to require the use of the in-vitro test as a companion diagnostic. This may limit our ability to commercialize ADCETRIS in the applicable treatment setting due to potential label requirements, prescriber practices, constraints on availability of the diagnostic, or other factors. If Ventana is unable to successfully develop the CD30 in-vitro diagnostic, or experiences delays in doing so, or we experience delays in clinical validation of the diagnostic, we will likely need to renegotiate the timing or content of our post-marketing commitment regarding the in-vitro diagnostic device with the FDA.

Regulations Outside of the United States

In addition to regulations in the U.S., we and our collaborators are and will be subject to regulations of other countries governing clinical trials, manufacturing, distribution and commercial sales of our products. We must obtain approval by the regulatory authorities of countries outside of the U.S. before we can commence clinical trials in those countries and approval of the regulators of such countries or economic areas before we may market products in those countries or areas. For example, to commercialize TUKYSA in Europe, we will need to comply with applicable European regulations. The approval requirements and processes can vary greatly, and the time required may be longer or shorter than that required for FDA approval. Requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from place to place.

Clinical Trials Regulation in Europe

In the EU, pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the EU has been implemented through national legislation of the EU member states. Under this system, an applicant must obtain approval from the national competent authority of an EU member state in which the clinical trial is to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial at a specific study site after the independent ethics committee for each site has issued a favorable opinion. The clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the individual EU member states and further detailed in applicable guidance documents. In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It is anticipated that the new Clinical Trials Regulation (EU) No 536/2014 may come into effect in late 2021with a three-year transition period for some types of clinical trials. It will overhaul the current system of approvals for clinical trials in the EU. Specifically, the new regulation, which will be directly applicable in all EU member states, aims at simplifying and streamlining the approval of clinical trials in the EU. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single entry point and strictly defined deadlines for the assessment of clinical trial applications.

Marketing Authorization Regulation in Europe

In the European Economic Area, which is comprised of the 27 member states of the EU plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a marketing authorization through one of the following procedures: centralized, mutual recognition, and decentralized. Under the centralized procedure, a single marketing authorization application is submitted to the Committee for Medicinal Products for Human Use of the European Medicines Agency, which then makes a recommendation to the EC. The EC makes the final determination on whether to approve the application. The centralized procedure is compulsory for the approval, among others, of human medicines containing a new active substance to treat cancer. The mutual recognition and decentralized procedures provide for mutual recognition of individual national approval decisions and are available for products that are not subject to the mandatory scope of the centralized procedure. The U.K., following its exit from the EU and EEA, and Switzerland conduct separate regulatory reviews of new drug applications. Until December 31st, 2022, the U.K. will also issue national approvals via "reliance route", by recognizing the centralized EU approvals of new medicines.

For the EMA, an application designated as standard review typically lasts approximately twelve to fourteen months depending on the length of time sponsors take to address EMA questions. An accelerated assessment procedure is applicable to marketing authorization applications for medicinal products that are expected to be of major public health interest. For applications that receive accelerated assessment designation and are able to remain on this timeline, the review may last approximately seven months depending on the length of time sponsors take to address EMA questions. It is not unusual, however, for applications that receive accelerated assessment designation to revert to standard review if, for example, the EMA has determined that the significance of the questions that the company needs to address would be more appropriate under the standard review timelines. At the end of the review period, EMA will issue an opinion either in support of granting a marketing authorization (positive opinion) or recommending refusal of a marketing authorization (negative opinion). In the event of a negative opinion, the company may request a re-examination of the application. The initial marketing authorization granted in the EU is valid for five years. Once renewed, the authorization will be valid for an unlimited period, unless the national competent authority or the EC decides on justified grounds to proceed with one additional five-year renewal. The renewal of a marketing authorization is subject to a re-evaluation of the risk-benefit balance of the product by the national competent authorities or the EMA.

Post-approval Regulation in Europe

In countries where we receive regulatory approvals, we are subject to a variety of post-authorization regulations, including with respect to clinical studies, product manufacturing, advertising and promotion, distribution, and safety reporting.

Various requirements apply to the manufacturing and placing of medicinal products on the EU market. The manufacturing of medicinal products in the EU requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, or APIs, including the manufacture of APIs outside of the EU with the intention to import the APIs into the EU. Similarly, the distribution of medicinal products into and within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU member states. Marketing authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU member states' requirements applicable to the manufacturing of medicinal products.

The advertising and promotion of medicinal products are subject to EU member states' laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual EU member states may apply to the advertising and promotion of medicinal products. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our future products and impose limitations on promotional activities with health care professionals.

The holder of an EU marketing authorization for a medicinal product must also comply with the EU's pharmacovigilance legislation, which includes requirements for conducting pharmacovigilance surveillance, or the assessment and monitoring of the safety of medicinal products. The EMA reviews periodic safety update reports submitted by marketing authorization holders. If the EMA has concerns that the risk-benefit profile of a product has changed, it can adopt an opinion advising that the existing marketing authorization for the product be amended. The agency can also require that the marketing authorization holder conducts post-authorization safety studies. Non-compliance with such obligations can lead to the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures.

Healthcare Regulation

U.S. federal and state healthcare laws and regulations are also applicable to our business. If we fail to comply with those laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected. The healthcare laws and regulations that may affect our operations include, without limitation, anti-kickback and false claims laws, regulations prohibiting off-label promotion activities, and transparency laws regarding payments or other items of value provided to healthcare providers.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception 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 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 its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated. Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively PPACA, 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, PPACA 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 civil and criminal false claims laws, including the federal civil False Claims Act, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false claim to, or the knowing use of false statements to obtain payment from, or approval by, the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease, or conceal an obligation to pay money to the federal government.

The FDA and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. In recent years, private whistleblowers have also pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of off-label promotion. If we are found to have promoted an approved product for off-label uses, we may be subject to significant liability, including significant civil and administrative financial penalties and other remedies as well as criminal penalties and other sanctions. Even when a company is not determined to have engaged in off-label promotion, the allegation from government authorities or market participants that a company has engaged in such activities could have a significant impact on the company's sales, business and financial condition. The U.S. government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. Like the Anti-Kickback Statute, PPACA amended the intent standard for certain healthcare fraud under HIPAA 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.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal Physician Payments Sunshine Act, created under PPACA and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to annually report information related to certain payments or other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and to report annually certain ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information related to payments and other transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse midwives during the previous year. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures," as adjusted for inflation. Covered manufacturers are required to submit reports on aggregate payment data to the Secretary of the U.S. Department of Health and Human Services on an annual basis.

Many states have similar statutes or regulations to the above federal laws and regulations that may be broader in scope than the aforementioned federal versions and apply regardless of payor, and many of which differ from each other in significant ways and may not have the same effect, further complicating compliance efforts. Additionally, our business operations in countries outside the United States, including Canada and the EU, may subject us to additional regulation.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations were found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal and civil and/or administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, administrative burdens, imprisonment, diminished profits and future earnings, exclusion from participation in government healthcare reimbursement programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and/or the curtailment or restructuring of our operations.

Anti-Corruption Legislation

We are also subject to numerous other laws and regulations that are not specific to the healthcare industry. For instance, the U.S. Foreign Corrupt Practices Act, or FCPA, generally prohibits paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, governmental staff members, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. In Europe, national anti-corruption laws prohibit giving, offering, or promising bribes to any person, including foreign government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. Various European anti-corruption laws have broad extraterritorial reach and therefore we may be subject to those laws even if we do not have an established entity in those countries and we may be held liable for bribes given, offered or promised to any person, including private persons, by employees and persons associated with us in order to obtain or retain business or a business advantage. As we expand our footprint and activities outside of the U.S. and Canada, our exposure to compliance risks under the FCPA and other similar laws will likewise increase.

Privacy and Security Laws

There are also numerous privacy and data protection laws to which we are currently, and/or may in the future, be subject. The U.S. federal government, individual U.S. states, EU member countries and other jurisdictions, including Switzerland and Canada, have adopted data protection laws and regulations which impose significant compliance obligations. For example, the use and international transfer of personal data collected in the EU is governed by the provisions of the EU General Data Protection Regulation, or the GDPR. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the control over personal data by individuals to whom the personal data relates, the information provided to the individuals, the documentation we must maintain, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU, provides an enforcement authority and authorizes the imposition of large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the non-compliant company, whichever is greater. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information. The GDPR has increased our responsibility and potential liability in relation to all types of personal data that we process, including in clinical trials, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. However, despite our ongoing efforts to bring our practices into compliance with the GDPR, we may not be successful either due to various factors within our control or other factors outside our control. Local data protection authorities can also have different interpretations of the GDPR, leading to potential inconsistencies amongst various EU member states.

Moreover, one of the primary safeguards allowing U.S. companies to import personal information from Europe has been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of Commerce. However, the Court of Justice of the EU, or the CJEU, recently invalidated the EU-U.S. Privacy Shield. The same decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the EC's Standard Contractual Clauses, provide sufficient protection for personal data transferred from Europe to the U.S. or most other countries without analyzing each transfer and implementing supplementary measures to protect the data. Following recent recommendations from the European Data Protection Board, we are undertaking a review of personal data transfers from the EU and will assess the impact of the CJEU decision on our operations. At present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. Where appropriate, we rely on individuals' explicit consent to transfer their personal information from Europe to the U.S. and other countries. In addition, we rely on inter-company Standard Contractual Clauses to provide appropriate safeguards for such transfers. The EC is expected to publish new Standard Contractual Clauses soon and to give companies relying on them for transfers 12 months to adapt. Authorities in Switzerland, whose data protection laws are similar to those of the EU, also invalidated use of the Swiss-U.S. Privacy Shield. Authorities in the United Kingdom, or U.K., may similarly invalidate use of the EU-U.S. Privacy Shield. The U.K.'s departure from the EU, known as Brexit, has created additional uncertainty with regard to data protection regulation in the U.K., as it is unclear whether the U.K. and EU will be able to negotiate a mutually agreeable data protection agreement that regulates data transfers between the U.K. and EU and what impact this will have on our business. If we are unable to rely on explicit consent to transfer individuals' personal information from Europe, which can be revoked, or if, upon review by authorities, our existing compliance solutions are found to be insufficient, we will face increased exposure to substantial fines under European data protection laws as well as injunctions against processing personal information from persons resident in Europe. The inability to import personal information from the European Economic Area, U.K. or Switzerland could restrict our clinical trial activities in Europe, limit our ability to collaborate with contract research organizations, service providers, contractors and other companies subject to European data protection laws, interfere with our ability to hire employees in Europe and require us to increase our data processing capabilities in Europe at significant expense.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, also imposes certain requirements on certain types of individuals and entities relating to the privacy and security of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

In any event, our failure or alleged failure (including as a result of deficiencies in our policies, procedures or measures relating to privacy, data protection, marketing or communications) to comply with laws, regulations, policies, legal or contractual obligations, industry standards or regulatory guidance relating to privacy or data protection, may result in governmental investigations and enforcement actions, litigation, fines and penalties or adverse publicity. In addition, new regulation, legislative actions or changes in interpretation of existing laws or regulations regarding privacy and data protection (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new laws, regulations and industry standards relating to privacy and data protection in the U.S., the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018 and the California Privacy Rights Act of 2020, which have been characterized as "GDPR-like" privacy laws, and we cannot determine the impact such new laws, regulations and standards may have on our business.

Coverage and Reimbursement

Sales of ADCETRIS, PADCEV, TUKYSA and any future products depend, in significant part, on the extent to which the costs of our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. Patients who are prescribed treatment for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients and providers are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Pharmaceutical products are typically reimbursed based on FDA labeled indications, recognized compendia listings, available medical literature, evidence of favorable clinical outcomes, determination of medical necessity and cost effectiveness.

Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Decisions regarding the extent of coverage and amount of reimbursement to be provided for each of our product candidates is individual to each insurer, can vary based on provider contract, and will be affected by state and federal laws providing for reimbursement formulas based on acquisition cost. Third-party payors continue to work diligently to control their spending on prescription drugs and medical service. The containment of healthcare costs has become a priority of the U.S. government and abroad, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and the governments of other countries have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net sales and negatively impact our operating results. Payors, commercial and public in the U.S. and abroad, must review the therapeutic value of our products before extending coverage under their plans to reimburse our products. If third-party payors do not find a product to be of therapeutic value, they may not cover it or, if they do, they may do so at an insufficient level of payment.

Many of the patients in the U.S. who seek treatment with ADCETRIS, PADCEV or TUKYSA may be eligible for Medicare or Medicaid benefits. The Medicare and Medicaid programs are administered by the Centers for Medicare and Medicaid Services, or CMS, and coverage and reimbursement for products and services under these programs are subject to changes in CMS regulations and interpretive policy determinations, in addition to statutory changes made by Congress. For example, PPACA increased the mandated Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP, expanded the rebate to Medicaid managed care utilization and increased the types of entities eligible for the federal 340B drug discount program. Federal budget decisions have reduced Medicare payment rates, and future budget decisions may reduce Medicare payment rates again. In addition, as a condition of federal funds being made available to cover our products under Medicaid, we are required to participate in the Medicaid drug rebate program. The rebate amount under this program varies by quarter, and is based on pricing data we report to CMS. In addition, because we participate in the Medicaid drug rebate program, we must make ADCETRIS, PADCEV and TUKYSA available to authorized users of the Federal Supply Schedule of the General Services Administration. This requires compliance with additional laws and requirements, including offering ADCETRIS, PADCEV and TUKYSA at a reduced price to federal agencies including the United States Department of Veterans Affairs and United States Department of Defense, the Public Health Service and the Indian Health Service. We are also required to offer discounted pricing to certain eligible not for profit entities that are eligible for 340B pricing under the Public Health Services Act. Participation in these programs requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations and the guidance governing such calculations is not always clear. Compliance with such requirements can require significant investment in personnel, systems and resources, but failure to properly calculate our prices, or offer required discounts or rebates could subject us to substantial criminal, civil and/or administrative penalties, as well as, administrative burdens and exclusion from or contract termination regarding these programs. The terms of these government programs could change in the future which may increase the discounts or rebates we are required to offer, possibly reducing the revenue derived from sales of our products to these entities.

Policies governing drug pricing vary widely from country to country. In many European countries, authorities regulate the pricing of a pharmaceutical product at launch or subsequent to launch through direct price controls such as international reference pricing. In addition, in many European countries, pharmaceutical products are funded largely by the national healthcare systems. As a result, patients are unlikely to use a pharmaceutical product that is not reimbursed by the national authorities. There can be no assurance as to the pricing and/or level of reimbursement that may be available for our products in countries with pricing and reimbursement policies in place at the national level.

Health Technology Assessment, or HTA, of pharmaceutical products is becoming an increasingly common part of the pricing and reimbursement procedures in EU member states. The HTA process, which is governed by the national laws of the applicable country, aims to measure the added value of a new health technology compared to existing ones by assessing its public health impact, therapeutic impact and economic and societal impact in the context and setting of the individual country's national healthcare system. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost and cost-effectiveness of individual pharmaceutical products in comparison to the local standard of care, as well as their potential implications for the healthcare system. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these pharmaceutical products by the competent authorities of individual EU member states. Pursuant to Directive 2011/24/EU, a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states was established. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This could lead to harmonization between EU member states of the criteria taken into account in the conduct of HTA and their impact on pricing and reimbursement decisions.

Healthcare Reform

PPACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly affected the pharmaceutical industry. PPACA has, among other things, expanded and increased industry rebates for products covered under Medicaid programs and changed the coverage requirements under the Medicare Part D program. In order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS. The required PHS discount on a given product is calculated based on the Average Manufacturers Price, or AMP, and Medicaid rebate amounts reported by the manufacturer. PPACA expanded the types of entities eligible to receive discounted PHS pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted PHS pricing on orphan drugs when used for the orphan indication. In addition, as PHS drug pricing is determined based on AMP and Medicaid rebate data, revisions, including the AMP rule, to the Medicaid rebate formula and AMP definition described above could cause the required PHS discount to increase.

There remain judicial, executive and Congressional challenges to certain aspects of PPACA, as well as efforts to repeal or replace PPACA. While Congress has not passed comprehensive repeal legislation, the tax reform legislation signed into law on December 22, 2017 included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA 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." Based on the repeal of the individual mandate, in December 2018, a federal district court in Texas ruled that PPACA is unconstitutional. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the district court ruling that the individual mandate was unconstitutional and remanded the case back to the district court to determine whether the remaining provisions of PPACA are invalid as well. In March 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review this case, and held oral arguments in November 2020. The U.S. Supreme Court is currently reviewing the case, although it is uncertain when a decision will be made. It is also unclear how recent changes to the composition of the U.S. Supreme Court may impact its review of this case, as well as other future cases. With the change in administration, further developments with respect to PPACA are likely.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2015, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In addition, the Drug Supply Chain Security Act, or DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023.

As described above in "Coverage and Reimbursement", federal and state legislatures, governments in countries outside the U.S., health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory changes and increasing pressure from social sources are likely to further influence the manner in which our products are priced, prescribed, purchased and reimbursed. For example, the Trump administration put forth a number of proposals aimed at containing prescription drug prices and announced several Executive Orders that sought to implement a number of his administration's proposals. As a result of the Executive Orders issued by the Trump Administration, the FDA released a final rule, effective November 30, 2020, that cleared a path for importation of some Canadian drugs into the U.S. Biological products were excluded from the rule's definition of "eligible prescription drug," however TUKYSA may be subject to importation from Canada under this rule, which could negatively affect TUKYSA sales in the U.S. The Biden administration is likely to similarly pursue and implement measures aimed at reducing pharmaceutical drug pricing and containing the cost of healthcare.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many third parties compete with us in developing various approaches to treating cancer. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approval and marketing than we do. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Smaller or 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, as well as in acquiring technologies complementary to our programs.

With respect to ADCETRIS, there are several other FDA approved drugs for its approved indications. BMS's nivolumab and Merck's pembrolizumab are approved for the treatment of certain patients with relapsed or refractory classical Hodgkin lymphoma, and Celgene's romidepsin and Acrotech Biopharma's' pralatrexate and belinostat are approved for relapsed or refractory sALCL among other T-cell lymphomas. Kyowa Kirin's mogamulizumab is approved for adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome. The competition ADCETRIS faces from these and other therapies is intensifying. Additionally, Merck is conducting a phase 3 clinical trial in relapsed or refractory classical Hodgkin lymphoma comparing pembrolizumab with ADCETRIS. An interim analysis of this clinical trial demonstrated a statistically significant improvement in progression-free survival for pembrolizumab compared with ADCETRIS, resulting in a label expansion to an earlier line of therapy, and we expect increased competition from pembrolizumab in this indication. We are also aware of multiple investigational agents currently being studied that, if successful, may compete with ADCETRIS in the future. Data have also been presented on several developing technologies, including bispecific antibodies and CAR modified T-cell therapies that may compete with ADCETRIS in the future. Further, there are many competing approaches used in the treatment of patients in ADCETRIS' approved indications, including auto-HSCT, allogeneic hematopoietic stem cell transplant, combination chemotherapy, clinical trials with experimental agents and single-agent regimens.

With respect to PADCEV, other treatments in pretreated metastatic urothelial cancer include checkpoint inhibitor monotherapy, generic chemotherapy and, for patients with select fibroblast growth factor receptor genetic alterations, Janssen's erdafitinib. There are other investigational agents that, if approved, could be competitive with PADCEV, such as Gilead's' sacituzumab govitecan, which is in a pivotal phase 2 study. Treatment in frontline metastatic urothelial cancer has traditionally been treated with chemotherapy alone but is evolving to include two checkpoint inhibitor therapies for cisplatin-ineligible patients with high PD-L1 expression or patients who are ineligible for platinum therapy. Several trials of investigational agents in combination with chemotherapy or other novel agents are ongoing. Continued development of PD-(L)1 targeted therapies across early stage bladder cancer and in metastatic bladder cancer in frontline combinations with chemotherapy, in frontline maintenance with the recent approval of avelumab, and in pretreated disease, could potentially impact PADCEV usage and enrollment to PADCEV clinical trials. In addition, the competitive positioning for PADCEV will also depend on, among other things, the extent to which we and Astellas are able to obtain regulatory approvals of PADCEV in additional indications in the U.S., including in the frontline metastatic urothelial cancer setting, and in territories outside the U.S.

With respect to TUKYSA, there are multiple marketed products which target HER2, including the antibodies trastuzumab and pertuzumab and the antibody drug conjugate T-DM1. In addition, lapatinib is an EGFR/HER2 oral kinase inhibitor for the treatment of metastatic breast cancer, and neratinib is an irreversible pan-HER kinase inhibitor indicated for extended adjuvant treatment and has been recently approved for patients who have received two or more prior anti-HER2-based regimens in the metastatic setting. Daiichi Sankyo and AstraZeneca have fam-trastuzumab deruxtecan-nxki, which was recently approved for patients who have received two or more prior anti-HER2-based regimens in the metastatic breast cancer setting and also in HER2 positive gastric cancer. Byondis has an antibody drug conjugate, SYD985, in a pivotal study in this patient population and MacroGenics has a HER2 targeted, Fc-optimized antibody, margetuximab, which was recently approved by the FDA.

With respect to tisotumab vedotin, in June 2018, Merck's pembrolizumab was approved for the treatment of recurrent or metastatic cervical cancer with disease progression on or after chemotherapy in patients whose tumors express PD-L1. We are also aware of other companies that currently have products in development for the treatment of late-stage cervical cancer which could be competitive with tisotumab vedotin, including Agenus, BMS, Iovance Biotherapeutics, Merck, Regeneron Pharmaceuticals, Sanofi-Aventis and Roche.

Many other pharmaceutical and biotechnology companies are developing and/or marketing therapies for the same types of cancer that our product candidates are designed and being developed to treat. For example, we believe that companies including AbbVie, ADC Therapeutics, Affimed, Agios, Amgen, Astellas, Bayer, Biogen, BMS, Celgene, Daiichi Sankyo, Eisai, Genentech, GSK, Gilead, ImmunoGen, Infinity, Janssen, Karyopharm, MacroGenics, MedImmune, MEI Pharma, Merck, Novartis, Pfizer, Puma Biotech, Sanofi-Aventis, Spectrum Pharmaceuticals, Takeda, Teva, and Xencor are developing and/or marketing products or technologies that may compete with ours. In addition, our ADC collaborators may develop compounds utilizing our technology that may compete with product candidates that we are developing.

We are aware of other companies that have technologies that may be competitive with ours, including AbbVie, ADC Therapeutics, Astellas, AstraZeneca, BMS, Daiichi Sankyo, Gilead, ImmunoGen, Janssen, MedImmune, Merck, Mersana, Pfizer, Roche, Sutro and Zymeworks, all of which have ADC technology. ImmunoGen has several ADCs in development that may compete with our product candidates. ImmunoGen has also established partnerships with other pharmaceutical and biotechnology companies to allow those other companies to utilize ImmunoGen's technology, including Sanofi-Aventis, Genentech, Novartis, Takeda and Lilly. We are also aware of a number of companies developing monoclonal antibodies directed at the same antigen targets or for the treatment of the same diseases as our product candidates.

In addition, in the U.S., the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" or "biosimilar" to or "interchangeable" with an FDA approved biological product. This pathway allows competitors to reference the FDA's prior approvals regarding innovative biological products and data submitted with a BLA to obtain approval of a biosimilar application twelve years after the time of approval of the innovative biological product. The twelve-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. In addition, the twelve-year exclusivity period does not prevent another company from independently developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. Exclusivity only assures that another company cannot rely on the FDA's prior approvals in approving a BLA for an innovator's biological product to support the biosimilar product's approval. Further, under the FDA's current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for other indications. In the EU, the EC has granted marketing authorizations for biosimilars pursuant to a set of general and product class-specific guidelines. We are aware of many pharmaceutical and biotechnology and other companies that are actively engaged in research and development of biosimilars or interchangeable products.

It is possible that our competitors will succeed in developing technologies that are more effective than ADCETRIS, PADCEV, TUKYSA, tisotumab vedotin, or our other product candidates or that would render our technology obsolete or noncompetitive, or will succeed in developing biosimilar, interchangeable or generic products for ADCETRIS, PADCEV, TUKYSA, tisotumab vedotin or our other product candidates. We anticipate that we will continue to face increasing competition in the future as new companies enter our market and scientific developments surrounding biosimilars and other cancer therapies continue to accelerate. We cannot predict to what extent the entry of biosimilars or other competing products will impact potential future sales of ADCETRIS, PADCEV, TUKYSA, tisotumab vedotin, or our other product candidates.

With respect to our current and potential future product candidates, we believe that our ability to compete effectively and develop products that can be manufactured cost-effectively and marketed successfully will depend on our ability to:

- advance our technology platforms;
- license additional technology;
- complete clinical trials which position our products for regulatory and commercial success;
- maintain a proprietary position in our technologies and products;
- obtain required government and other public and private approvals on a timely basis;
- attract and retain key personnel;
- commercialize effectively;
- obtain reimbursement for our products in approved indications;
- comply with applicable laws, regulations and regulatory requirements and restrictions with respect to the commercialization of our products, including with respect to any changed or increased regulatory restrictions; and
- enter into additional collaborations to advance the development and commercialization of our product candidates.

Manufacturing

ADCETRIS

We rely on contract manufacturing organizations to supply ADCETRIS for our clinical trials and for commercial sale. For the monoclonal antibody used in ADCETRIS, we have contracted with AbbVie for clinical and commercial supplies. For the drug linker used in ADCETRIS, we have contracted with Millipore Sigma, a subsidiary of Merck KGaA, for clinical and commercial supplies. We have multiple contract manufacturers for conjugating the drug linker to the antibody and producing ADCETRIS drug product. In addition, we rely on other third parties to supply the raw materials used to produce ADCETRIS, and to perform additional steps in the manufacturing process, including storage and distribution of ADCETRIS and our product candidates. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce, store and distribute sufficient quantities of ADCETRIS for use in our clinical trials and for commercial sale.

AbbVie Biotechnology. In 2004, we entered into a development and supply agreement with AbbVie (formerly a part of Abbott Laboratories) to manufacture developmental, clinical and commercial quantities of anti-CD30 monoclonal antibody, which is a component of ADCETRIS. The agreement generally provides for the supply by AbbVie and the purchase by us of such anti-CD30 monoclonal antibody. Under terms of the supply agreement, we may purchase a portion of our required anti-CD30 monoclonal antibody from a second source third-party supplier. We are required to make a minimum annual purchase. The anti-CD30 monoclonal antibody is purchased by us based upon a rolling forecast. The supply agreement will continue until 2025 with an automatic one-year term extension unless either party provides written termination notice to the other party. Either party has the right to terminate the supply agreement if the other party materially breaches its obligations thereunder.

Millipore Sigma. In 2010, we entered into a commercial supply agreement with Sigma Aldrich Fine Chemicals, or SAFC, which was subsequently acquired by Millipore Sigma, an affiliate of Merck KGaA. Under this agreement, Millipore Sigma manufactures commercial quantities of the drug linker that is a component of ADCETRIS. Under terms of the supply agreement, we may purchase a portion of our required drug linker from a second source third-party supplier. We are required to make a minimum annual purchase. The drug linker is purchased by us based upon a rolling forecast. The supply agreement will continue until 2029 with automatic term extension unless either party provides written notice of termination to the other party. Either party has the right to terminate the supply agreement if the other party materially breaches its obligations thereunder.

PADCEV

Under the terms of our collaboration and commercialization agreements with Astellas, we rely on Astellas to provide commercial and clinical supply of PADCEV. For the foreseeable future, we expect to continue to rely on Astellas and other third parties to produce, store and distribute sufficient quantities of PADCEV for commercial sale and for use in our clinical trials. We believe that the existing supplies of PADCEV and Astellas' contract manufacturing relationships will be sufficient to accommodate current commercial and clinical needs. However, we or Astellas may need to obtain additional manufacturing arrangements or increase manufacturing capability to meet potential future commercial needs with respect to PADCEV, which could require additional capital investment by us or cause us potential delays if Astellas or we encounter challenges in negotiating commercially reasonable arrangements with these manufacturers. In particular, we are responsible for establishing a second source supply chain for PADCEV, whether through internal or third party sources.

TUKYSA

With respect to TUKYSA, we rely on multiple contract manufacturers and other third parties to perform manufacturing services for us including Sterling Pharma Solutions Limited, or Sterling, for production of the starting materials for TUKYSA, Esteve Quimica, S.A., or Esteve to produce the active pharmaceutical ingredient, Hovione to complete spray drying and Corden Plankstadt to produce the tablets for TUKYSA. In 2020, we entered into commercial supply agreements with each of Sterling, Esteve Quimica and Corden, and are in the process of negotiating a commercial supply agreement with Hovione. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce and store sufficient quantities of TUKYSA. We have limited prior experience as an organization manufacturing TUKYSA and small molecule drug products generally, and we have relatively new working relationships with many of the third party manufacturers involved in TUKYSA manufacture. While we believe that the existing supplies of TUKYSA will be sufficient to accommodate current clinical and forecasted commercial needs at this time, we expect that we will need to put in place additional manufacturing arrangements or expand our current manufacturing arrangements with third-party manufacturers to meet potential future commercial needs and while we are currently negotiating those arrangements, we cannot assure you that we can enter into such arrangements on commercially reasonable terms or at all.

Sterling. We have a commercial supply agreement with Sterling to manufacture starting materials for TUKYSA. The agreement provides that we will purchase starting materials pursuant to rolling forecasts and will purchase a minimum percentage of our requirements for the starting materials from Sterling. The agreement will remain in effect until 2025, after which it will continue automatically for up to two additional years subject to termination by either party giving written notice to the other party. Either party has the right to terminate the agreement if the other party commits any breach of the agreement and does not remedy, make a bona fide attempt to remedy or enter into negotiations to resolve, the breach after notice to do so, if capable of remedy.

Esteve Quimica. Our commercial supply agreement with Esteve provides that we will order the active pharmaceutical agreement for TUKYSA pursuant to rolling forecasts. The agreement will remain in effect until 2025, after which it will automatically renew subject to termination by us by giving written notice to Esteve. Either party has the right to terminate the agreement if the other party fails to cure a material breach.

Corden. We have a commercial supply agreement with Corden to produce TUKYSA tablets. The agreement provides that we will order pursuant to rolling forecasts and will purchase a minimum percentage of our requirements from Corden. The agreement will remain in effect until 2025, after which it will be renewed if not terminated with written notice prior to the expiration of the term. Either party has the right to terminate the agreement if the other party commits a breach and does not cure or commence and diligently continue actions to cure such default.

Product Candidates

For the clinical supply of our product candidates, we rely on multiple contract manufacturers and other third parties to perform manufacturing services for us. In 2017, we acquired a biologics manufacturing facility located in Bothell, Washington. While we use the facility to support our clinical supply needs, for the foreseeable future, we expect to continue to rely on contract manufacturers for much of the supply of our product candidates for our clinical trials. With respect to tisotumab vedotin, we currently rely on drug product supply provided by Genmab and have little control over their supply chains or the contract manufacturers Genmab utilizes. For the near-term, we expect to continue to rely on Genmab for manufacturing of clinical supplies of tisotumab vedotin. Under the commercialization agreement we entered into with Genmab in October 2020, we will be responsible for overseeing the clinical and commercial manufacturing supply chain of tisotumab vedotin following a transition period. We will need to obtain appropriate manufacturing arrangements and increase manufacturing capability to meet potential future commercial needs, and could experience potential delays if we encounter challenges in negotiating commercially reasonable arrangements with manufacturers or in transitioning oversight of the manufacturing process from Genmab to us.

Commercial Operations

We have allocated commercial resources, including sales, marketing, supply chain management and reimbursement capabilities, to commercialize ADCETRIS and TUKYSA in the U.S. and Canada, and PADCEV in the U.S. We believe the U.S. market for ADCETRIS, PADCEV, and TUKYSA in their approved indications, and Canadian market for ADCETRIS and TUKYSA in their approved indications, are addressable with a targeted sales and marketing organization. We intend to continue promoting our products in the U.S. and Canada for these and any additional indications we may obtain in the future. Takeda has commercial rights for ADCETRIS in the rest of the world. Takeda has received marketing authorizations by regulatory authorities for ADCETRIS in more than 75 countries outside North America, and Takeda continues to pursue marketing authorizations in other countries.

In the U.S., we sell ADCETRIS, PADCEV, and TUKYSA through a limited number of specialty distributors. Three of our major distributors, together with entities under their common control—AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation—each accounted for 10% or more of our total net product sales in 2020, 2019 and 2018. We also sell TUKYSA to a limited number of specialty pharmacies.

Health care providers purchase ADCETRIS, PADCEV, and TUKYSA through these specialty distributors and the product is drop shipped directly to the health care provider. ADCETRIS and PADCEV are infused products and generally shipped directly to health care providers and facilities for administration to patients. TUKYSA is an oral product ordered by prescription and typically dispensed to patients by the network specialty pharmacies, at physician in-office dispensing sites, or by hospital/Integrated Delivery Network pharmacies.

In Europe, we have allocated commercial resources, including sales, marketing, supply chain management and reimbursement capabilities, to support the anticipated TUKYSA commercial launches in Europe, subject to obtaining the required regulatory and pricing and reimbursement approvals.

Human Capital Resources

As of December 31, 2020, we had 2,092 employees. Of these employees, 1,246 were engaged in or support research, development and clinical activities, 382 were in administrative and business related positions, and 464 were in sales and marketing. We consider our employee relations to be good.

Diversity, Equity and Inclusion

We believe that fostering diversity, equity, and inclusion is a key element to discovering, developing, and bringing transformative therapies to patients with cancer. As of the end of 2020, 57% of our global workforce and 37% of our leadership (at the executive director level and above) were female. In addition, as of the end of 2020, 33% of our U.S. workforce and 36% of our U.S. leadership (at the executive director level and above) were racially or ethnically diverse. We strive to build a workforce representative of the people we serve and to nurture an inclusive culture where all voices are welcomed, heard, and respected. In 2020, we adopted additional initiatives to further build our capacity to meet our diversity, equity and inclusion goals.

Recruiting and Retention

We believe that we have been successful in attracting and retaining talented personnel to support our expanding business, though competition for personnel in our industry is intense. We monitor recruiting efforts using a variety of metrics such as internal placement rates, cycle times, cost per hire, information on the retention of business critical hires (such as medical directors and executives), and the percentage of budgeted openings filled on time and on budget. We also track voluntary and involuntary turnover rates for the company as a whole, for business-critical talent and by gender, race or ethnicity, time in role and job level.

Compensation and Benefits

We offer competitive pay and benefits designed to attract and retain exceptional talent and drive company performance. In setting appropriate compensation levels, we look at the average base pay rate for each position based on market data. At the time of our last annual compensation review, effective February 2020, for regular employees who were eligible for a pay increase, the average ratio of base pay to this market rate was 100%. We also offer an annual cash incentive program, a sales incentive program and long-term equity incentive plans designed to assist in attracting, retaining and motivating employees and promoting the creation of long-term value for stockholders.

Our standard employee benefits in the U.S. include paid and unpaid leaves, medical, dental and vision insurance coverage, a 401(k) plan, short- and long-term disability, life insurance, flexible spending accounts and an employee stock purchase plan. We also offer a variety of voluntary benefits that allow employees to select options that meet their needs, including telehealth, an employee assistance program, backup childcare, adoption assistance, a travel solution for nursing mothers, education assistance, fitness reimbursements, and wellness programs. We benchmark our benefits program against others in our industry on an annual basis. In addition, in 2020, we conducted an anonymous survey of U.S. employees focused on employee engagement and satisfaction with our total rewards programs.

Succession Planning and Leadership Development

We establish retention plans for our executives and other business-critical talent and review their total compensation and unvested equity annually. Succession, development, and retention plans for our executive officers are reviewed at the Board level. In addition, we hold company-wide talent-planning reviews both at the executive and departmental levels. To help accelerate the development of leaders across the company, we have established the Seagen Leadership Academy, a program that provides training, leadership opportunities, mentorship and support to high-potential talent at the director level and above.

COVID-19

We are continuing to closely monitor the impact of the evolving effects of the COVID-19 pandemic on our business. We have established a cross-functional COVID-19 working group, which meets periodically to discuss policies and protocols, strategic planning, business continuity, and other matters relating to the pandemic. We have made proactive efforts designed to protect the health and safety of our workforce, patients, and healthcare professionals, and to continue our business operations so we can advance our goal of bringing important medicines to patients. As part of these efforts, we instituted a mandatory work-from-home policy for employees who can perform their jobs offsite.

We are continuing essential research, manufacturing, and laboratory activities onsite and maintain a number of additional precautionary measures designed to protect our onsite employees. These measures include temperature checks, screening protocols, masks, social distancing, contact tracing, and making testing available. We also monitor the progress of our essential onsite activities for impacts relating to the COVID-19 pandemic.

Our field-based personnel have paused most in-person customer interactions in healthcare settings and have been using primarily electronic communications to support healthcare professionals and patients. They are engaging in limited in-person interactions where state and local laws and regulations allow, the institution or office is accepting in-person interactions and our field-based personnel are comfortable engaging in-person with healthcare providers.

We believe that the measures we have implemented are appropriate and are helping to reduce transmission of COVID-19, and we will continue to monitor conditions and related guidance from governmental authorities and adjust our activities as appropriate.

Corporate Information

We were incorporated in Delaware on July 15, 1997, as Seattle Genetics, Inc. In October 2020, we changed our corporate name from Seattle Genetics, Inc. to Seagen Inc., reflecting the global expansion of our operations. Our principal executive offices are located at 21823 30th Drive SE, Bothell, Washington 98021. Our telephone number is (425) 527-4000, and our website address is *www.seagen.com*. Seagen®, ADCETRIS®, PADCEV®, and TUKYSA® are our registered trademarks in the United States. All other trademarks, tradenames and service marks included in this Annual Report on Form 10-K are the property of their respective owners.

We file electronically with the Securities and Exchange Commission, or SEC, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at www.seagen.com, free of charge, through a hyperlink on our website, copies of these reports, as soon as reasonably practicable after electronically filing such reports with, or furnishing them to, the SEC. Information found on, or accessible through, our website is not part of, and is not incorporated into, this Annual Report on Form 10-K. In addition, the SEC maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes. If any of the events described in the following risk factors occurs, our business, operating results and financial condition could be seriously harmed. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10-K.

Risks Related to Our Products, Product Candidates and Research and Development

Our success depends on our ability to effectively commercialize our products. If we and our collaborators are unable to effectively commercialize our products and to expand their utilization, our ability to generate significant revenue and our prospects for profitability will be adversely affected.

Our three marketed products are ADCETRIS®, or brentuximab vedotin, PADCEV®, or enfortumab vedotin-ejfv, which received accelerated approval from the U.S. Food and Drug Administration, or FDA, in December 2019, and TUKYSA®, or tucatinib, which received approval from the FDA in April 2020. Our ability to generate revenue from product sales and our prospects for profitability are substantially dependent on our and our collaborators' ability to effectively commercialize ADCETRIS, PADCEV and TUKYSA and expand their utilization. We may not be able to fully realize the commercial potential of our products, or commercial sales of our products may be lower than our projections, for a number of reasons, including:

- we and our collaborators may be unable to effectively commercialize our products, including in any new markets or in any new indications for which we receive marketing approval;
- we may not be able to establish or demonstrate in the medical community the safety, efficacy or value of our products and their potential advantages compared to existing and future therapeutics in their approved indications, including, with respect to ADCETRIS, in the newly diagnosed, previously untreated Stage III and IV classical Hodgkin lymphoma indication, or the frontline Hodgkin lymphoma indication;
- we and our collaborators may not be able to obtain and maintain regulatory and other required governmental approvals to market our products for their currently approved indications in any additional territories or for any additional indications, including any additional approvals for PADCEV or TUKYSA, which would limit the sales and commercial potential of the applicable product;
- new competitive therapies in ADCETRIS' approved indications, including immuno-oncology agents such as PD-1 inhibitors (e.g., pembrolizumab and nivolumab) and other novel agents (e.g., mogamulizumab), in PADCEV's approved indication, including antibody drug conjugates (e.g., sacituzumab govitecan) and other targeted agents (e.g., erdafitinib for patients with select fibroblast growth factor receptor, or FGFR, genetic alterations), and in TUKYSA's approved indication, including HER2-targeting agents (e.g., fam-trastuzumab deruxtecan-nxki, neratinib, margetuximab and SYD985), have been approved by regulatory authorities or may be submitted in the near term to regulatory authorities for approval, and these competitive products could negatively impact commercial sales of ADCETRIS, PADCEV or TUKYSA, respectively;
- there may be changes to the labeling for our products, including ADCETRIS, PADCEV or TUKYSA, that further restrict how we market and sell our products, including as a result of data collected from any of the clinical trials that we and our collaborators are conducting or may in the future conduct for our products, or from investigator-sponsored studies of our products, and/or as a result of the use of our products in their approved indications;
- the estimated incidence rate of new patients or the duration of therapy in the approved indications for our products may be lower than our projections;
- there may continue to be adverse results or events reported in connection with the use of our products or product candidates, including in any of the clinical trials that we or our collaborators are conducting, or may conduct in the future, for our products or product candidates;

- the negative impacts to our commercialization efforts, and those of our collaborators, resulting from the risks and evolving effects of the COVID-19 pandemic may increase or become more severe;
- in the case of PADCEV, our joint commercialization efforts in the U.S. under our collaboration with an affiliate of Astellas Pharma Inc., or Astellas, may be unsuccessful or we may encounter challenges in joint decision making and joint execution that adversely affect PADCEV product sales;
- our products may be impacted by adverse reimbursement and coverage policies from government and private payors such as Medicare, Medicaid, insurance companies, health maintenance organizations and other plan administrators, or may be subject to pricing pressures enacted by industry organizations or state and federal governments, including as a result of increased scrutiny over pharmaceutical pricing or otherwise;
- the relative price of our products may be higher than alternative treatment options, and therefore their reimbursement may be limited by private and governmental insurers;
- physicians may be reluctant to prescribe our products due to side effects associated with their use or until longer term efficacy and safety data exist;
- there may be changed or increased regulatory restrictions;
- we may not have adequate financial or other resources to effectively commercialize our products; and
- we may not be able to obtain adequate commercial supplies of our products to meet demand or at an acceptable cost.

In addition, the success of our product collaborations and the activities of our collaborators will significantly impact the development and commercialization of our products. We cannot control the amount and timing of resources that our collaborators dedicate to the development and commercialization of ADCETRIS, PADCEV or TUKYSA, or to their marketing and distribution. Our ability to generate royalty revenues from ADCETRIS product sales by Takeda Pharmaceutical Company Limited, or Takeda, and TUKYSA product sales by our collaborator, a subsidiary of Merck & Co., Inc., or Merck, depends on their respective abilities to obtain regulatory approvals for ADCETRIS and TUKYSA in their territories, and to achieve market acceptance of, and to otherwise effectively market, ADCETRIS and TUKYSA in their territories. Our ability to generate revenues from PADCEV product sales in the U.S. and in Astellas' territories depends on our and Astellas' ability to effectively jointly commercialize PADCEV in the U.S, and on Astellas' ability to obtain regulatory approvals for, achieve market acceptance of, and otherwise effectively market, PADCEV in Astellas' territories. Moreover, international sales of our products could be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions or barriers and changes in tariffs, global trade and political tensions, the evolving effects of the COVID-19 pandemic or otherwise.

We are closely evaluating the impacts of the evolving effects of the COVID-19 pandemic on our ability and the ability of our collaborators to effectively market, sell and distribute our products and to develop our products and product candidates. While our field-based personnel are engaging in limited in-person interactions, they are primarily using electronic communication, such as emails, phone calls and video conferences. Many healthcare professionals that we normally call on are working a greater proportion of their working schedule from home and are facing additional demands on their time during the ongoing COVID-19 pandemic. We are experiencing increased competition for virtual appointments with healthcare professionals and a significant reduction in the number of interactions our sales personnel are having with physicians. We expect the different quality of electronic interactions as compared with in-person interactions, as well as the reduced quantity of interactions during the COVID-19 pandemic, to reduce the effectiveness of our sales personnel, as well as those of our collaborators, which could negatively affect our product sales and those of our collaborators, as well as physician awareness of our products. With respect to PADCEV and TUKYSA specifically, we have not launched a product using primarily virtual communication channels in the past and cannot predict the effects that this approach will ultimately have on demand for PADCEV or TUKYSA. However, we believe that the need to conduct these activities virtually is negatively impacting our ability to connect with key customers, including those familiar with competitive products, and our ability to conduct payor engagements. We face a number of challenges that will limit our ability to fully resume in-person interactions for the foreseeable future, including increasing COVID-19 infection rates in many states, the potential for more severe outbreaks, the need to navigate varying restrictions for entering healthcare facilities and employee childcare obligations during virtual school sessions. In addition, the effects of

the COVID-19 pandemic continue to evolve rapidly, and we may subsequently be forced to, or subsequently determine that we should, resume a more restrictive remote work model, whether as a result of further spikes or surges in COVID-19 infection or hospitalization rates or otherwise. Moreover, the long-term effects of the COVID-19 pandemic are also unknown and it is possible that following the pandemic, healthcare institutions could alter their policies with respect to in person visits by pharmaceutical company representatives. COVID-19 related restrictions could also present product distribution challenges as we utilize recently-initiated distribution channels for TUKYSA. We also expect that the conversion of medical conferences to a virtual format may reduce our ability to effectively disseminate scientific information about our products, which may result in decreased physician awareness of our products, their approved indications and their efficacy and safety. The evolving effects of the COVID-19 pandemic may also negatively affect our product sales due to challenges in patient access to healthcare settings, significant increases in unemployment and the resulting loss of individual health insurance coverage, and inability to access government healthcare programs due to backlogs, some or all of which appear to be affecting diagnosis rates and may affect side effect management, course of treatment and increase enrollment in our patient support programs. With respect to ADCETRIS specifically, impacts associated with the COVID-19 pandemic appear to be reducing the rate of Hodgkin lymphoma diagnoses, which appears to have contributed to the slower growth of ADCETRIS sales in 2020 as compared to 2019. In addition, we have experienced lower than expected levels of our research and development spending, in part as a result of the COVID-19 pandemic. This includes some delays in clinical trial enrollment as well as reduced travel due to the conversion of medical and scientific meetings to virtual format. While we do not at this time anticipate the need to revise our publicly reported projected clinical milestone dates as a result of the effects of the COVID-19 pandemic, there may be some impacts to our clinical study timelines, which, depending upon the duration and severity of the evolving effects of the COVID-19 pandemic, could ultimately delay data availability. In addition, many of our non-essential on-site research activities are currently significantly reduced as a result of the COVID-19 pandemic, which may negatively impact the number of investigational new drug application, or IND, candidates entering our clinical pipeline in future years. The extent to which the risks and evolving effects of the COVID-19 pandemic impact our business, our ability to generate sales of and revenues from our approved products, and our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate duration and severity of the pandemic, government actions, such as travel restrictions, quarantines and social distancing requirements in the U.S. and in other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and in other countries to contain and treat the disease, including the effectiveness and timing of vaccine programs in the U.S. and worldwide.

While we anticipate that sales of ADCETRIS will increase in 2021 as compared to 2020, we have experienced and expect continued impacts associated with the COVID-19 pandemic, which appear to be reducing the rate of Hodgkin lymphoma diagnoses, and an increase in gross-to-net deductions that we believe is due to a shift in the locations where ADCETRIS is administered, which has increased the proportion of ADCETRIS sales through the federal 340B drug discount program. We expect that, going forward, our ability to maintain or continue to grow our ADCETRIS sales, if at all, will depend primarily on our ability to establish or demonstrate to the medical community the value of ADCETRIS and its potential advantages compared to existing and future therapeutics in its approved indications, including in the frontline Hodgkin lymphoma indication, and the extent to which physicians make prescribing decisions with respect to ADCETRIS. Other important factors affecting our ADCETRIS sales include the incidence flow of patients eligible for treatment in ADCETRIS' approved indications, the extent to which coverage and adequate levels of reimbursement for ADCETRIS are available from governments and other third-party payors, the impact of any healthcare reform measures that may be upheld, or adopted in the future, including measures that could result in more rigorous coverage criteria or reduce the price that we receive for ADCETRIS, increasing competition from competing therapies including pembrolizumab in multiple indications, including in the relapsed or refractory classical Hodgkin lymphoma indication, impacts resulting from the evolving effects of the COVID-19 pandemic including lower diagnosis rates, and the potential future approval of ADCETRIS in any additional indications. For these reasons, we cannot assure you that ADCETRIS sales will continue to grow or that we can maintain sales of ADCETRIS at or near current levels. In addition, as a result of these and other factors, our future ADCETRIS product sales can be difficult to accurately predict from period to period.

Our ability to realize the anticipated benefits from our investment in PADCEV is subject to a number of risks and uncertainties, including our and Astellas' ability to successfully jointly market and commercialize PADCEV in the U.S. in its approved indication, the extent to which we and Astellas are able to obtain regulatory approvals of PADCEV in additional indications in the U.S., including in the frontline metastatic urothelial cancer setting, and in territories outside the U.S., our ability and Astellas' ability to successfully comply with rigorous post-marketing requirements, including obtaining the FDA's agreement as to the confirmation of clinical benefit of PADCEV based on the results of the EV-301 clinical trial, the acceptance of PADCEV by the medical community and patients, the extent to which physicians make prescribing decisions with respect to PADCEV, the incidence flow of patients eligible for treatment in PADCEV's approved indication, the duration of therapy for patients receiving PADCEV, the extent to which coverage and adequate levels of reimbursement for PADCEV are available from governments and other third-party payors, the impact of any healthcare reform measures that may be adopted in the future, including measures that could potentially result in more rigorous coverage criteria and additional downward pressure on the price that we receive for PADCEV, potential competition from competing therapies, the impact of conducting launch activities virtually during the COVID-19 pandemic and other impacts resulting from the evolving effects of the COVID-19 pandemic including potential negative impacts of reduced cancer diagnosis rates. In addition, as a result of these and other factors, including the lack of significant historical sales data, PADCEV sales are currently difficult to predict from period to period.

Our ability to realize the anticipated benefits of our investment in TUKYSA is subject to a number of risks and uncertainties, including our and Merck's ability to successfully launch, market and commercialize TUKYSA in our respective territories in its approved indication, the extent to which we and Merck are able to obtain regulatory and other required governmental and pricing and reimbursement approvals of TUKYSA in additional territories, the extent to which we and Merck are able to obtain regulatory approvals of TUKYSA in additional indications, including earlier lines of breast cancer and other HER2-positive cancers, the acceptance of TUKYSA by the medical community and patients, competition from other therapies, our and Merck's ability to accurately predict and supply product demand, the extent to which coverage and reimbursement will be available from governments and other third-party payors, our capacity to effectively commercialize a product outside of the U.S., the impact of conducting launch activities virtually during the COVID-19 pandemic and other impacts resulting from the evolving effects of the COVID-19 pandemic including potential negative impacts of reduced cancer diagnosis rates. In addition, as a result of these and other factors, including the lack of significant historical sales data, TUKYSA sales are currently difficult to predict from period to period.

Our ability to grow our product sales in future periods is also dependent on price increases, and we periodically increase the price of our products. Price increases on our products and negative publicity regarding drug pricing and price increases generally, whether on our products or products distributed by other pharmaceutical companies, could negatively affect market acceptance of, and sales of, our products. In any event, we cannot assure you that price increases we have taken or may take in the future will not in the future negatively affect our product sales.

Our success also depends on our ability to obtain regulatory approvals for our product candidates and for our current products in additional territories, as well as our ability to expand the labeled indications of use for our current products, and, if the requisite approvals are obtained, our ability to successfully launch and commercialize our products in their approved indications. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Neither we nor our collaborators are permitted to market our product candidates in the U.S. or other countries until we obtain marketing approvals from the FDA and other applicable regulatory authorities, and we or our collaborators may never receive regulatory approval for the commercial sale of any of our product candidates. Likewise, we and our collaborators are required to obtain marketing approvals from applicable regulatory authorities in order to market our products in additional territories and to expand the labeled indications of use for our current products.

We have made and are continuing to make significant investments in a number of product candidates, including tisotumab vedotin and ladiratuzumab vedotin, and in seeking additional regulatory approvals for ADCETRIS, PADCEV and TUKYSA. However, obtaining marketing approval is a lengthy, expensive and uncertain process, approval is never assured, and we have limited experience in preparing and submitting the applications necessary to gain regulatory approvals. As an organization, we have limited experience applying for regulatory approvals in jurisdictions outside the U.S. and Canada. Further, the FDA and other regulatory agencies have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for our products and product candidates, including any regulatory approvals for ADCETRIS, PADCEV or TUKYSA in additional indications or in additional territories. In this regard, even if we believe the data collected from preclinical studies or clinical trials of our products and product candidates are promising, the FDA or any other regulatory authority or their respective advisors may disagree with our interpretations of this data. For example, while we submitted a regulatory application for TUKYSA to the U.K. Medicines and Healthcare Product Regulatory Authority, or MHRA, the regulatory application we submitted may not be approved in a timely manner or at all. In addition, in September 2020, we and Astellas reported that the EV-301 trial met its primary endpoint of overall survival, and, in October 2020, we and Astellas announced positive topline results from the second cohort of patients in the EV-201 trial. Although we and Astellas plan to submit a supplemental BLA to the FDA based on the EV-301 trial as the confirmatory trial following PADCEV's accelerated approval by the FDA and the EV-301 trial is also intended to support global regulatory submissions, and although we plan to submit an sBLA based on the results of the second cohort of the EV-201 trial, regulatory authorities, including the FDA, or their advisors may disagree with our interpretation of the data from these trials. The FDA may not convert PADCEV's accelerated approval to regular approval in the U.S., and regulatory authorities may not accept or approve any other regulatory applications for PADCEV, in a timely manner or at all. In addition, although the FDA granted Breakthrough Therapy designation to PADCEV in combination with pembrolizumab, for treatment of patients with unresectable locally advanced or metastatic urothelial cancer who are unable to receive cisplatin-based chemotherapy in the first-line setting, this Breakthrough Therapy designation does not increase the likelihood that PADCEV will receive marketing approval in this indication or will otherwise receive any additional marketing approvals. Likewise, although we reported positive results from the pivotal phase 2 innovaTV 204 trial and we and Genmab A/S, or Genmab, submitted a Biologics License Application, or BLA, to the FDA seeking accelerated approval for tisotumab vedotin based on the innovaTV 204 trial, we cannot be certain that the data from the innovaTV 204 trial will be sufficient to support accelerated approval. We cannot predict whether the BLA that we and Genmab submitted for tisotumab vedotin will be accepted or approved in a timely manner or at all. We also cannot assure you that any of our product candidates will receive any marketing approvals. In fact, it is possible that none of our product candidates will ever become commercial products. As a result, we may not realize the anticipated benefits of our investments in our product candidates.

Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our products in any additional indications or territories, or of any future approved product. Regulatory agencies also may approve a product for fewer or narrower indications than requested, or with a label that includes only subtypes of a particular indication rather than a more general disease classification. In addition, our products and product candidates could take a significantly longer time to gain new or initial regulatory approvals than we expect or may never gain new or initial regulatory approvals, which could delay or eliminate any potential product revenue from sales of our product candidates or of our products in any additional indications or territories and significantly delay or prevent us from achieving profitability. In this regard, part of our growth strategy is to continue to explore the use of ADCETRIS in different CD30-expressing lymphomas, to seek approval for PADCEV in our territories outside the U.S., and to continue to explore the use of PADCEV and TUKYSA in additional indications. However, we and/or our collaborators may be unable to obtain any regulatory approvals for the commercial sale of any of our products in any additional indications or territories in a timely manner or at all. For example, as part of the Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all regulatory submissions in a given time frame. However, the FDA does not always meet its PDUFA target action dates, and if the FDA were to fail to meet its PDUFA target action date in the future for any of our future regulatory applications, the commercialization of the affected product candidate, or of the affected product in any additional indications, could be delayed or impaired. In addition, while regulatory authorities have not to date notified us of any delays in their review of our regulatory applications and we have not yet experienced any obvious delays as a result of the effects of the COVID-19 pandemic, it is possible that we could experience delays in the timing of regulatory review and/or our interactions with regulatory authorities due to reduced working hours of governmental employees or by the diversion of authorities' efforts and attention to approval of other therapeutics or other activities related to COVID-19, which could delay any approval

decisions with respect to our or Merck's regulatory applications for TUKYSA outside of the U.S., or our progress in advancing our development efforts with respect to other products and product candidates. Our interactions with regulatory authorities in other jurisdictions and across multiple products and product candidates continue but we cannot rule out the possibility of negative impacts on such interactions in the future as the effects of the pandemic continue to evolve.

Even if approved for commercial sale, our ability to realize the anticipated benefits from our investments in our product candidates and our efforts to expand the labeled indications of use and territories for our current products is subject to a number of risks and uncertainties, including our and our collaborators' ability to successfully launch, market and commercialize our products, our reliance, in the case of PADCEV and tisotumab vedotin, on Astellas and Genmab, respectively, to effectively jointly launch and commercialize PADCEV and any potential future approved tisotumab vedotin product with us, our and our collaborators' ability to successfully comply with rigorous post-marketing requirements, including confirmation of clinical benefit of PADCEV based on the results of the Phase 3 confirmatory trial, EV-301, that we and Astellas are required to complete as a result of the accelerated approval of PADCEV by the FDA, the acceptance of our approved products by the medical community and patients, and the extent to which coverage and reimbursement for our products will be available from government and health administration authorities, private health insurers and other third-party payors. For example, although PADCEV was launched in the U.S. in December 2019 and although TUKYSA was launched in the U.S. in April 2020, the launch and commercialization of these products are at an early stage and may not be successful. In addition, the impacts of the evolving effects of the COVID-19 pandemic, including potential negative impacts of reduced cancer diagnosis rates, could limit our ability to continue to effectively launch PADCEV and TUKYSA and restrictions on in-person interactions with healthcare providers will likely negatively impact our ability to connect with key customers, including those familiar with competitive products, and our ability to conduct payor engagements. If we are unable to successfully continue to launch and commercialize PADCEV jointly with Astellas in the U.S., or to successfully continue to launch and commercialize TUKYSA in the U.S., our growth prospects and our prospects for profitability would be adversely affected. Likewise, although TUKYSA received regulatory approvals in the EU and certain other countries outside the U.S. and Canada and we have submitted a regulatory application for TUKYSA to the MHRA, we have no prior experience as an organization launching or commercializing a product outside the U.S. and Canada, which could adversely affect our ability to maximize the commercial potential of TUKYSA. Further, while our TUKYSA collaboration with Merck is intended to accelerate global availability of TUKYSA, we are wholly reliant on Merck's ability to effectively launch and commercialize TUKYSA in territories outside of the U.S., Canada and Europe, and we have limited control of Merck's actions. In addition, in many countries, the proposed pricing for a drug must be approved before it may be lawfully marketed, and in some cases there are additional individual country requirements, which will delay entry of a product into a market or, if pricing is not approved, will prevent us from selling a product in a country where we have received regulatory approval. The launch of a newly approved product or of an existing product in a new market, including the launch of TUKYSA in markets where TUKYSA has obtained regulatory approval outside the U.S. and any other markets where it may receive regulatory approval, if any, could be delayed due to a variety of factors, including supply constraints, delays in arranging a commercial infrastructure, delays in obtaining pricing and reimbursement approvals or other factors, any of which risks could be heightened by the risks and the evolving effects of the COVID-19 pandemic. If we or Merck experience delays or unforeseen difficulties due to any of these factors, planned launches in the countries in question would be delayed, which could negatively impact anticipated revenue from TUKYSA. In addition, if we or Merck are unable to obtain favorable pricing and reimbursement approvals in territories that represent significant potential markets, including the EU, our anticipated revenue from and growth prospects for TUKYSA in Europe and other regions could be negatively affected.

If we or our collaborators are unable to obtain and maintain necessary or desirable regulatory approvals for our products and product candidates, including for ADCETRIS, PADCEV and TUKYSA, in a timely manner, if at all, if the FDA or other regulatory authorities do not approve product labeling that is necessary or desirable for the successful commercialization of an approved product, or if sales of an approved product do not reach the levels we expect, then our anticipated revenue from our products and product candidates and our prospects for profitability would be adversely affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Reports of adverse events or safety concerns involving our products or product candidates could delay or prevent us from obtaining or maintaining regulatory approvals or could negatively impact sales of our products or the prospects for our product candidates.

Reports of adverse events or safety concerns involving our products could interrupt, delay or halt clinical trials of our products, including the post-approval confirmatory studies that regulatory agencies have required us or our collaborators to complete. In addition, reports of adverse events or safety concerns involving our products could result in regulatory authorities requiring that we update the applicable product's prescribing information, or limiting, denying or withdrawing approval of our products for any or all indications, including previously approved indications. There are no assurances that patients receiving our products will not experience serious adverse events, including fatal events, in the future, whether the serious adverse events are disclosed in the prescribing information or are newly reported. Further, there are no assurances that patients receiving our products with co-morbid diseases not previously studied, such as autoimmune diseases, will not experience new or different serious adverse events in the future.

The prescribing information for ADCETRIS includes warnings and precautions for various toxicities, as well as a boxed warning related to the risk that JC virus infection resulting in progressive multifocal leukoencephalopathy and death can occur in patients receiving ADCETRIS. The prescribing information for PADCEV and TUKYSA also includes warnings and precautions for various toxicities and reactions, including certain fatal reactions. We may be required to update the prescribing information for our products, including boxed warnings, limitations of use, contraindications, warnings and precautions, and adverse reactions, based on reports of adverse events or safety concerns, or implement a Risk Evaluation and Mitigation Strategy, or REMS. Side effects and toxicities associated with our products could affect the willingness of physicians to prescribe, and patients to utilize, our products and thus harm commercial sales of our products. Implementation of a REMS could advantage products that compete with ours or make it more difficult or expensive for us to distribute our products.

Likewise, reports of adverse events or safety concerns involving our product candidates could interrupt, delay or halt clinical trials of our product candidates, or could result in our or our collaborators' inability to obtain regulatory approvals of our product candidates. Although we announced positive results from the innovaTV 204 trial, data continues to be generated in this trial and in other tisotumab vedotin trials. There may still be important new or evolving facts about the safety, efficacy, and risk versus benefit of each of our product candidates, including tisotumab vedotin, which may negatively impact our ability to develop and commercialize these product candidates. For example, in response to prior safety events observed in our clinical trials of PADCEV and tisotumab vedotin, including serious side effects and patient deaths, we have in the past, and may in the future, institute additional precautionary safety measures such as dosing caps and delays, enhanced monitoring for side effects, and modified patient inclusion and exclusion criteria. Additional and/or unexpected safety events could be observed in these or other trials that could delay or prevent us from advancing the clinical development of, or obtaining regulatory approvals for, our products and product candidates or require us to alter the approved labeling of our products, and may adversely affect our business, results of operations and prospects.

Concerns regarding the safety of our products or product candidates as a result of undesirable side effects identified during clinical testing or otherwise could cause the FDA to order us to cease further development or commercialization of our products or the product candidates. Undesirable side effects caused by our products or product candidates could also result in denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, the requirement of additional trials, implementation of a REMS or the inclusion of unfavorable information in our product labeling, and in turn delay or prevent us from commercializing the applicable product or product candidate. In addition, actual or potential drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial for our products or product candidates or result in potential product liability claims. Any of these events could prevent us from developing or commercializing the applicable product or product candidate, and could significantly harm our business, results of operations and prospects.

Clinical trials are expensive and time consuming, may take longer than we expect or may not be completed at all, and their outcome is uncertain.

We and our collaborators are currently conducting multiple clinical trials for our products and product candidates and plan to commence additional trials of our products and product candidates in the future. Many of these trials, including phase 3 and pivotal phase 2 trials, were initiated based on only limited clinical data and we cannot be certain that the design or conduct of, or data collected from, these trials will be sufficient to support FDA or any regulatory approvals outside the U.S.

Each of our clinical trials requires the investment of substantial expense and time and the outcome of these trials is uncertain. Later-stage clinical trials may differ in significant ways from earlier stage clinical trials and may have different outcomes. Differences in earlier- and later-stage clinical trials may include changes to inclusion and exclusion criteria, efficacy endpoints and statistical design. In this regard, despite the positive initial results we and Astellas reported from the EV-103 trial, we cannot be certain that PADCEV will demonstrate sufficient efficacy in other trials, including in the EV-302 trial, other cohorts of the EV-103 trial or any future trials or cohorts. Moreover, despite the positive initial data from the EV-103 trial, PADCEV may not demonstrate sufficient efficacy in any other clinical trials in a frontline setting and may never be approved for use in any frontline setting, which would significantly delay or prevent us from achieving profitability. Likewise, despite the positive results we reported from the HER2CLIMB trial, we cannot be certain that TUKYSA will demonstrate sufficient efficacy in other trials, including the HER2CLIMB-02 trial, and, despite the positive results we reported from the innovaTV 204 trial, we cannot be certain that tisotumab vedotin will demonstrate sufficient efficacy in other trials or will ever be approved for commercial sale. In addition, there may still be important facts about the safety, efficacy, and risk versus benefit of PADCEV, TUKYSA and tisotumab vedotin that are not known to us at this time which may negatively impact our ability to develop and commercialize PADCEV, TUKYSA or tisotumab vedotin as single agents or in combination with other agents. In this regard, in the first cohort of the EV-201 trial, there was one death due to interstitial lung disease, which occurred outside the safety-reporting period of the trial and was confounded by prolonged high-dose steroid use and suspected pneumonia, and in the initial results of the EV-103 trial, there was one death deemed to be treatment-related by the investigator, attributed to multiple organ dysfunction syndrome. There was also one death deemed to be treatment-related by the investigator in the innovaTV 204 trial. In addition, in response to prior safety events observed in our clinical trials of PADCEV and tisotumab vedotin, including serious side effects and patient deaths, we have in the past, and may in the future, institute additional precautionary safety measures such as dosing caps and delays, enhanced monitoring for side effects, and modified patient inclusion and exclusion criteria. Additional and/or unexpected safety events or our failure to generate additional efficacy data in our clinical trials that support registration could significantly impact the value of PADCEV, TUKYSA and tisotumab vedotin to our business. Many companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in late-stage clinical trials after achieving encouraging or positive results in early-stage development. We cannot be certain that we will not face similar setbacks in our ongoing or planned clinical trials, including in the ongoing pivotal trials for PADCEV and TUKYSA. If we or our collaborators fail to produce positive results in our ongoing or planned clinical trials of PADCEV, TUKYSA, tisotumab vedotin or any of our other product candidates, the development timeline and regulatory approval and commercialization prospects for PADCEV, TUKYSA, tisotumab vedotin and our other product candidates, and, correspondingly, our business, financial condition, results of operations and growth prospects, would be materially adversely affected.

The timing of the commencement, continuation and completion of each of our clinical trials may be subject to delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delays in accumulating the required number of clinical events for data analyses, delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site, and shortages of available drug supply. In the context of the COVID-19 pandemic, we are working to advance our clinical trial activities, while also actively assessing and seeking to mitigate risks to our patients, partners, employees and clinical trial site personnel. Some of the sites participating in our clinical trials are affected by site closings, reduced capacity or other effects of the COVID-19 pandemic. We are actively monitoring all clinical activities and currently are experiencing impacts to our ability to monitor patients, activate sites, screen and enroll patients, complete site monitoring and manage samples. The extent of the impact of these factors on a particular clinical trial depends on the current stage of activities at a given site, for example, study start up versus post-enrollment, and the impact on a clinical trial depends on the number of impacted sites participating in that clinical trial. In addition, we believe that rates of cancer diagnoses are lower than they would otherwise be as a result of the impacts of the COVID-19 pandemic, which may also negatively impact enrollment. While we do not at this time anticipate the need to revise our publicly reported projected clinical milestone dates as a result of the effects of the COVID-19 pandemic, there may be some impacts to our clinical study timelines, which, depending upon the duration and severity of the evolving effects of the COVID-19 pandemic, could ultimately delay data availability. In addition, our ability to recruit and retain principal investigators and site staff could be adversely impacted by the risks of exposure to COVID-19 and by the conversion of medical conferences to virtual format. Further, due to the suspension of data monitoring activities at sites that do not currently allow remote monitoring, as well as impacts on the ability to monitor patients, maintain patient treatment according to the trial protocols and to manage samples, there is also the potential of negative impacts on data quality. While we are actively utilizing digital monitoring measures and other mitigations designed to prevent negative data quality impacts, if there were in fact a negative impact on data quality, we or our collaborators could be required to repeat, extend the duration of, or increase the size of clinical trials, which could significantly delay potential commercialization and require greater expenditures. We expect that similar factors will impact clinical studies operationalized by our collaborators. We cannot at this time fully forecast the scope of impacts that the evolving effects of the COVID-19 pandemic may have on our ability to initiate trial sites, enroll and assess patients, handle the operational aspects of trials such as drug and sample management, run studies in accordance with the protocol and best practices and report trial results.

Additionally, beyond impacts related to the evolving effects of the COVID-19 pandemic, patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials, perceived side effects and the availability of alternative or new treatments. From time to time we have experienced enrollment-related delays in clinical trials, including in connection with the COVID-19 pandemic, and we will likely continue to experience similar delays in our current and future trials.

Many of our future and ongoing clinical trials are being or will be coordinated or conducted with Takeda, Astellas, Merck, Genmab, Bristol-Myers-Squibb Company, or BMS, and other collaborators, which may delay the commencement or adversely affect the continuation or completion of these trials. In addition, our collaborators have operational control over some of the studies we conduct jointly and we do not have full visibility into these studies run by our collaborators. We also depend on medical institutions to conduct our clinical trials in compliance with Good Clinical Practice, or GCP, and to the extent they fail to enroll patients for our clinical trials, fail to conduct our trials in accordance with GCP, or are delayed for a significant time in achieving full enrollment, whether due to the risks and evolving effects of the COVID-19 pandemic or otherwise, our clinical trials and regulatory filings regarding our products and product candidates may be negatively impacted including possible changes to data, results, or conclusions, increased costs, and delays to regulatory timelines, which may harm our reputation and business. In addition, we conduct clinical trials in countries outside the U.S. which may subject us to further delays and expenses as a result of increased drug shipment costs and additional regulatory requirements, as well as expose us to risks associated with different standards of medical care, and currency transactions insofar as changes in the relative value of the U.S. dollar to the local currency where the trial is being conducted may impact our actual costs. In addition, conducting clinical trials in countries that are experiencing heightened impact from the evolving effects of the COVID-19 pandemic may exacerbate these risks.

Clinical trials must be conducted in accordance with FDA or other applicable government guidelines and are subject to oversight by the FDA, other governmental agencies, including data protection authorities, the data safety monitoring boards for such trials and the IRBs or Ethics Committees for the institutions in which such trials are being conducted. In addition, clinical trials must be conducted with supplies of our products or product candidates produced under cGMP and other requirements in the country in which the trial is being conducted, and may require large numbers of test patients. We or our collaborators, the FDA, other governmental agencies or the applicable data safety monitoring boards, IRBs and Ethics Committees could delay, suspend, halt or modify our clinical trials of our products or any of our product candidates, for numerous reasons, including:

- ADCETRIS, PADCEV, TUKYSA or the applicable product candidate may have unforeseen safety issues or adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- deficiencies in the conduct of the clinical trial, including failure to conduct the clinical trial in accordance with regulatory requirements, GCP, clinical protocols or regulations relating to data protection;
- problems, errors or other deficiencies with respect to data collection, data processing and analysis;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- the time required to determine whether ADCETRIS, PADCEV, TUKYSA or the applicable product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- ADCETRIS, PADCEV, TUKYSA or the applicable product candidate may not appear to be more effective than current therapies;
- the quality or stability of ADCETRIS, PADCEV, TUKYSA or the applicable product candidate may fall below acceptable standards;
- our inability and the inability of our collaborators to produce or obtain sufficient quantities of ADCETRIS, PADCEV, TUKYSA or the applicable product candidate to complete the trials;
- our inability and the inability of our collaborators to reach agreement on acceptable terms with prospective trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites;
- our inability and the inability of our collaborators to obtain IRB or Ethics Committee approval to conduct a clinical trial at a prospective site;
- changes in governmental regulations or administrative actions that adversely affect our ability and the ability of our collaborators to continue to conduct or to complete clinical trials;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our clinical research organizations and other third parties;
- our inability and the inability of our collaborators to recruit and enroll patients to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications;
- our inability and the inability of our collaborators to retain patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up;

- our inability and the inability of our collaborators to ensure adequate statistical power to detect statistically significant treatment effects, whether through our inability to enroll or retain patients in trials or because the specified number of events designated for a completed trial have not occurred; or
- the risks and evolving effects of the COVID-19 pandemic.

In addition, we or our collaborators may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, including unexpected adverse events that may occur when our product candidates are combined with other therapies.

Negative or inconclusive clinical trial results could adversely affect our ability and the ability of our collaborators to obtain regulatory approvals of our product candidates, including tisotumab vedotin, or to market ADCETRIS, PADCEV or TUKYSA and/or expand ADCETRIS, PADCEV or TUKYSA into additional indications and territories. In addition, clinical trial results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. For example, although we reported positive results from the HER2CLIMB trial and submitted a regulatory application for TUKYSA to the MHRA, the regulatory application we submitted may not be approved in a timely manner or at all. Similarly, we and Astellas reported that the EV-301 trial met its primary endpoint of overall survival and reported positive topline results from the second cohort of patients in the EV-201 trial. However, despite these results and although we and Astellas plan to submit a supplemental BLA to the FDA based on the EV-301 trial as the confirmatory trial following PADCEV's accelerated approval by the FDA and EV-301 is also intended to support global regulatory submissions, and although we and Astellas plan to submit an sBLA to the FDA based on the results of the second cohort of the EV-201 trial, regulatory authorities, including the FDA, or their advisors may disagree with our interpretation of the data from these trials. As a result, the FDA may not convert PADCEV's accelerated approval to regular approval in the U.S., and regulatory authorities may not accept or approve any other regulatory applications for PADCEV, in a timely manner or at all. Further, although we announced positive results from the innovaTV 204 trial and we and Genmab submitted a BLA to the FDA seeking accelerated approval for tisotumab vedotin based on the results of the innovaTV 204 trial, the FDA, or its advisors, may disagree with our interpretation of the data from the innovaTV 204 trial and may otherwise determine not to accept or approve the BLA that we and Genmab submitted for tisotumab vedotin in a timely manner or at all. Likewise, although we reported positive results in our ECHELON-2 trial, regulatory agencies outside of the territories where ADCETRIS has been approved in the ECHELON-2 treatment setting, or their advisors, may disagree with Takeda's interpretations of data from the ECHELON-2 trial and may not approve the expansion of the ADCETRIS labeled indications of use to the ECHELON-2 treatment setting. Moreover, adverse medical events during a clinical trial, including patient fatalities, could cause a trial to be redone or terminated, require us to cease development of a product candidate or the further development or commercialization of ADCETRIS, PADCEV or TUKYSA, result in our failure to expand ADCETRIS, PADCEV or TUKYSA into additional indications and territories, adversely affect our ability to market ADCETRIS, PADCEV or TUKYSA, and may result in other negative consequences to us, including the inclusion of unfavorable information in our product labeling. Further, some of our clinical trials are overseen by an independent data monitoring committee, or IDMC, and an IDMC may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial. In addition, we may be required to implement additional risk mitigation measures that could require us to suspend our clinical trials if certain safety events occur.

The successful commercialization of our products and our product candidates will depend on a variety of factors, including the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies, and the acceptance of our products by the medical community and patients.

Successful sales of our current and any future approved products will depend, in part, on the extent to which coverage and reimbursement for our products will be available from government and health administration authorities, private health insurers and other third-party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of new products and require increasing levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage. In light of this pricing scrutiny, we cannot be sure that we and our collaborators will achieve and continue to have coverage available for our products and any product candidates that we or our collaborators commercialize and, if available, that the reimbursement rates will be adequate and grant access to all eligible patients. If we or our collaborators are unable to obtain coverage and adequate levels of reimbursement for our current and any future approved products that we or our collaborators commercialize, their marketability will be negatively and materially impacted. For example, we cannot be certain that third-party payors will continue to provide coverage and adequate reimbursement for ADCETRIS in the frontline Hodgkin lymphoma indication based on the relative price and perceived benefit of ADCETRIS as compared to alternative treatment options, which may materially harm our ability to maintain or increase sales of ADCETRIS or may otherwise negatively affect future ADCETRIS sales. Similarly, we cannot be certain that third-party payors will provide coverage and adequate reimbursement for PADCEV or TUKYSA based on their relative price and perceived benefits as compared to alternative treatment options or otherwise, which may materially harm our and our collaborators' ability to successfully commercialize PADCEV and TUKYSA in our respective designated territories. In addition, we have experienced an increase in gross-to-net deductions that we believe is due to a shift in the locations where ADCETRIS is administered, which has increased the proportion of ADCETRIS sales through the federal 340B drug discount program, and we may experience additional shifts from commercial payor coverage to government payor coverage in the U.S., which would further increase gross-to-net deductions.

In many jurisdictions, including in Europe, the proposed pricing for a drug must be approved in an individual country before it may be lawfully marketed, which could delay entry of a product into a market or, if pricing is not approved, may prevent us or our collaborators from selling a product in a country where we or our collaborators have received regulatory approval. In European countries where we have obtained regulatory approval of TUKYSA, we will seek pricing and reimbursement agreements for TUKYSA in accordance with local timelines. As an organization, we did not have any experience applying for pricing and reimbursement approvals in jurisdictions outside the U.S. and Canada prior to our applications with respect to TUKYSA. Further, authorities in Europe have substantial discretion in the pricing and reimbursement approval process and in determining when or whether coverage will be obtained for our products or product candidates, including any approvals for our medicines in initial and additional indications or in additional territories. In addition, in some cases, they may lower the price for a medicine after the price has been established. The launch of TUKYSA outside of the U.S. could be delayed due to a variety of factors, including supply constraints, delays in arranging a commercial infrastructure, delays encountered by our collaborator, Merck, delays in obtaining pricing and reimbursement approvals or other delays related to regulatory requirements. If we or Merck experience delays or unforeseen difficulties due to any of these factors, planned launches in the countries in question would be delayed, which could negatively impact anticipated revenue from TUKYSA. In addition, if we or Merck are unable to obtain favorable pricing and reimbursement approvals in the countries that represent significant potential markets, our anticipated revenue from and growth prospects for TUKYSA in Europe and other regions could be negatively affected.

Eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that captures the value delivered to patients, payers and the overall healthcare system, allows for continued investment in innovative treatments for cancer patients or that covers our costs, including research, development, manufacture, sale and distribution. In addition, obtaining and maintaining adequate coverage and reimbursement status is time-consuming and costly. Third-party payors may deny coverage and reimbursement status altogether of a given drug product, or cover the product but may also establish prices at levels that are too low to enable us to realize an appropriate return on our investment in product development or limit access to select patient populations reducing revenue potential. Further, in the U.S., there is no uniform policy of coverage and reimbursement among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided is made on a payor-by-payor basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Because the rules and regulations regarding coverage and reimbursement change frequently, in some cases at short notice, even when there is favorable coverage and reimbursement, future changes may occur that adversely impact the favorable status.

The unavailability or inadequacy of third-party coverage and reimbursement could have a material adverse effect on the market acceptance of our current and any future approved products and the future revenues we may expect to receive from those products. In addition, we are unable to predict what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be upheld or enacted in the future, or what effect such legislation or regulation would have on our business. Continuing negative publicity regarding pharmaceutical pricing practices and ongoing governmental and societal scrutiny create significant uncertainty regarding regulation of the healthcare industry and third-party coverage and reimbursement in the U.S. and other jurisdictions. If healthcare policies or reforms intended to curb healthcare costs are implemented or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical products generally, the prices that we charge for our current and any future approved products may be limited, our revenues from sales of our current and any future approved products may be negatively impacted.

The degree of market acceptance among patients, physicians, and third-party payors is also important to our ability to successfully commercialize our current and any future approved products. The degree of acceptance will depend on a number of factors including the clinical benefits of our products, effectiveness of our marketing, sales and distribution strategy and operations, the acceptance of our product by patients, physicians and third-party payors, the perceived advantages and relative cost, safety and efficacy of alternative treatments, and the acceptance and degree of adoption of our products by institutional treatment pathways and institutional, local, and national clinical guidelines such as the National Comprehensive Cancer Networks® Clinical Practice Guidelines in Oncology, or the NCCN Guidelines, or other country-specific guidelines. In the U.S., many oncology practices and healthcare providers rely on the NCCN Guidelines or other institutional practice pathways in decisions related to treatment of patients and utilization of medicines. To the extent that our current or any future approved products are not included or positioned favorably in such treatment guidelines and pathways, the full utilization potential of our products may not be reached, which may harm our ability to successfully commercialize our current or any future approved products. For example, in the ADCETRIS frontline Hodgkin lymphoma indication, the NCCN Guidelines have been interpreted as being more restrictive than our labeled indication and since these guidelines and related interpretations have been translated into treatment pathways for many institutions, our ability to maintain or increase sales of ADCETRIS may be materially harmed or future ADCETRIS sales may otherwise be negatively affected.

Our product candidates are in various stages of development, and it is possible that none of our product candidates will ever become commercial products.

Although we announced positive results from the innovaTV 204 trial of our late-stage product candidate, tisotumab vedotin and we and Genmab submitted a BLA to the FDA seeking accelerated approval for tisotumab vedotin, we cannot be certain that the data from the innovaTV 204 trial will be sufficient to support accelerated approval. We cannot predict whether the BLA that we and Genmab submitted for tisotumab vedotin will be accepted or approved in a timely manner or at all. Our clinical pipeline also includes ladiratuzumab vedotin, which is in phase 2 clinical development, and other product candidates that are in phase 1 clinical development. In addition, we have multiple preclinical and research-stage programs that employ our proprietary technologies. We will require significant financial resources and additional personnel in order to continue to advance the development of, pursue, potentially obtain and maintain regulatory approvals for, and potentially commercialize tisotumab vedotin, if we are able to do so at all.

If a product candidate fails at any stage of development or fails to receive regulatory approval, or we or our collaborators otherwise determine to discontinue development of that product candidate, we will not have the anticipated revenues from that product candidate to fund our operations, and we may not receive any return on our investment in that product candidate. Preclinical studies and any encouraging or positive preliminary and interim data from our clinical trials of our product candidates may not be predictive of the results of ongoing or later clinical trials. Even if we or our collaborators are able to complete our planned clinical trials of our product candidates according to our current development timeline, any encouraging or positive results from clinical trials of our product candidates in earlier stage trials may not be replicated in subsequent later-stage trials. For example, although we reported positive results from the innovaTV 204 trial of tisotumab vedotin, we cannot be certain that tisotumab vedotin will demonstrate sufficient efficacy in other trials. In addition, we are developing products and product candidates in indications in which competition is intense, and it is possible that a clinical trial we run may meet its safety and efficacy endpoints but we may choose not to advance the development and commercialization of a product or product candidate in one or more indications due to changes in the competitive environment and the rapid evolution of the standard of care. As a result, we and our collaborators may conduct lengthy and expensive clinical trials of our products and product candidates only to learn that a product or product candidate is not an effective treatment or is not superior to existing approved therapies in the applicable indication, or has an unacceptable safety profile. Any of these results could prevent or significantly delay regulatory approval for the applicable product in any additional indications or of the applicable product candidate or could cause us to discontinue or limit the further development of such product or product candidate. If we or our collaborators fail to produce positive results in our ongoing or planned clinical trials of tisotumab vedotin or any of our other product candidates, the development timeline and regulatory approval and commercialization prospects for that product candidate, and our ability to recoup our investment in that product candidate, would be materially adversely affected.

Due to the uncertain and time-consuming clinical development and regulatory approval process, we may not successfully develop any of our product candidates, or we may choose to discontinue the development of product candidates for a variety of reasons such as safety, risk versus benefit profile, exclusivity, competitive landscape, or prioritization of our resources. It is possible that none of our product candidates will ever become commercial products. In addition, we have to make decisions about which clinical stage and pre-clinical product candidates to develop and advance, and we may not have the resources to invest in certain product candidates, or clinical data and other development considerations may not support the advancement of one or more product candidates. Decision-making about which product candidates to prioritize involves inherent uncertainty, and our development program decision-making and resource prioritization decisions may not improve our results of operations or prospects or enhance the value of our common stock. Our failure to effectively advance our development programs could have a material adverse effect on our business and prospects, and cause the price of our common stock to decline. In addition, many of our non-essential on site research activities are currently significantly reduced as a result of the COVID-19 pandemic, which may negatively impact the number of IND candidates entering our clinical pipeline in future years.

Any failures or setbacks in our ADC development program or our other platform technologies could negatively affect our business and financial position.

ADCETRIS, PADCEV and our tisotumab vedotin and ladiratuzumab vedotin product candidates are all based on our antibody-drug conjugate, or ADC, technology, which utilizes proprietary stable linkers and potent cell-killing synthetic agents. Our ADC technology is also the basis of our license agreements with AbbVie Biotechnology Ltd., or AbbVie, Astellas, Genentech, Inc., a member of the Roche Group, or Genentech, GlaxoSmithKline LLC, or GSK, and Progenics Pharmaceuticals Inc., or Progenics, and our collaboration agreements with Takeda, Astellas, and Genmab. Any failures or setbacks in our ADC development program or with respect to our additional proprietary technologies, including adverse effects resulting from the use of this technology in human clinical trials and/or the imposition of clinical holds on our trials of our product candidates, could have a detrimental impact on the continued commercialization of our products in their current or any potential future approved indications and on our product candidate pipeline, as well as our ability to maintain and/or enter into new corporate collaborations regarding our ADC technology, which would negatively affect our business and financial position.

We face intense competition and rapid technological change, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many third parties compete with us in developing various approaches to treating cancer. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approval and marketing than we do. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Smaller or 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, as well as in acquiring technologies complementary to our programs.

With respect to ADCETRIS, there are several other FDA approved drugs for its approved indications. BMS's nivolumab and Merck's pembrolizumab are approved for the treatment of certain patients with relapsed or refractory classical Hodgkin lymphoma, and Celgene's romidepsin and Acrotech Biopharma's pralatrexate and belinostat are approved for relapsed or refractory systemic anaplastic large cell lymphoma, or sALCL, among other T-cell lymphomas. Kyowa Kirin's mogamulizumab is approved for adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome. The competition ADCETRIS faces from these and other therapies is intensifying. Additionally, Merck is conducting a phase 3 clinical trial in relapsed or refractory classical Hodgkin lymphoma comparing pembrolizumab with ADCETRIS. An interim analysis of this clinical trial demonstrated a statistically significant improvement in progression-free survival for pembrolizumab compared with ADCETRIS, resulting in a label expansion to an earlier line of therapy, and we expect increased competition from pembrolizumab in this indication. We are also aware of multiple investigational agents currently being studied that, if successful, may compete with ADCETRIS in the future. Data have also been presented on several developing technologies, including bispecific antibodies and CAR modified T-cell therapies that may compete with ADCETRIS in the future. Further, there are many competing approaches used in the treatment of patients in ADCETRIS' approved indications, including autologous hematopoietic stem cell transplant, allogeneic hematopoietic stem cell transplant, combination chemotherapy, clinical trials with experimental agents and single-agent regimens.

With respect to PADCEV, other treatments in pretreated metastatic urothelial cancer include checkpoint inhibitor monotherapy, generic chemotherapy and, for patients with select FGFR genetic alterations, Janssen's erdafitinib. There are other investigational agents that, if approved, could be competitive with PADCEV, such as Gilead's sacituzumab govitecan, which is in a pivotal phase 2 study. Treatment in front line metastatic urothelial cancer has traditionally been treated with chemotherapy alone but is evolving to include two checkpoint inhibitor therapies for cisplatin-ineligible patients with high PD-L1 expression or patients who are ineligible for platinum therapy. Several trials of investigational agents in combination with chemotherapy or other novel agents are ongoing. Continued development of PD-(L)1 targeted therapies across early stage bladder cancer and in metastatic bladder cancer in frontline combinations with chemotherapy, in frontline maintenance with the recent approval of avelumab, and in pretreated disease, could potentially impact PADCEV usage and enrollment to PADCEV clinical trials.

With respect to TUKYSA, there are multiple marketed products which target HER2, including the antibodies trastuzumab and pertuzumab and the antibody drug conjugate T-DM1. In addition, lapatinib is an EGFR/HER2 oral kinase inhibitor for the treatment of metastatic breast cancer, and neratinib is an irreversible pan-HER kinase inhibitor indicated for extended adjuvant treatment and has been recently approved for patients who have received two or more prior anti-HER2-based regimens in the metastatic setting. Daiichi Sankyo and AstraZeneca have fam-trastuzumab deruxtecan-nxki which was recently approved for patients who have received two or more prior anti-HER2-based regimens in the metastatic breast cancer setting and also in HER2 positive gastric cancer. Byondis has an antibody drug conjugate, SYD985, in a pivotal study in this patient population and MacroGenics has a HER2 targeted, Fc-optimized antibody, margetuximab, which was recently approved by the FDA.

With respect to tisotumab vedotin, in June 2018, Merck's pembrolizumab was approved for the treatment of recurrent or metastatic cervical cancer with disease progression on or after chemotherapy in patients whose tumors express PD-L1. We are also aware of other companies that currently have products in development for the treatment of late-stage cervical cancer which could be competitive with tisotumab vedotin, including Agenus, BMS, Iovance Biotherapeutics, Merck, Regeneron Pharmaceuticals, Sanofi-Aventis and Roche.

Many other pharmaceutical and biotechnology companies are developing and/or marketing therapies for the same types of cancer that our product candidates are designed and being developed to treat. For example, we believe that companies including AbbVie, ADC Therapeutics, Affimed, Agios, Amgen, Astellas, Bayer, Biogen, BMS, Celgene, Daiichi Sankyo, Eisai, Genentech, GSK, Gilead, ImmunoGen, Infinity, Janssen, Karyopharm, MacroGenics, MedImmune, MEI Pharma, Merck, Novartis, Pfizer, Puma Biotech, Sanofi-Aventis, Spectrum Pharmaceuticals, Takeda, Teva, and Xencor are developing and/or marketing products or technologies that may compete with ours. In addition, our ADC collaborators may develop compounds utilizing our technology that may compete with product candidates that we are developing.

We are aware of other companies that have technologies that may be competitive with ours, including AbbVie, ADC Therapeutics, Astellas, AstraZeneca, BMS, Daiichi Sankyo, Gilead, ImmunoGen, Janssen, MedImmune, Merck, Mersana, Pfizer, Roche, Sutro, and Zymeworks, all of which have ADC technology. ImmunoGen has several ADCs in development that may compete with our product candidates. ImmunoGen has also established partnerships with other pharmaceutical and biotechnology companies to allow those other companies to utilize ImmunoGen's technology, including Sanofi-Aventis, Genentech, Novartis, Takeda and Lilly. We are also aware of a number of companies developing monoclonal antibodies directed at the same antigen targets or for the treatment of the same diseases as our product candidates.

In addition, in the U.S., the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" or "biosimilar" to or "interchangeable" with an FDA approved biological product. This pathway allows competitors to reference the FDA's prior approvals regarding innovative biological products and data submitted with a BLA to obtain approval of a biosimilar application 12 years after the time of approval of the innovative biological product. The 12-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. In addition, the 12-year exclusivity period does not prevent another company from independently developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. Exclusivity only assures that another company cannot rely on the FDA's prior approvals in approving a BLA for an innovator's biological product to support the biosimilar product's approval. Further, under the FDA's current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for other indications. In the EU, the EC has granted marketing authorizations for biosimilars pursuant to a set of general and product class-specific guidelines. We are aware of many pharmaceutical and biotechnology and other companies that are actively engaged in research and development of biosimilars or interchangeable products.

It is possible that our competitors will succeed in developing technologies that are more effective than ADCETRIS, PADCEV, TUKYSA, tisotumab vedotin or our other product candidates or that would render our technology obsolete or noncompetitive, or will succeed in developing biosimilar, interchangeable or generic products for ADCETRIS, PADCEV, TUKYSA, tisotumab vedotin or our other product candidates. We anticipate that we will continue to face increasing competition in the future as new companies enter our market and scientific developments surrounding biosimilars and other cancer therapies continue to accelerate. We cannot predict to what extent the entry of biosimilars or other competing products will impact potential future sales of ADCETRIS, PADCEV, TUKYSA, tisotumab vedotin or our other product candidates.

Risks Related to Regulatory Approval and Oversight, and Other Legal Compliance Matters

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 are subject to extensive ongoing obligations and continued regulatory review from applicable regulatory agencies with respect to any product for which we have obtained regulatory approval, including ADCETRIS, PADCEV and TUKYSA in each of their approved indications, such as continued adverse event reporting requirements and the requirement to have some of our promotional materials pre-cleared by the FDA. There may also be additional post-marketing obligations, 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 accelerated approval of PADCEV included a requirement for a confirmatory trial, EV-301, to confirm the clinical benefit and provide additional long-term efficacy data that may inform product labeling. If the FDA does not agree with our interpretation of the data from this post-marketing study, it could withdraw approval of PADCEV or require the inclusion of unfavorable safety information in our product labeling, which could seriously harm our business. Moreover, in connection with PADCEV's accelerated approval, the labeling and advertising and promotion of PADCEV are subject to additional regulatory requirements, which entail significant expense and could negatively impact the commercialization of PADCEV. In addition, the use of any of our products may uncover additional adverse events that require us to update the product's prescribing information, limit or prevent that product's widespread use or that result in the withdrawal of that product from the market. Any problems with a product or any violation of ongoing regulatory obligations could result in restrictions on the applicable product, including the withdrawal of the applicable product from the market.

ADCETRIS is approved under conditional marketing authorization in relapsed Hodgkin lymphoma, relapsed cutaneous T-cell lymphoma, and in both relapsed and frontline sALCL in the EU under regulations which allow for approval of products for cancer or other serious or life threatening illnesses based on a surrogate endpoint or on a clinical endpoint other than survival or irreversible morbidity. Takeda is subject to certain post-approval requirements, including the requirement to conduct clinical trials to confirm clinical benefit. Takeda's failure to provide these additional clinical data from confirmatory studies could result in the European Commission, or EC, withdrawing approval of ADCETRIS in the EU for certain indications, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Takeda in the EU and could adversely affect our results of operations. The FDA's approval of ADCETRIS in combination with chemotherapy for patients with previously untreated CD30-expressing peripheral T-cell lymphoma, or the frontline PTCL indication, included a post-marketing commitment to develop a clinically validated in-vitro diagnostic device for the selection of patients with CD30-expressing PTCL, not including sALCL, for treatment with ADCETRIS in this indication. We and Takeda have a collaboration with Ventana Medical Systems, Inc., or Ventana, under which Ventana is working to develop, manufacture and commercialize a companion diagnostic test to measure CD30 expression levels in tissue specimens. If Ventana develops an in-vitro diagnostic device that we are able to clinically validate, the FDA or another regulatory authority may revise our label for the frontline PTCL indication or in connection with any future approvals to require the use of the in-vitro test as a companion diagnostic. This may limit our ability to commercialize ADCETRIS in the applicable treatment setting due to potential label requirements, prescriber practices, constraints on availability of the diagnostic, or other factors. If Ventana is unable to successfully develop the CD30 in-vitro diagnostic, or experiences delays in doing so, or we experience delays in clinical validation of the diagnostic, we will likely need to renegotiate the timing or content of our post-marketing commitment regarding the in-vitro diagnostic device with the FDA.

We and the manufacturers of our current and any future approved products are also required, or will be required, to comply with current Good Manufacturing Practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products and product candidates, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject an approved product, its manufacturer and the manufacturer's facilities to continual review and inspections, including periodic unannounced inspections. The subsequent discovery of previously unknown problems with our current or any future approved products, including adverse events of unanticipated severity or frequency, or problems with the facilities where our current or any future approved products are manufactured, including potential staffing shortages, production slowdowns and the extensive reliance on virtual oversight of third-party manufacturing in connection with the COVID-19 pandemic, 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, delays in regulatory timelines 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 U.S.;
- restrictions on operations, including costly new manufacturing requirements; and
- product recalls or seizures.

The policies of the FDA and other regulatory agencies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or of ADCETRIS, PADCEV or TUKYSA 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 U.S. 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.

Healthcare law and policy changes may have a material adverse effect on us.

In recent years, there have been a number of legislative and regulatory actions and executive orders that have made reforms to the U.S. healthcare system. For example, the federal government has implemented reforms to government healthcare programs in the U.S., including changes to the methods for, and amounts of, Medicare reimbursement and changes to the Medicaid Drug Rebate Program. The implementation of certain of these policy changes has decreased our revenues and increased our costs, and federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Further legislative and regulatory changes, and increasing pressure from social sources, are likely to further influence the manner in which our products are priced, reimbursed, prescribed and purchased. For example, additional reforms could result in further reductions in coverage and levels of reimbursement for our products, expansion of U.S. government rebate programs, increases in the rebates payable under these programs, requests for additional or supplemental rebates, and additional downward pressure on the prices that we and our collaborators receive for our products.

The Trump administration put forth a number of proposals aimed at containing prescription drug prices and announced several Executive Orders that sought to implement a number of the administration's proposals. For example, as a result of Executive Orders, the FDA released a final rule, effective November 30, 2020, that cleared a path for importation of some Canadian drugs into the U.S. Biological products were excluded from the rule's definition of "eligible prescription drug," however TUKYSA may be subject to importation from Canada under this rule, which could negatively affect TUKYSA sales in the U.S. We expect the Biden administration to similarly pursue and implement measures aimed at reducing pharmaceutical drug pricing. Also, in the current climate, price increases on our products and negative publicity regarding drug pricing and price increases generally, whether on our products or products distributed by other pharmaceutical companies, could negatively affect market acceptance of, and sales of, our products.

Some states are also considering legislation and ballot initiatives that would control the prices and coverage and reimbursement levels of drugs, including laws to allow importation of pharmaceutical products from lower cost jurisdictions outside the U.S. and laws intended to impose price controls on state drug purchases.

In addition, governments in countries outside the U.S. control the costs of pharmaceuticals. Many European countries and Canada have established pricing and reimbursement policies that contain costs by referencing the price of the same or similar products in other countries. In these instances, if coverage or the level of reimbursement is reduced, limited or eliminated in one or more countries, we may be unable to obtain or maintain anticipated pricing or reimbursement in other countries or in new markets. This may create the opportunity for third-party cross-border trade or may influence our decision whether to sell a product in one or more countries, thus adversely affecting our geographic expansion plans.

It is also possible that governments may take additional action to reform the healthcare system in response to the evolving effects of the COVID-19 pandemic.

We cannot assure you as to the ultimate content, timing, or effect of future healthcare law and policy changes, nor is it possible at this time to estimate the impact of any such potential changes; however, such changes or the ultimate impact of changes could materially and adversely affect our revenue or sales of our current and or potential future products, as well as those of our collaborators.

We are subject to various state, federal and international laws and regulations, including healthcare laws and regulations, that may impact our business and could subject us to significant fines and penalties or other negative consequences.

Our operations may be directly or indirectly subject to various healthcare laws, including, without limitation, the federal Anti-Kickback Statute, federal civil and criminal false claims laws, regulations prohibiting off-label promotions and federal transparency requirements. These laws may impact, among other things, the sales, marketing and education programs for ADCETRIS, PADCEV, TUKYSA and any future approved products.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration not intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a conviction for violation of the federal Anti-Kickback Statute requires mandatory exclusion from participation in federal healthcare programs.

The federal civil and criminal false claims laws, including the civil False Claims Act, prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false claim to, or the knowing use of false statements to obtain payment from or approval by the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease, or conceal an obligation to pay money to the federal government. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper marketing, promotion or other activities.

The FDA and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. In recent years, private whistleblowers have also pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of off-label promotion. If we are found to have promoted an approved product for off-label uses, we may be subject to significant liability, including significant civil and administrative financial penalties and other remedies as well as criminal penalties and other sanctions. Even when a company is not determined to have engaged in off-label promotion, the allegation from government authorities or market participants that a company has engaged in such activities could have a significant impact on the company's sales, business and financial condition. The U.S. government has also required companies to enter into complex corporate integrity agreements, deferred prosecution agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies.

The federal transparency requirements under the Physician Payments Sunshine Act require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to annually report information related to certain payments or other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and to report annually certain ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information related to payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse midwives during the previous year. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year plus up to an aggregate of $1 million per year for "knowing failures," as adjusted for inflation.

Other healthcare laws and regulations that may affect our ability to operate include, among others, the federal civil monetary penalties statute and the federal Health Insurance Portability and Accountability Act, or HIPAA. In addition, many states and jurisdictions outside the U.S. have similar laws and regulations, such as anti-kickback, anti-bribery and corruption, false claims and transparency, to which we are currently and/or may in the future, be subject. Additional information about these requirements is provided under "Government Regulation – Healthcare Regulation" above. In addition, the number and complexity of healthcare laws and regulations applicable to our business continue to increase.

We are also subject to numerous other laws and regulations that while not specific to the healthcare industry, do apply to the healthcare industry in important ways. For instance, the U.S. Foreign Corrupt Practices Act, or FCPA, generally prohibits paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, governmental staff members, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. In Europe, national anti-corruption laws prohibit giving, offering, or promising bribes to any person, including foreign government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. Various European anti-corruption laws have broad extraterritorial reach and therefore we may be subject to those laws even if we do not have an established entity in those countries and we may be held liable for bribes given, offered or promised to any person, including private persons, by employees and persons associated with us in order to obtain or retain business or a business advantage. As we expand our footprint and activities outside of the U.S. and Canada, our exposure to compliance risks under the FCPA and other similar laws will likewise increase.

In an effort to comply with these laws and regulations, we have implemented a compliance program designed to actively identify, prevent and mitigate risk through the implementation of compliance policies and systems and by promoting a culture of compliance. We also actively work to revise and evolve our compliance program in an effort to keep pace with evolving compliance risks and the growing scale of our business. Although we take our obligation to maintain our compliance with these various laws and regulations seriously and our compliance program is designed to detect and prevent the violation of these laws and regulations, we cannot guarantee that our compliance program will be sufficient or effective, that we will be able to integrate the operations of newly formed affiliates or acquired businesses into our compliance program on a timely basis, that our employees will comply with our policies and that our employees will notify us of any violation of our policies, that we will have the ability to take appropriate and timely corrective action in response to any such violation, or that we will make decisions and take actions that will necessarily limit or avoid liability for whistleblower claims that individuals, such as employees or former employees, may bring against us or that governmental authorities may prosecute against us based on information provided by individuals. If we are found to be in violation of any of the laws and regulations described above or other applicable state and federal healthcare laws, we may be subject to penalties, including significant civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, administrative burdens, imprisonment, diminished profits and future earnings, exclusion from government healthcare reimbursement programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and/or the curtailment or restructuring of our operations, any of which could have a material adverse effect on our business, results of operations and growth prospects. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal, state and healthcare laws outside the U.S. is costly and time-consuming for our management.

We are subject to evolving privacy and security laws, and our failure to comply could result in penalties and reputational damage.

We are subject to numerous privacy and data protection laws and regulations governing healthcare and other information. The U.S. federal government, individual U.S. states, EU member countries and other jurisdictions, including Switzerland and Canada, have adopted data protection laws and regulations which impose significant compliance obligations. For example, the use and international transfer of personal data collected in the EU is governed by the provisions of the EU General Data Protection Regulation, or the GDPR. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the control over personal data by individuals to whom the personal data relates, the information provided to the individuals, the documentation we must maintain, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU, provides an enforcement authority and authorizes the imposition of large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the non-compliant company, whichever is greater. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information. The GDPR has increased our responsibility and potential liability in relation to all types of personal data that we process, including in clinical trials, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. However, despite our ongoing efforts to bring our practices into compliance with the GDPR, we may not be successful either due to various factors within our control or other factors outside our control. Local data protection authorities can also have different interpretations of the GDPR, leading to potential inconsistencies amongst various EU member states.

Moreover, one of the primary safeguards allowing U.S. companies to import personal information from Europe has been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of Commerce. However, the Court of Justice of the EU, or the CJEU, recently invalidated the EU-U.S. Privacy Shield. The same decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the EC's Standard Contractual Clauses, provide sufficient protection for personal data transferred from Europe to the U.S. or most other countries without analyzing each transfer and implementing supplementary measures to protect the data. Following recent recommendations from the European Data Protection Board, we are undertaking a review of personal data transfers from the EU and will assess the impact of the CJEU decision on our operations. At present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. Where appropriate, we rely on individuals' explicit consent to transfer their personal information from Europe to the U.S. and other countries. In addition, we rely on inter-company Standard Contractual Clauses to provide appropriate safeguards for such transfers. The EC is expected to publish new Standard Contractual Clauses soon and to give companies relying on them for transfers 12 months to adapt. Authorities in Switzerland, whose data protection laws are similar to those of the EU, also invalidated use of the Swiss-U.S. Privacy Shield. Authorities in the United Kingdom, or U.K., may similarly invalidate use of the EU-U.S. Privacy Shield. The U.K.'s departure from the EU, known as Brexit, has created additional uncertainty with regard to data protection regulation in the U.K., as it is unclear whether the U.K. and EU will be able to negotiate a mutually agreeable data protection agreement that regulates data transfers between the U.K. and EU and what impact this will have on our business. If we are unable to rely on explicit consent to transfer individuals' personal information from Europe, which can be revoked, or if, upon review by authorities, our existing compliance solutions are found to be insufficient, we will face increased exposure to substantial fines under European data protection laws as well as injunctions against processing personal information from persons resident in Europe. The inability to import personal information from the European Economic Area, U.K. or Switzerland could restrict our clinical trial activities in Europe, limit our ability to collaborate with contract research organizations, service providers, contractors and other companies subject to European data protection laws, interfere with our ability to hire employees in Europe and require us to increase our data processing capabilities in Europe at significant expense.

In addition, in the U.S., HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, governs certain types of individuals and entities with respect to the conduct of certain electronic healthcare transactions and imposes certain obligations on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their subcontractors that use, disclose, access, or otherwise process individually identifiable health information, with respect to the security, privacy and transmission of individually identifiable health information. HIPAA applies to certain aspects of our business and failure to comply with its requirements could result in the imposition of fines and penalties, and additional negative consequences.

In any event, our failure or alleged failure (including as a result of deficiencies in our policies, procedures or measures relating to privacy, data protection, marketing or communications) to comply with laws, regulations, policies, legal or contractual obligations, industry standards or regulatory guidance relating to privacy or data protection, may result in governmental investigations and enforcement actions, litigation, fines and penalties or adverse publicity. In addition, new regulation, legislative actions or changes in interpretation of existing laws or regulations regarding privacy and data protection, together with applicable industry standards, may increase our costs of doing business. In this regard, we expect that there will continue to be new laws, regulations and industry standards relating to privacy and data protection in the U.S., the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018 and the California Privacy Rights Act of 2020, which have been characterized as "GDPR-like" privacy laws, and we cannot determine the impact such new laws, regulations and standards may have on our business.

As we continue to expand our operations internationally, we are subject to an increased risk of conducting activities in a manner that violates applicable anti-bribery or anti-corruption laws. We are also subject to laws and regulations covering data privacy and the protection of health-related and other personal information. These laws and regulations could create liability for us or increase our cost of doing business, any of which could have a material adverse effect on our business, results of operations and growth prospects.

We are continuing to expand our operations internationally, and are building a commercial infrastructure in Europe. In this regard, we currently have multiple subsidiaries in jurisdictions outside the U.S., including a number of subsidiaries in Europe, and plan in the future to have subsidiaries in additional jurisdictions. Our business activities outside of the U.S. are and will continue to be subject to the FCPA, which is described above, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we currently and may in the future operate, including the recently established French Anti-corruption Law on Transparency, Fight against Corruption and the Modernization of the Economy, referred to as Sapin II. In Europe, national anti-corruption laws prohibit giving, offering, or promising bribes to any person, including foreign government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. Various European anti-corruption laws have broad extraterritorial reach and therefore we may be subject to those laws even if we do not have an established entity in those countries and we may be held liable for bribes given, offered or promised to any person, including private persons, by employees and persons associated with us in order to obtain or retain business or a business advantage. In the course of expanding our operations internationally, we will need to establish and expand business relationships with various third parties, such as independent contractors, distributors, vendors, and advocacy groups, and we will interact with physicians, which are generally considered foreign officials in Europe, as well as with regulatory authorities who may be deemed to be foreign officials under the FCPA or similar laws of other countries that may govern our activities. Any interactions with any such parties or individuals that are found to be in violation of such laws could result in substantial fines and penalties and could materially harm our business. Furthermore, any finding of a violation under one country's laws may increase the likelihood that we will be prosecuted and be found to have violated another country's laws. If our business practices outside the U.S. are found to be in violation of the FCPA, the Sapin II or other similar laws, we may be subject to significant civil and criminal penalties which could have a material adverse effect on our business, results of operations and growth prospects. We are also subject to laws and regulations covering data privacy and the protection of health-related and other personal information. In this regard, EU member states and other jurisdictions outside the U.S., including Switzerland, have adopted data protection laws and regulations, such as the GDPR, which impose significant compliance obligations. Failure to comply with these laws could lead to government enforcement actions and significant penalties against us, which could have a material adverse effect on our business, results of operations and growth prospects.

Enhanced governmental and private scrutiny over, or investigations or litigation involving, pharmaceutical manufacturer donations to patient assistance programs offered by charitable foundations may require us to modify our programs and could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

We have a patient assistance program and also occasionally make donations to independent charitable foundations that help financially needy patients. These types of programs designed to assist patients in affording pharmaceuticals have become the subject of scrutiny. In recent years, some pharmaceutical manufacturers were named in class action lawsuits challenging the legality of their patient assistance programs and support of independent charitable patient support foundations under a variety of federal and state laws. Our patient assistance program and support of independent charitable foundations could become the target of similar litigation. At least one insurer also has directed its network pharmacies to no longer accept manufacturer co-payment coupons for certain specialty drugs the insurer identified. In addition, certain state and federal enforcement authorities and members of Congress have initiated inquiries about co-pay assistance programs. Some state legislatures have also been considering proposals that would restrict or ban co-pay coupons.

In addition, there has been regulatory review and enhanced government scrutiny of donations by pharmaceutical companies to patient assistance programs operated by charitable foundations. For example, the HHS Office of Inspector General has established specific guidelines permitting pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria, and do not link aid to use of a donor's product. If we or our vendors or donation recipients are deemed to fail to comply with laws or regulations in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. Further, numerous organizations, including pharmaceutical manufacturers, have received subpoenas from the U.S. Department of Justice and other enforcement authorities seeking information related to their patient assistance programs and support, and certain of these organizations have entered into significant civil settlements with applicable enforcement authorities. In connection with these civil settlements, the U.S. government has and may in the future require the affected companies to enter into complex corporate integrity agreements that impose significant reporting and other requirements on those companies. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

Product liability and product recalls could harm our business, and we may not be able to obtain adequate insurance to protect us against product liability losses.

The current and future use of our products and product candidates by us and our corporate collaborators in clinical trials and the sale of our products, expose us to product liability claims. These claims have and may in the future be made directly by patients or healthcare providers or indirectly by pharmaceutical companies, our corporate collaborators or others selling such products. Additionally, in connection with our acquisition of the manufacturing facility from BMS, we agreed to enter into certain transitional services agreements under which we manufactured certain clinical drug product components for BMS for a period of time. As a result, it is possible that we may be named as a defendant in product liability suits that may allege that drug products we manufactured for BMS have resulted in injury to patients. We may experience substantial financial losses in the future due to product liability claims. We have obtained product liability coverage, including coverage for human clinical trials and product sold commercially. However, such insurance is subject to coverage limits and exclusions, as well as significant deductibles. In addition, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against all losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured amounts, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Product recalls may be issued at our discretion, or at the discretion of government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell our products for some time and by adversely affecting our reputation.

Our operations involve hazardous materials and are subject to environmental, health and safety controls and regulations.

We are subject to environmental, health and safety laws and regulations, including those governing the use of hazardous materials, and we spend considerable time complying with such laws and regulations. Our business activities involve the controlled use of hazardous materials and although we take precautions to prevent accidental contamination or injury from these materials, we cannot completely eliminate the risk of using these materials. In addition, with respect to our manufacturing facility, we may incur substantial costs to comply with environmental laws and regulations and may become subject to the risk of accidental contamination or injury from the use of hazardous materials in our manufacturing process. It is also possible that our manufacturing facility may expose us to environmental liabilities associated with historical site conditions that we are not currently aware of and did not cause. In this regard, some environmental laws impose liability for contamination on current owners and operators of affected sites, regardless of fault. In the event of an accident or environmental discharge, or new or previously unknown contamination is discovered or new cleanup obligations are otherwise imposed in connection with any of our currently or previously owned or operated facilities, we may be held liable for any resulting damages, which may materially harm our business, financial condition and results of operations.

Changes in funding for the FDA, the SEC and other government agencies, or reduced working hours of governmental employees or by the diversion of the efforts and attention of governmental agencies to approval of other therapeutics or other activities related to the COVID-19 pandemic, could prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal 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 payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the FDA, the U.S. Securities and Exchange Commission, or SEC, and other government agencies on which our operations may rely is inherently fluid and unpredictable. With respect to the COVID-19 pandemic, it is possible that we could experience delays in the timing of regulatory review and/or our interactions with regulatory authorities due to reduced working hours or absenteeism of governmental employees or by the diversion of authorities' efforts and attention to approval of other therapeutics or other activities related to COVID-19, which could delay any approval decision with respect to the regulatory application we submitted to the MHRA for TUKYSA, or our progress in advancing our development efforts with respect to other products and product candidates. Our interactions with regulatory authorities in other jurisdictions and across multiple products and product candidates continue but we cannot rule out the possibility of negative impacts on such interactions in the future as the pandemic continues to evolve.

Disruptions at the FDA and other agencies may 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 and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could potentially impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Reliance on Third Parties

We depend on collaborative relationships with other companies to assist in the development and commercialization of our products and some of our product candidates and for the development and commercialization of other product candidates utilizing or incorporating our technologies. If we are not able to locate suitable collaborators or if our collaborators do not perform as expected, this may negatively affect our ability to commercialize our products, develop and commercialize our product candidates and/or generate revenues through technology licensing, or may otherwise negatively affect our business.

We have established collaborations with third parties to develop and market each of our products and some of our current and future product candidates. Because control of development and commercialization is shared with our collaborators under these collaborations, we do not have sole discretion and control over the development and commercialization of the applicable products and product candidates. For example, we entered into a collaboration agreement with Takeda in December 2009 that granted Takeda rights to develop and commercialize ADCETRIS outside of the U.S. and Canada, and we entered into a collaboration agreement with Merck in September 2020 that granted Merck rights to develop and commercialize TUKYSA outside of the U.S., Canada and Europe. In addition, we have entered into collaborations with Astellas for the development and commercialization of PADCEV, with Genmab for the development and commercialization of tisotumab vedotin, and with Merck for the development and commercialization of ladiratuzumab vedotin. Our collaborations also include clinical trial collaborations to develop, in combination, our product or product candidates and the products or product candidates of one or more third parties. For example, we have clinical trial collaborations with BMS to evaluate the combination of nivolumab with ADCETRIS in various settings and with Merck to evaluate the combination of pembrolizumab in combination with PADCEV in various settings.

We also have ADC license agreements with AbbVie, Astellas, Genentech, Genmab, GSK and Progenics to allow them to use our proprietary ADC technology, and our ADC licensees conduct all research, product development, manufacturing and commercialization of any product candidates under these agreements.

Our dependence on collaborative arrangements to assist in the development and commercialization of our products and some of our product candidates and on license arrangements for the development and commercialization of other product candidates utilizing or incorporating our technologies subjects us to a number of risks, including:

- we are not able to control the amount and timing of resources that our collaborators and licensees devote to the development or commercialization of products and product candidates under a collaboration or license agreement, including ADCETRIS, PADCEV, TUKYSA and tisotumab vedotin;
- disputes may arise between us and our collaborators or licensees that result in the delay or termination of the research, development or commercialization of the applicable products and product candidates or that result in costly litigation or arbitration that diverts management's attention and resources;
- with respect to collaborations under which we have an active role, we may have differing opinions, processes or priorities than our collaborators, or we may encounter challenges in joint decision making and joint execution, including with respect to any joint development or commercialization plans or co-promotion activities, which may delay or otherwise harm the research, development, launch or commercialization of the applicable products and product candidates, including ADCETRIS, PADCEV, TUKYSA and tisotumab vedotin;
- our current and potential future collaborators and licensees 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, use standards or processes for conducting clinical trials that differ from ours or require a new formulation of a product candidate for clinical testing;
- significant delays in the development of product candidates by current and potential collaborators and licensees could allow competitors to bring products to market before product candidates utilizing or incorporating our technologies are approved and impair the ability of current and potential future collaborators and licensees to effectively commercialize these product candidates;

- our relationships with our collaborators and licensees may divert significant time and effort of our scientific staff and management team and require the effective allocation of our resources to multiple internal collaborative projects;
- our current and potential future collaborators and licensees may not pursue regulatory approvals in a timely manner, may not be successful in their efforts to obtain regulatory approvals, or may not launch or commercialize a product in their territories in a timely manner;
- our current and potential future collaborators and licensees may receive regulatory sanctions relating to other aspects of their business, or could take actions with respect to our jointly-developed product, that could adversely affect the development, approval or commercialization of the applicable products or product candidates or our reputation with regulatory agencies;
- our current and potential future collaborators and licensees 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 proprietary information or expose us to potential litigation;
- business combinations or significant changes in a collaborator's or licensee's business strategy may adversely affect such party's willingness or ability to complete its obligations under any arrangement;
- a collaborator or licensee could independently move forward with competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborators that are developed by such collaborator or licensee either independently or in collaboration with others, including our competitors;
- our current and potential future collaborators and licensees may experience financial difficulties; and
- our collaboration or license agreements may be terminated, breached or allowed to expire, or our collaborators or licensees may reduce the scope of our agreements with them, which could have a material adverse effect on our financial position by reducing or eliminating the potential for us to receive technology access and license fees, milestones and royalties, and/or reimbursement of development costs, and which could require us to devote additional efforts and to incur the additional costs associated with pursuing internal development and commercialization of the applicable products and product candidates.

If our collaborative and license arrangements are not successful as a result of any of the above factors, or any other factors, then our ability to advance the development and commercialization of the applicable products and product candidates and to otherwise generate revenue from these arrangements and to become profitable will be adversely affected, and our business and business prospects may be materially harmed. In particular, if Takeda or Merck were to terminate the ADCETRIS collaboration or the TUKYSA collaboration, respectively, which they may do for any reason upon prior written notice to us, we would not receive milestone payments, co-funded development payments or royalties for the sale of ADCETRIS outside the U.S. and Canada or for TUKYSA outside the U.S., Canada and Europe. As a result of any such termination, we may have to engage another collaborator to complete the ADCETRIS or TUKYSA development process and to commercialize ADCETRIS or TUKYSA in our collaborators' current territories, or to complete the development process and undertake commercializing ADCETRIS or TUKYSA in our collaborators' current territories ourselves, either of which could significantly delay the continued development and commercialization of ADCETRIS or TUKYSA and increase our costs. Similarly, Astellas, Genmab and Merck each have the right to opt out of their co-development obligations relating to PADCEV, tisotumab vedotin and ladiratuzumab vedotin, respectively. If Astellas, Genmab or Merck were to opt out of their co-development collaborations with us, this would significantly delay the commercialization and development of PADCEV or the development of tisotumab vedotin or ladiratuzumab vedotin, as applicable, and increase our costs. Any of these events could significantly harm our financial position, adversely affect our stock price and require us to incur all the costs of developing and commercializing the applicable product or product candidate, which would otherwise be co-funded by our collaboration partners. Moreover, in the case of PADCEV and tisotumab vedotin, the success of PADCEV and any approved tisotumab vedotin product will depend, in part, on our ability to effectively jointly commercialize PADCEV and tisotumab vedotin with Astellas and Genmab, respectively, in accordance with our joint commercialization obligations and joint commercialization plans. The success, if any, of our joint commercialization efforts with Astellas and Genmab, as well as the activities of Astellas and Genmab, will significantly impact the commercialization of PADCEV and the potential future commercialization of an approved tisotumab vedotin product, respectively. The product candidates being developed under our collaboration and license agreements are in various stages of development and we cannot guarantee that any of the product candidates under our collaborations will be successful. In this regard, certain of our ADC licensees have advanced product candidates utilizing or incorporating our ADC technology to later stage clinical trials that were not successful. In the future, we may not be able to locate third-party collaborators to assist in commercializing any future products in regions outside the U.S., and we may lack the capital and resources necessary to market these products in certain regions outside the Unites States alone.

We currently rely on third-party manufacturers and other third parties for production of our drug products and our dependence on these manufacturers may impair the continued development and commercialization of our products and product candidates.

Although we own a biologics manufacturing facility located in Bothell, Washington, we rely and expect to continue to rely on corporate collaborators and contract manufacturing organizations to supply drug product for commercial supply and our IND-enabling studies and clinical trials.

For the monoclonal antibody used in ADCETRIS, we have contracted with AbbVie for clinical and commercial supplies. For the drug linker used in ADCETRIS, we have contracted with Millipore Sigma, an affiliate of Merck KGaA, for clinical and commercial supplies. We have multiple contract manufacturers for conjugating the drug linker to the antibody and producing the ADCETRIS product. We rely on Astellas to supply PADCEV for our clinical trials and for commercial sale, and Astellas oversees the manufacturing supply chain for PADCEV. With respect to TUKYSA, we rely on multiple contract manufacturers and other third parties to perform manufacturing services for us including Sterling Pharma Solutions Limited for production of the starting materials for TUKYSA, Esteve Quimica to produce the active pharmaceutical ingredient, Hovione to complete spray drying and Corden Plankstadt to produce the tablets for TUKYSA. We have entered into commercial supply agreements with each of Sterling, Esteve Quimica and Corden, and are in the process of negotiating a commercial supply agreement with Hovione. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce and store sufficient quantities of ADCETRIS and TUKYSA, and on Astellas and other third parties to produce and store sufficient quantities of PADCEV, for use in our clinical trials and for commercial sale. If our contract manufacturers, collaborators or other third parties fail to deliver our products for clinical use or sale on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may bear costly losses or be required to delay or suspend clinical trials or otherwise discontinue development, production

and sale of our products. With respect to TUKYSA specifically, we have limited prior experience as an organization manufacturing TUKYSA and small molecule drug products generally, and have relatively new working relationships with many of the third-party manufacturers involved in TUKYSA manufacture. These factors increase the chance that we could encounter manufacturing challenges that could increase our costs, cause delays or otherwise negatively impact our business. Moreover, there are a limited number of facilities in which each of our products can be produced, and any interruption of the operation of those facilities due to the risks and evolving effects of the COVID-19 pandemic or other events such as equipment malfunction or failure or damage to the facility by natural disasters or as the result of regulatory actions or contractual disputes could result in the cancellation of shipments, loss of product in the manufacturing process, a shortfall in product supply, or limit our or our collaborators' ability to sell our products. Further, we and our collaborators depend on outside vendors for the supply of raw materials used to produce our products. If the third-party suppliers were to cease production or otherwise fail to supply us or our collaborators with quality raw materials and we or our collaborators were unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have our products manufactured to meet clinical and commercial requirements would be adversely affected. While we believe that the existing supplies of PADCEV and Astellas' contract manufacturing relationships will be sufficient to accommodate current clinical and commercial needs, we or Astellas may need to obtain additional manufacturing arrangements or increase manufacturing capability to meet potential future commercial needs with respect to PADCEV, which could require additional capital investment by us or cause us potential delays if Astellas encounters challenges in negotiating commercially reasonable arrangements with these manufacturers. While we believe that the existing supplies of TUKYSA will be sufficient to accommodate current clinical and forecasted commercial needs at this time, we expect that we will need to put in place additional manufacturing arrangements or expand our current manufacturing arrangements with third-party manufacturers to meet potential future commercial needs and while we are currently negotiating those arrangements, we cannot assure you that we can enter into such arrangements on commercially reasonable terms or at all. Forecasting demand for a new product can be challenging and in the event demand for TUKYSA exceeds our estimates or in the event that our commercial manufacturers of TUKYSA encounter unexpected failures or setbacks in completing manufacturing services in accordance with applicable quality standards, our TUKYSA launch in the U.S. could be negatively impacted by short-term product supply challenges, which would adversely impact our TUKYSA revenues and could negatively affect our relationships with patients and healthcare professionals. In addition, any failures or delays in manufacturing adequate product supplies and in putting in place or expanding our manufacturing and supply infrastructure could delay or impede our and Merck's ability to launch and commercialize TUKYSA in any markets outside the U.S. where TUKYSA has obtained regulatory approval and any additional markets where it may obtain regulatory approval, if any. While we do not currently anticipate disruptions to the supply of our products due to the evolving effects of the COVID-19 pandemic, if the COVID-19 pandemic continues for an extended period of time or the effects of the COVID-19 pandemic become more severe, or any of the parties in our supply chain are adversely impacted by the evolving effects of the COVID-19 pandemic, such as staffing shortages, productions slowdowns and/or disruptions in delivery systems, then there could be disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products. Any supply disruptions would adversely impact our ability to generate sales of and revenues from our products, and our business, financial condition, results of operations and growth prospects could be materially adversely affected. Further, in connection with the COVID-19 pandemic and in an effort to increase the wider availability of needed medical and other supplies and products, we and our third-party suppliers may elect to or governments may require us or our third-party suppliers to allocate raw materials used in manufacturing or manufacturing capacity (for example pursuant to the U.S. Defense Production Act) in a way that adversely affects our ability to have our products manufactured to meet clinical and commercial requirements.

For the clinical supply of our product candidates, we rely, and expect for the foreseeable future to continue to rely, on multiple contract manufacturers and other third parties to perform manufacturing services for us. If these third-party manufacturers cease or interrupt production, fail to supply satisfactory materials, products or services for any reason or experience performance delays or quality concerns, or if materials or products are lost in transit or in the manufacturing process, such challenges or interruptions could substantially impact clinical trial drug supply, with the potential for additional costs, delays and an adverse effect on our business. With respect to tisotumab vedotin, we currently rely on drug product supply provided by Genmab and have little control over their supply chains or the contract manufacturers they utilize. For the near-term, we expect to continue to rely on Genmab for manufacturing of clinical supplies of tisotumab vedotin. Under the commercialization agreement we entered into with Genmab in October 2020, we will be responsible for overseeing the clinical and commercial manufacturing supply chain of tisotumab vedotin following a transition period. We will need to obtain appropriate manufacturing arrangements and increase manufacturing capability to meet potential future commercial needs, and could experience potential delays if we encounter challenges in negotiating commercially reasonable arrangements with manufacturers or in transitioning oversight of the manufacturing process from Genmab to us.

In order to obtain regulatory approval of any product candidate or regulatory approval for any product in a new jurisdiction, we or our supplier or suppliers for that product or product candidate must obtain approval to manufacture and supply product, in some cases based on qualification data provided as part of a BLA, a New Drug Application, or NDA, or another application for regulatory approval. In addition, the manufacturing facilities utilized to manufacture the product or product candidate will be subject to pre-approval regulatory inspections. Any delay in generating, or failure to generate, data required in connection with submission of the chemistry, manufacturing and controls, or CMC, portions of any BLA, NDA or other application for regulatory approval, or challenges in the regulatory inspection process, could negatively impact our ability to meet our anticipated submission dates, result in delay in any approval decisions and/or negatively affect our ability to obtain regulatory approval at all. Any failure of us, our collaborators or a manufacturer to obtain approval from a regulatory authority to manufacture and supply product or any delay in obtaining and distributing adequate supplies of a newly-approved product, including PADCEV and TUKYSA, on a timely basis or in accordance with applicable specifications and local requirements could negatively impact our ability to successfully launch and commercialize the applicable product or product candidate and to generate sales of that product or product candidate at the levels we expect. We or our collaborators may also encounter difficulties in meeting the regulatory requirements applicable to the manufacturing process for these agents, in managing the additional complexity of manufacturing for a number of markets outside the U.S. or in responding to changes in the amount or timing of supply needs. Any failures or delays to meet these requirements could substantially delay or impede our ability to obtain regulatory approvals for and to market these agents, which could negatively impact our operating results and adversely affect our business.

To date, we have depended on a small number of collaborators for a substantial portion of our revenue. The loss of any one of these collaborators or changes in their product development or business strategy could result in a material decline in our revenue.

We have collaborations with a limited number of companies. To date, a substantial portion of our revenue has resulted from payments made under agreements with our corporate collaborators, and although ADCETRIS sales currently comprise a greater proportion of our revenue, we expect that a portion of our revenue will continue to come from corporate collaborations. Even though we market ADCETRIS in the U.S. and Canada, our revenues still depend in part on Takeda's ability to market ADCETRIS outside of the U.S. and Canada. Likewise, even though we market TUKYSA in the U.S., our revenues will still depend in part on Merck's ability and willingness to market TUKYSA outside of the U.S., Canada and Europe. In addition, under our agreements with Astellas, we and Astellas bear the costs of their own sales organizations in the U.S., equally share certain other costs associated with commercializing PADCEV in the U.S. and equally share in any profits realized in the U.S. The loss of our collaborators, especially Takeda or Astellas, changes in product development or business strategies of our collaborators, or the failure of our collaborators to perform their obligations under their agreements with us for any reason, including paying license or technology fees, milestone payments, royalties or reimbursements, could have a material adverse effect on our financial performance. Payments under our existing and potential future collaboration agreements are also subject to significant fluctuations in both timing and amount, which could cause our revenue to fall below the expectations of securities analysts and investors and cause a decrease in our stock price.

We are dependent upon a small number of distributors for a significant portion of our net sales, and the loss of, or significant reduction or cancellation in sales to, any one of these distributors could adversely affect our operations and financial condition.

We sell ADCETRIS and PADCEV through a limited number of specialty distributors. Healthcare providers order ADCETRIS and PADCEV through these distributors. We receive orders from distributors and generally ship product directly to the healthcare provider. We sell TUKYSA through a distribution network of specialty pharmacies, integrated delivery network hospitals and practices that dispense in the office. These distributors and distribution network partners do not set or determine demand for our products; however, our ability to effectively commercialize our products will depend, in part, on their performance. Although we believe we can find alternative distributors and partners on relatively short notice, the loss of a major distributor or partner could materially and adversely affect our results of operations and financial condition. In addition, business disruptions arising from the COVID-19 pandemic could negatively affect the ability of some of our distributors or distribution network partners to pay amounts owed to us in a timely manner or at all.

Risks Related to Our Intellectual Property

If we are unable to enforce our intellectual property rights or if we fail to sustain and further procure additional intellectual property rights, we may not be able to successfully commercialize our products or any future products and competitors may be able to develop competing therapies.

Our success depends, in part, on obtaining and maintaining patent protection and successfully enforcing these patents and defending them against third-party challenges in the U.S. and other countries. We own multiple U.S. and foreign patents and pending patent applications for our technologies. We also have rights to issued U.S. patents, patent applications, and their foreign counterparts, relating to our monoclonal antibody, linker and drug-based technologies. Our rights to these patents and patent applications are derived in part from worldwide licenses from third parties. In addition, we have licensed certain of our U.S. and foreign patents and patent applications to third parties.

The standards that the U.S. Patent and Trademark Office, or USPTO, and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents we currently own or obtain in the future may have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our products. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. In addition, changes to patent laws in the U.S. or other countries may be applied retroactively to affect the validity, enforceability, or term of our patent. For example, the U.S. Supreme Court has modified some legal standards applied by the USPTO in examination of U.S. patent applications, which may decrease the likelihood that we will be able to obtain patents and may increase the likelihood of challenges to patents we obtain or license. In addition, changes to the U.S. patent system have come into force under the Leahy-Smith America Invents Act, or the America Invents Act, including changes from a "first-to-invent" system to a "first to file" system, changes to examination of U.S. patent applications and changes to the processes for challenging issued patents. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review, or IPR, and post-grant review and covered business methods. These proceedings are conducted before the Patent Trial and Appeal Board, or PTAB, of the USPTO. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. In this regard, the IPR process permits any person (except a party who has been litigating the patent for more than a year) to challenge the validity of some patents on the grounds that it was anticipated or made obvious by prior art. As a result, non-practicing entities associated with hedge funds, pharmaceutical companies who may be our competitors and others have challenged certain valuable pharmaceutical U.S. patents based on prior art through the IPR process. A decision in such a proceeding adverse to our interests could result in the loss of valuable patent rights which would have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any event, the America Invents Act and any other potential future changes to the U.S. patent system could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, we rely on external agents to perform certain activities to maintain our patents. Although we carefully select and oversee

these agents, the failure of an agent to properly perform these maintenance activities, whether through mistake or otherwise, could adversely affect our intellectual property rights.

We rely on trade secrets and other proprietary information where we believe patent protection is not appropriate or obtainable. However, trade secrets and other proprietary information are difficult to protect. We have taken measures to protect our unpatented trade secrets and know-how, including the use of confidentiality and assignment of inventions agreements with our employees, consultants and certain contractors. It is possible, however, that these persons may breach the agreements or that our competitors may independently develop or otherwise discover our trade secrets or other proprietary information. Our research collaborators may publish confidential data or other restricted information to which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information may be impaired.

We have been and may in the future be subject to litigation, which could result in substantial damages and may divert management's time and attention from our business.

We are engaged in multiple legal disputes with Daiichi Sankyo Co. Ltd., or Daiichi Sankyo. We are in a dispute with Daiichi Sankyo regarding the ownership of certain technology used by Daiichi Sankyo in its cancer drug ENHERTU and certain product candidates. Arbitration relating to the dispute is progressing with a hearing date scheduled starting June 14, 2021. In addition, we filed a complaint in the U.S. District Court for the Eastern District of Texas to commence an action for infringement of our U.S. Patent No. 10,808,039, or the '039 Patent, by Daiichi Sankyo's importation into, offer for sale, sale, and use in the U.S. of ENHERTU. Daiichi Sankyo (as well as Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, LP, or AstraZeneca) subsequently filed an action in the U.S. District Court for the District of Delaware seeking a declaratory judgment that ENHERTU does not infringe the '039 Patent. Daiichi Sankyo, Inc. and AstraZeneca also filed two Petitions for Post-Grant Review with the U.S. Patent Office seeking to have claims of the '039 Patent cancelled as unpatentable. As a result of these disputes, we have incurred and will continue to incur litigation expenses. In addition, from time to time, we may become involved in other lawsuits, claims and proceedings relating to the conduct of our business, including but not limited to those pertaining to the defense and enforcement of our patent or other intellectual property rights and our contractual rights.

These and other potential future litigations are subject to inherent uncertainties, and the actual costs to be incurred relating to litigations may be impacted by unknown factors. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the course of these and potential future litigations, we may be subject to additional claims and counterclaims that may result in liabilities or require us to take or refrain from certain actions, and we may not prevail. Monitoring, defending against and pursuing legal actions can be time-consuming for our management and detract from our ability to fully focus our internal resources on our business activities, which could result in delays of our clinical trials or our development and commercialization efforts. In addition, we may incur substantial legal fees and costs in connection with these and potential future litigations. Decisions adverse to our interests in these and potential future litigations could result in the payment of substantial damages, or possibly fines, or affect our intellectual property rights and could have a material adverse effect on our cash flow, results of operations and financial position. Successful challenges to our patent or other intellectual property rights could result in a loss of rights in the relevant jurisdiction and may allow third parties to use our proprietary technologies without a license from us or our collaborators. In addition, the uncertainty associated with litigation could lead to increased volatility in our stock price.

We and our collaborators rely on license agreements for certain aspects of our products and product candidates and technologies such as our ADC technology. Failure to maintain these license agreements or to secure any required new licenses could prevent us from continuing to develop and commercialize our products and product candidates.

We have entered into agreements with third-party commercial and academic institutions to license technology for use in ADCETRIS, TUKYSA, our product candidates and technologies such as our ADC technology. Currently, we have license agreements with BMS, the University of Miami and Array BioPharma, Inc., among others. In addition to royalty provisions and other payment obligations, some of these license agreements contain diligence and milestone-based termination provisions, in which case our failure to meet any agreed upon royalty or diligence requirements or milestones may allow the licensor to terminate the agreement. Many of our license agreements grant us exclusive licenses to the underlying technologies. In addition, Astellas has agreements to license technology for use in PADCEV. We rely on Astellas to maintain these license agreements. If Astellas fails to maintain these license agreements, if our licensors terminate our license agreements or if we or our collaborators are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize our products or product candidates. Further, we have had in the past, and we or our collaborators may in the future have, disputes with our licensors, which may impact our ability to develop and commercialize our products or product candidates or require us to enter into additional licenses. An adverse result in potential future disputes with our or our collaborators' licensors may impact our ability to develop and commercialize our products and product candidates, or may require us to enter into additional licenses or to incur additional costs in litigation or settlement. In addition, continued development and commercialization of our products and product candidates will likely require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

We may incur substantial costs and lose important rights or may not be able to continue to commercialize our products or to commercialize any of our product candidates that may be approved for commercial sale as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be required to obtain patent and other intellectual property rights from others.

We may face potential lawsuits by companies, academic institutions or others alleging infringement of their intellectual property. Because patent applications can take a few years to publish, there may be currently pending applications of which we are unaware that may later result in issued patents that adversely affect the continued commercialization of our products or future commercialization of our product candidates. In addition, we are monitoring the progress of multiple pending patent applications of other organizations that, if granted, may require us to license or challenge their enforceability in order to continue commercializing our products or to commercialize our product candidates that may be approved for commercial sale. Our challenges to patents of other organizations may not be successful, which may affect our ability to commercialize our products or product candidates. As a result of the patent infringement lawsuits that have been filed or may be filed against us in the future by third parties alleging infringement by us of patent or other intellectual property rights, we may be required to pay substantial damages, including lost profits, royalties, treble damages, attorneys' fees and costs, for past infringement if it is ultimately determined that our products infringe a third-party's intellectual property rights. Even if infringement claims against us are without merit, the results may be unpredictable. In addition, defending lawsuits takes significant time, may be expensive and may divert management's attention from other business concerns. Further, we may be stopped from developing, manufacturing or selling our products until we obtain a license from the owner of the relevant technology or other intellectual property rights, or be forced to undertake costly design-arounds, if feasible. If such a license is available at all, it may require us to pay substantial royalties or other fees.

We are or may be from time to time involved in the defense and enforcement of our patent or other intellectual property rights in a court of law, USPTO interference, IPR, post-grant review or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding in the U.S. and elsewhere. In addition, if we choose to go to court to stop a third party from infringing our patents, that third party has the right to ask the court to rule that these patents are invalid, not infringed and/or should not be enforced. Under the America Invents Act, a third party may also have the option to challenge the validity of certain patents at the PTAB, whether they are accused of infringing our patents or not, and certain entities associated with hedge funds, pharmaceutical companies and other entities have challenged valuable pharmaceutical patents through the IPR process. These lawsuits and administrative proceedings are expensive and consume time and other resources, and we may not be successful in these proceedings or in stopping infringement. In addition, there is a risk that a court will decide that these patents are not valid or not infringed or otherwise not enforceable, or that the PTAB will decide that certain patents are not valid, and that we do not have the right to stop a third party from using the patented subject matter. Successful challenges to our patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction and may allow third parties to use our proprietary technologies without a license from us or our collaborators, which may also result in loss of future royalty payments. Furthermore, if such challenges to our rights are not resolved promptly in our favor, our existing business relationships may be jeopardized and we could be delayed or prevented from entering into new collaborations or from commercializing potential products, which could adversely affect our business and results of operations. In addition, we may challenge the patent or other intellectual property rights of third parties and if we are unsuccessful in actions we bring against the rights of such parties, through litigation or otherwise, and it is determined that we infringe the intellectual property rights of such parties, we may be prevented from commercializing potential products in the relevant jurisdiction, or may be required to obtain licenses to those rights or develop or obtain alternative technologies, any of which could harm our business.

Risks Related to Our Operations, Managing Our Growth and Other Risks

Our business is currently being adversely affected and could be materially and adversely affected in the future by the evolving effects of the COVID-19 pandemic as a result of the current and potential future impacts on our commercialization efforts, supply chain, regulatory and clinical development activities and other business operations, in addition to the impact of a global economic slowdown.

Our business is currently being adversely affected and could be materially and adversely affected in the future by the evolving effects of the COVID-19 pandemic. In accordance with guidance issued by the Centers for Disease Control and Prevention, the World Health Organization and local authorities, beginning in March 2020, we implemented a mandatory work-from-home policy for employees who can perform their jobs offsite. Our essential research, manufacturing and laboratory activities are ongoing, and we maintain a number of additional precautionary measures to protect these onsite employees, such as temperature checks, screening protocols, masks, social distancing, contact tracing and making testing available. However, if we are unable to obtain adequate supplies of personal protective equipment due to shortages or encounter other challenges related to the evolving COVID-19 pandemic, we may have to place or may experience additional limitations on our in person activities. In addition, our increased reliance on personnel working from home may negatively impact productivity or disrupt, delay or otherwise adversely impact our business. This could also increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. In addition, our oversight of third-party manufacturers is currently being conducted by virtual means, which may increase the chance of a manufacturing quality issue. Impacts related to the COVID-19 pandemic could materially and adversely affect our business, our ability to generate sales of and revenues from our approved products, and our ability to advance the development of our products and product candidates, as described elsewhere in this “Risk Factors” section. The magnitude of such impacts will depend, in large part, on the ultimate duration and severity of the evolving effects of the COVID-19 pandemic.

The effects of the COVID-19 pandemic continue to rapidly evolve. These effects have increased market volatility and could result in a significant long-term disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, the current recession or additional market corrections resulting from the effects of the COVID-19 pandemic could materially affect our business and the value of our common stock. The extent to which the evolving effects of the COVID-19 pandemic impact our business, our ability to generate sales of and revenues from our approved products, and our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate duration and severity of the pandemic, government actions, such as travel restrictions, quarantines and social distancing requirements in the U.S. and in other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and in other countries to contain and treat the disease, including the effectiveness and timing of vaccination programs in the U.S. and worldwide. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, sales of our products, our clinical and regulatory activities, our research programs, healthcare systems or the global economy as a whole. However, these effects could materially and adversely affect our business, financial condition, results of operations and growth prospects. In addition, to the extent the evolving effects of the COVID-19 pandemic adversely affect our business, financial condition, results of operations and growth prospects, they may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this "Risk Factors" section. It is also possible that future global pandemics could also occur and also materially and adversely affect our business, financial condition, results of operations and growth prospects.

If we are unable to manage our growth, our business, financial condition, results of operations and prospects may be adversely affected.

We have experienced and expect to continue to experience significant growth in the number of our employees and in the scope of our operations, including in connection with our transition into a multi-product oncology company, our operation of a manufacturing facility and our continuing international expansion. In this regard, the anticipated continued growth of ADCETRIS, the continued launch and commercialization of PADCEV and TUKYSA in the U.S., the anticipated launch and commercialization of TUKYSA in Europe and the potential launch and commercialization of any other future approved products may require expansion of our sales force and commercial organization. We may need to commit significant additional funds, management and other resources to the growth of our commercial organization. In addition, our expansion in Europe also requires the expansion of other functions, including clinical development, drug safety, quality, finance and compliance. We may not be able to achieve any necessary growth in a timely or cost-effective manner or realize a positive return on our investment, and we may not have the financial resources to achieve the necessary growth in a timely manner or at all, any of which could negatively impact our ability to successfully launch and commercialize a newly-approved product and harm the commercial potential of our current and any future approved products. In any event, this rapid growth and additional complexity places significant demands on our management, operational and financial resources, and our current and planned personnel, systems, procedures and controls may not be adequate to support our growth. In particular, we are using new distribution channels for TUKYSA that require us to implement additional control systems to monitor inventory that has been purchased by specialty pharmacies and not yet dispensed to patients. A failure to correctly implement and monitor these new control systems could result in a control failure or error in our financial accounting. In addition, this growth places significant demands on our third party suppliers and they may not have the resources and personnel to adequately support our commercial plans and launch needs, including in regions outside the U.S. To effectively manage our growth, we must continue to improve existing, and implement new, operational and financial systems, procedures and controls and must expand, train and manage our growing employee base, and there can be no assurance that we will effectively manage our growth without experiencing operating inefficiencies, control deficiencies, compliance issues or other problems. We expect that we may need to increase our management personnel to oversee our expanding operations, and recruiting and retaining qualified individuals is difficult. Likewise, we could experience limitations on our ability to recruit, hire and retain personnel at all levels of the organization as a result of the COVID-19 pandemic, and without reductions in the pace, scale or complexity of our business, this could result in strain on our staff, loss of talent, failure to capitalize fully on opportunities, control deficiencies and other challenges, which could adversely affect our business, financial condition, results of operations and prospects. In addition, the physical expansion of our operations may lead to significant costs and may divert our management and capital resources. If we are unable to manage our growth effectively, or are unsuccessful in recruiting and retaining qualified management personnel, our business, financial condition, results of operations and prospects may be adversely affected.

Risks associated with our expanding operations in countries outside the U.S. could materially adversely affect our business.

We are expanding our operations internationally. We have an expanding number of subsidiaries in jurisdictions outside the U.S., including multiple subsidiaries in Europe, and we are building a commercial infrastructure in Europe and expanding our commercial infrastructure in Canada. Consequently, we are, and will increasingly be, subject to risks related to operating internationally. Risks associated with conducting operations internationally include:

- the increased complexity and costs inherent in managing international operations, including in geographically disparate locations;
- diverse regulatory, drug safety, drug supply, financial and legal requirements, and any future changes to such requirements, in one or more countries where we are located or do business;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- adverse tax consequences, including changes in applicable tax laws and regulations;
- applicable trade laws, tariffs, export quotas, custom duties or other trade restrictions, and any changes to them;
- economic weakness, including inflation, or political or economic instability in particular economies and markets outside the U.S.;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating in another country;
- liabilities for activities of, or related to, our international operations;
- challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations and different languages;
- reliance on vendors who are located far from our headquarters and with whom we have not worked previously;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.; and
- laws and regulations relating to data security and the unauthorized use of, or access to, commercial and personal information.

As a result of our expanding international operations, including potentially with respect to our commercial presence in Europe and expanding commercial infrastructure in Canada, our business and corporate structure has and will become substantially more complex. In addition, as a business, we do not have significant experience conducting operations outside of the U.S. and Canada. There can be no assurance that we will effectively manage the increased complexity and broader scope of our operations without experiencing operating inefficiencies, control deficiencies, compliance issues or other problems. Significant management time and effort will be required to effectively manage the increasing complexity and broader scope of our operations, and our failure to successfully do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Further, since a portion of the regulatory framework in the U.K. is derived from EU directives and regulations, Brexit, has had, and will continue to have, an impact upon the regulatory regime applicable to potential future marketing authorizations for ADCETRIS, PADCEV, TUKYSA and our product candidates. In particular, Great Britain is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the European Medicines Agency, and a separate marketing authorization will be required to market our product candidates in Great Britain. In addition, it is unclear what additional financial, trade, regulatory and legal implications the withdrawal of the U.K. from the EU. may have on us. These and other risks described elsewhere in these risk factors associated with expanding our international operations could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We have engaged in, and may in the future engage in, strategic transactions that increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We actively evaluate various strategic transactions on an ongoing basis, including licensing or otherwise acquiring complementary products, technologies or businesses. Any potential future acquisitions or in-licensing transactions entail numerous risks, including but not limited to:

- risks associated with satisfying the closing conditions relating to such transactions and realizing their anticipated benefits;
- increased operating expenses and cash requirements;
- difficulty integrating acquired technologies, products, operations, and personnel with our existing business;
- the potential disruption of our historical core business;
- diversion of management's attention in connection with both negotiating the acquisition or license and integrating the business, technology or product;
- retention of key employees;
- difficulties in assimilating employees and corporate cultures of any acquired companies;
- uncertainties in our ability to maintain key business relationships of any acquired companies;
- strain on managerial and operational resources;
- difficulty implementing and maintaining effective internal control over financial reporting at businesses that we acquire, particularly if they are not located near our existing operations;
- exposure to unanticipated liabilities of acquired companies or companies in which we invest;
- the potential need to write down assets or recognize impairment charges; and
- potential costly and time-consuming litigation, including stockholder lawsuits.

As a result of these or other problems and risks, businesses, technologies or products we acquire or invest in or obtain licenses to may not produce the revenues, earnings or business synergies that we anticipated, acquired or licensed product candidates or technologies may not result in regulatory approvals, and acquired or licensed products may not perform as expected. As a result, we may incur higher costs and realize lower revenues than we had anticipated. We cannot assure you that any acquisitions or investments we have made or may make in the future will be completed or that, if completed, the acquired business, licenses, investments, products, or technologies will generate sufficient revenue to offset the negative costs or other negative effects on our business. Failure to manage effectively our growth through acquisitions or in-licensing transactions could adversely affect our growth prospects, business, results of operations, financial condition, and cash flow.

In addition, we may spend significant amounts, issue dilutive securities, assume or incur significant debt obligations, incur large one-time expenses and acquire intangible assets or goodwill in connection with acquisitions and in-licensing transactions that could result in significant future amortization expense and write-offs. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Other pharmaceutical companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for these opportunities. Even if appropriate opportunities are available, we may not be able to successfully identify them or we may not have the financial resources necessary to pursue them, and if pursued, we may be unable to structure and execute transactions in the anticipated timeframe, or at all.

Even if we are able to successfully identify and acquire complementary products, technologies or businesses, we cannot assure you that we will be able to successfully manage the risks associated with integrating acquired products, technologies or businesses or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing transaction. Further, while we seek to mitigate risks and liabilities of potential acquisitions and in-licensing transactions through, among other things, due diligence, there may be risks and liabilities that such due diligence efforts fail to discover, that are not disclosed to us, or that we inadequately assess. Any failure in identifying and managing these risks, liabilities and uncertainties effectively could have a material adverse effect on our business and adversely affect our results of operations and financial condition. Additionally, we may not realize the anticipated benefits of such transactions, including the possibility that expected synergies and accretion will not be realized or will not be realized within the expected time frame.

If we lose our key personnel or are unable to attract and retain additional qualified personnel, our future growth and ability to compete would suffer.

We are highly dependent on the efforts and abilities of the principal members of our senior management. Additionally, we have scientific personnel with significant and unique expertise in monoclonal antibodies, ADCs and related technologies, and TUKYSA. The loss of the services of any one of the principal members of our managerial or scientific staff may prevent us from achieving our business objectives.

In addition, the competition for qualified personnel in the biotechnology field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. In order to continue to commercialize our products, and advance the development and commercialization of our additional product candidates, we will be required to expand our workforce, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development, sales and marketing, both in the U.S. and in Europe. We continue to face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, as well as academic and other research institutions, and with increasing reliance on remote work arrangements, the geographic market in which we compete for talent is expanding. Our failure to compete effectively in this area could negatively affect our sales of our current and any future approved products. To the extent we are not able to retain these individuals on favorable terms or attract any additional personnel that may be required, our business may be harmed. For example, we may not be successful in attracting or retaining key personnel necessary to effectively commercialize PADCEV and TUKYSA, build and operate a commercial infrastructure in Europe or to support the potential launch and commercialization of our product candidates, alone or jointly with our collaborators, if we receive regulatory approval. If our commercial organization is not appropriately sized or equipped to adequately market our current and any future approved products, the commercial potential of our current and any future approved products may be diminished, and our business and prospects for profitability may be adversely affected.

If we experience a significant disruption in our information technology systems or breaches of data security, our business could be adversely affected.

We rely on information technology systems to keep financial records, capture laboratory data, maintain clinical trial data, commercial sales data and corporate records, communicate with staff and external parties and operate other critical functions. The effects of the COVID-19 pandemic have intensified our dependence on information technology systems as many of our critical business activities are currently being conducted remotely and our increased reliance on personnel working from home could increase our cybersecurity risk. Our information technology systems are potentially vulnerable to disruption due to breakdown, malicious intrusion and computer viruses or other disruptive events including but not limited to natural disaster. If we were to experience a prolonged system disruption in our information technology systems or those of certain of our vendors, it could delay or negatively impact the development and commercialization of our products and product candidates, which could adversely impact our business. Although we maintain offsite back-ups of our data, if operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring function on an acceptable timeframe. In addition, our information technology systems are potentially vulnerable to data security breaches, whether by employees or others, which may expose sensitive or personal data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, patients in our clinical trials, customers and others, any of which could have a material adverse effect on our business, financial condition and results of operations. Moreover, a security breach or privacy violation that leads to destruction, loss, alteration, unauthorized use or access, disclosure or modification of, personally identifiable information or personal

data, could harm our reputation, compel us to comply with federal, state and/or international breach notification laws, subject us to mandatory corrective or regulatory action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, including the GDPR, which could disrupt our business, result in increased costs or loss of revenue, and/or result in significant legal and financial exposure. In addition, a data security breach could result in loss of clinical trial data or damage to the integrity of that data. If we are unable to implement and maintain adequate organizational and technical measures to prevent such security breaches or privacy violations, or to respond adequately in the event of a breach, our operations could be disrupted, and we may suffer loss of reputation, problems with regulatory authorities, financial loss and other negative consequences. Moreover, failure to maintain effective internal accounting controls related to data security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and could subject us to regulatory scrutiny. In addition, security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Risks Related to Our Financial Condition and Capital Requirements

Our operating results are difficult to predict and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.

Our operating results are difficult to predict and may fluctuate significantly from quarter to quarter and year to year. As a result, although we provide product sales guidance from time to time, you should not rely on product sales results in any period as being indicative of future performance. In addition, such guidance is based on assumptions that may be incorrect or that may change from quarter to quarter, and it may be particularly difficult to correctly forecast product sales for newly-approved products or in indications for existing products for which we have recently received marketing approval. Moreover, our product sales have, on occasion, been below the expectations of securities analysts and investors and have been below prior period sales, and our sales in the future may also be below prior period sales, our own guidance and/or the expectations of securities analysts and investors. To the extent that we again do not meet our guidance or the expectations of analysts or investors, our stock price may be adversely impacted, perhaps significantly. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

- customer ordering patterns for our products, which may vary significantly from period to period;
- the overall level of demand for our products, including the impact of any competitive or biosimilar products and the duration of therapy for patients treated with our products;
- the extent to which coverage and reimbursement for our products is available from government and health administration authorities, private health insurers, managed care programs and other third-party payors;
- our ability to establish or demonstrate in the medical community the safety, efficacy or value of our products and their potential advantages compared to existing and future therapies in their approved indications, including in ADCETRIS' frontline Hodgkin lymphoma and frontline PTCL indications, PADCEV's FDA approved indication and TUKYSA's FDA approved indication;
- changes in the amount of deductions from gross sales, including government-mandated rebates, chargebacks and discounts that can vary because of changes to the government discount percentage, including increases in the government discount percentage resulting from price increases we have taken or may take in the future, or due to different levels of utilization by entities entitled to government rebates and discounts and changes in patient demographics;
- increases in the scope of eligibility for customers to purchase our products at the discounted government price or to obtain government-mandated rebates on purchases of our products;
- changes in our cost of sales due to potential new product launches, royalties owed under technology license agreements or write-offs of inventory;
- the incidence rate of new patients in the approved indications for our products;

- the evolving effects of the COVID-19 pandemic, including those leading to current and potential future reductions in the rate of cancer diagnoses;
- the timing, cost and level of investment in our sales and marketing efforts to support our products sales;
- the timing, cost and level of investment in our research and development, pre-commercialization and other activities involving ADCETRIS, PADCEV, TUKYSA, tisotumab vedotin and our other product candidates by us or our collaborators; and
- expenditures we will or may incur to develop and/or commercialize any additional products, product candidates, or technologies that we may develop, in-license, or acquire.

In addition, even if we and/or our collaborators are able to obtain regulatory approvals for our product candidates, due to the lack of any historical sales data from the commercialization of any of our product candidates, sales of a newly-approved product such as PADCEV or TUKYSA will be difficult to predict from period to period. As a result, sales results or trends for PADCEV, TUKYSA or any of our future approved products in any period may not necessarily be indicative of future performance. In any event, if we are unable to obtain and maintain necessary or desirable regulatory approvals for our products and product candidates, including for ADCETRIS, PADCEV and TUKYSA, in a timely manner, if at all, if the FDA or other regulatory authorities do not approve product labeling that is necessary or desirable for the successful commercialization of an approved product, or if sales of an approved product do not reach the levels we expect, our anticipated revenue from our products and product candidates and our prospects for profitability would be adversely affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Moreover, we have entered into collaboration and license agreements with other companies that include development funding and milestone and royalty payments to us, and we expect that amounts earned from our collaboration agreements will continue to be an important source of our revenues. Accordingly, our revenues will also depend on development funding and the achievement of development and clinical milestones under our existing collaboration and license agreements, including, in particular, our ADCETRIS collaboration with Takeda, our PADCEV collaboration with Astellas and our ladiratuzumab vedotin and TUKYSA collaborations with Merck, as well as entering into potential new collaboration and license agreements. These upfront and milestone payments may vary significantly from quarter to quarter and any such variance could cause a significant fluctuation in our operating results from one quarter to the next.

Further, changes in our operations, such as increased development, manufacturing and clinical trial expenses in connection with our expanding pipeline programs, or our undertaking of additional programs, or business activities, or entry into strategic transactions, including potential future acquisitions of products, technologies or businesses may also cause significant fluctuations in our expenses. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price, the magnitude of the expense that we must recognize may vary significantly. Additionally, we have implemented long-term incentive plans for our employees, and the incentives provided under these plans are contingent upon the achievement of certain regulatory milestones. Costs of performance-based compensation under our long-term incentive plans are not recorded as an expense until the achievement of the applicable milestones is deemed probable of being met, which may result in large fluctuations to the expense we must recognize in any particular period.

For these and other reasons, it is difficult for us to accurately forecast future sales of our current or any future approved products, collaboration and license agreement revenues, royalty revenues, operating expenses or future profits or losses. As a result, our operating results in future periods could be below our guidance or the expectations of securities analysts or investors, which could cause the trading price of our common stock to decline, perhaps substantially.

We have a history of net losses. We expect to continue to incur net losses and may not achieve future sustained profitability for some time, if at all.

We have incurred substantial net losses in each of our years of operation, other than the year ended December 31, 2020. We have incurred these losses principally from costs incurred in our research and development programs and from our selling, general and administrative expenses. We expect to continue to spend substantial amounts on research and development, including amounts for conducting clinical trials of our products and product candidates as well as commercializing our products for the treatment of patients in their approved indications. In addition, we expect to make substantial expenditures to further develop and potentially commercialize tisotumab vedotin and our other product candidates. We may also pursue new operations or continue the expansion of our existing operations, including with respect the development of our commercial infrastructure in Europe and our plans to otherwise continue to expand our operations internationally. Accordingly, even though we reported net income for the year ended December 31, 2020 due to the collaboration and license agreement revenues related to the agreements we entered into with Merck during 2020, we nonetheless expect to incur net losses in the future and may not achieve sustained profitability for some time, if at all. Although we recognize revenue from product sales and we continue to earn amounts under our collaboration agreements, our revenue and profit potential is unproven and our future operating results are difficult to predict. Even if we do achieve profitability in the future, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

We may need to raise additional capital that may not be available to us.

We expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees, and support our development, manufacturing, commercialization, and planned global expansion, which may require us to raise additional capital. In addition, we may pursue new operations or continue the expansion of our existing operations, including with respect to our development of a commercial infrastructure in Europe and our plans to otherwise continue to expand our operations internationally. Our commitment of resources to the continuing development, regulatory and commercialization activities for our products, the research, continued development and manufacturing of our product candidates, our pursuit of regulatory approvals for and preparing to potentially launch and commercialize our product candidates, and the anticipated expansion of our pipeline and operations may require us to raise additional capital. Further, we actively evaluate various strategic transactions on an ongoing basis, including licensing or otherwise acquiring complementary products, technologies or businesses, and we may require significant additional capital in order to complete or otherwise provide funding for such transactions. We may seek additional funding through some or all of the following methods: corporate collaborations, licensing arrangements and public or private debt or equity financings. We do not know whether additional capital will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If we are unable to raise additional funds when we need them, we may be required to delay, reduce the scope of, or eliminate one or more of our development programs, which may adversely affect our business and operations. Our future capital requirements will depend upon a number of factors, including:

- the level of sales and market acceptance of ADCETRIS, PADCEV, TUKYSA or of any future approved products;
- the time and costs involved in obtaining regulatory approvals of our products in additional indications or territories, if any, and potentially of any of our other product candidates;
- the size, complexity, timing, progress and number of our clinical programs and our collaborations;
- the timing, receipt and amount of milestone-based payments or other revenue from our collaborations or license arrangements, including royalty revenue generated from commercial sales of ADCETRIS by Takeda, revenue generated under our collaboration with Astellas and anticipated royalty revenue generated by commercial sales of TUKYSA by Merck;
- the cost of establishing and maintaining clinical supplies of our products and product candidates and commercial supplies of our current and any future approved products;
- the extent of our investment in development, manufacturing and commercialization outside the U.S.;

- the costs associated with acquisitions or licenses of additional technologies, products, or companies as well as licenses we may need to commercialize our current or any future approved products;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- expenses associated with future securities class action or derivative lawsuits, as well as any other potential litigation;
- the potential costs associated with international, state and federal taxes; and
- competing technological and market developments.

In addition, changes in our spending rate may occur that would consume available capital resources sooner, such as increased development, manufacturing and clinical trial expenses in connection with our expanding pipeline programs or our undertaking of additional programs, business activities or entry into additional strategic transactions, including potential future acquisitions of products, technologies or businesses. Moreover, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

During the past several years, domestic and international financial markets have experienced extreme disruption from time to time, including, among other things, high volatility and significant declines in stock prices and severely diminished liquidity and credit availability for both borrowers and investors. Such adverse capital and credit market conditions could make it more difficult to obtain additional capital on favorable terms, or at all, which could have a material adverse effect on our business and growth prospects. For example, our ability to raise additional capital may be adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the U.S. and worldwide resulting from the evolving effects of the COVID-19 pandemic.

The potential future impairment of intangible assets and goodwill may negatively affect our results of operations and financial position.

As of December 31, 2020, we recorded $558.4 million of intangible assets, net and goodwill on our condensed consolidated balance sheet. Our intangible assets and goodwill are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Our results of operations and financial position in future periods could be negatively impacted should future impairments of intangible assets or goodwill occur.

Risks Related to Our Common Stock

Our stock price is volatile and our shares may suffer a decline in value.

The market price of our stock has in the past been, and is likely to continue in the future to be, very volatile. During the year ended December 31, 2020, our closing stock price fluctuated between $95.75 and $211.93 per share. As a result of fluctuations in the price of our common stock, you may be unable to sell your shares at or above the price you paid for them. The market price of our common stock may be subject to substantial volatility in response to many risk factors listed in this section, and others beyond our control, including:

- the levels of ADCETRIS, PADCEV and TUKYSA product sales;
- announcements of FDA or other regulatory approval or non-approval of our products, including TUKYSA, or any of our product candidates or specific label indications for or restrictions, warnings or limitations in its use, or delays in the regulatory review or approval process;
- announcements regarding the results of discovery efforts and preclinical, clinical and commercial activities by us, or those of our competitors;

- announcements regarding the results of the clinical trials we and our collaborators are conducting or may in the future conduct for our products and product candidates;
- announcements regarding, or negative publicity concerning, adverse events or safety concerns associated with the use of ADCETRIS, PADCEV, TUKYSA or our product candidates;
- issuance of new or changed analysts' reports and recommendations regarding us or our competitors;
- termination of or changes in our existing collaborations or licensing arrangements, or establishment of new collaborations or licensing arrangements;
- our failure to achieve the perceived benefits of our strategic transactions as rapidly or to the extent anticipated by financial analysts or investors;
- our entry into additional material strategic transactions including licensing or acquisition of products, businesses or technologies;
- actions taken by regulatory authorities with respect to our product candidates, our clinical trials or our regulatory filings;
- our raising of additional capital and the terms upon which we may raise any additional capital;
- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;
- developments or disputes concerning our proprietary rights, including with respect to our disputes with Daiichi Sankyo;
- developments regarding any future purported securities class action lawsuits, as well as any other potential litigation;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- changes in government regulations; and
- economic or other external factors.

The stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have historically experienced significant volatility that has often been unrelated or disproportionate to the operating performance of particular companies, including in connection with the COVID-19 pandemic, which has resulted in decreased market prices, notwithstanding the lack of a fundamental change in the underlying business models or prospects of those companies. In this regard as a result of the risks and evolving effects of the COVID-19 pandemic, Brexit and/or significant changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing trade and healthcare spending and delivery outside the U.S., the financial markets could experience significant volatility that could also negatively impact the markets for biotechnology and pharmaceutical stocks. These broad market fluctuations have adversely affected and may in the future adversely affect the market price of our common stock. In this regard, worsening economic conditions and other adverse impacts or developments relating to the evolving effects of the COVID-19 pandemic may negatively affect the market price of our common stock, regardless of our actual operating performance.

In the past, class action or derivative litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. In this regard, we have become, and may in the future again become, subject to claims and litigation alleging violations of the securities laws or other related claims, which could harm our business and require us to incur significant costs. Lawsuits brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources, which could result in delays of our clinical trials or our development and commercialization efforts.

Substantial future sales of shares of our common stock or equity-related securities could cause the market price of our common stock to decline.

Sales of a substantial number of shares of our common stock into the public market, including sales by members of our management or board of directors or entities affiliated with such members, could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock and could impair our ability to raise capital through the sale of additional equity or equity-related securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of December 31, 2020, we had 180,902,151 shares of common stock outstanding, all of which shares are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144. In addition, we may issue a substantial number of shares of our common stock or equity-related securities, including convertible debt, to meet our capital needs, including in connection with funding potential future acquisition or licensing opportunities, capital expenditures or product development costs, which issuances could be substantially dilutive and could adversely affect the market price of our common stock. Likewise, future issuances by us of our common stock upon the exercise, conversion or settlement of equity-based awards or other equity-related securities would dilute existing stockholders' ownership interest in our company and any sales in the public market of these shares, or the perception that these sales might occur, could also adversely affect the market price of our common stock.

Moreover, we have in the past and may in the future grant rights to some of our stockholders that require us to register the resale of our common stock or other securities on behalf of these stockholders and/or facilitate public offerings of our securities held by these stockholders, including in connection with potential future acquisition or capital-raising transactions. For example, in connection with our September 2015 public offering of common stock, we entered into a registration rights agreement with entities affiliated with Baker Bros. Advisors LP, or the Baker Entities, that together, based on information available to us as of December 31, 2020, collectively beneficially owned approximately 26% of our common stock. Under the registration rights agreement, if at any time and from time to time the Baker Entities demand that we register their shares of our common stock for resale under the Securities Act of 1933, as amended, or the Securities Act, we would be obligated to effect such registration. In December 2020, pursuant to the registration rights agreement, we registered for resale, from time to time, up to 47,366,602 shares of our common stock held by the Baker Entities. Our registration obligations under the registration rights agreement cover all shares now held or hereafter acquired by the Baker Entities, will continue in effect for up to ten years, and include our obligation to facilitate certain underwritten public offerings of our common stock by the Baker Entities in the future. Accordingly, we expect to register additional shares held by the Baker Entities for resale from time to time, including in certain cases, shares that we have previously registered for resale by the Baker Entities, whether in connection with the expiration of registration statements that we previously filed with the SEC or otherwise. If the Baker Entities, by exercise of these registration and/or underwriting rights and our registration of shares held by the Baker Entities for resale from time to time, or otherwise, sell a large number of our shares, or the market perceives that the Baker Entities intend to sell a large number of our shares, including in connection with our registrations of shares held by the Baker Entities for resale, this could adversely affect the market price of our common stock. We have also filed registration statements to register the sale of our common stock reserved for issuance under our equity incentive and employee stock purchase plans. Accordingly, these shares will be able to be freely sold in the public market upon issuance as permitted by any applicable vesting requirements.

Our existing stockholders have significant control of our management and affairs.

Based solely on the most recent Schedules 13G and 13D filed with the SEC, reports filed with the SEC under Section 16 of the Exchange Act, and our outstanding shares of common stock as of December 31, 2020, our executive officers and directors and holders of greater than five percent of our outstanding common stock beneficially owned approximately 62% of our voting power as of December 31, 2020. As a result, these stockholders, acting together, are able to control our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. Consequently, this concentration of ownership may have the effect of delaying, deferring or preventing a change in control, including a merger, consolidation, takeover or other business combination involving us or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control, which might affect the market price of our common stock.

Anti-takeover provisions could make it more difficult for a third party to acquire us.

Our Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by the stockholders, which authority could be used to adopt a "poison pill" that could act to prevent a change of control of Seagen that has not been approved by our Board of Directors. The rights of the holders of common stock may be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control of Seagen without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. Further, certain provisions of our charter documents, including provisions eliminating the ability of stockholders to take action by written consent and limiting the ability of stockholders to raise matters at a meeting of stockholders without giving advance notice, may have the effect of delaying or preventing changes in control or management of Seagen, which could have an adverse effect on the market price of our stock. In addition, our charter documents provide for a classified board, which may make it more difficult for a third party to gain control of our Board of Directors. Similarly, state anti-takeover laws in Delaware and Washington related to corporate takeovers may prevent or delay a change of control of Seagen.

General Risk Factors

Changes in tax laws or regulations may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New tax laws, statutes, rules, regulations or ordinances could be enacted at any time, including as a result of the recent U.S. presidential and congressional elections, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. In addition, as we continue to expand our operations internationally, we may become increasingly subject to taxation in additional jurisdictions. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets, result in significant one-time charges, increase our future tax expense or otherwise have a material adverse effect on our business, cash flow, financial condition or results of operations.

If any of our facilities are damaged or our clinical, research and development or other business processes are interrupted, our business could be seriously harmed.

We conduct most of our business in a limited number of facilities. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates or interrupt the sales process for our products. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

Increasing use of social media could give rise to liability.

We are increasingly relying on social media tools as a means of communications. To the extent that we continue to use these tools as a means to communicate about our products and product candidates or about the diseases that our products and our product candidates are intended to treat, there are significant uncertainties as to either the rules that apply to such communications, or as to the interpretations that health authorities will apply to the rules that exist. As a result, despite our efforts to comply with applicable rules, there is a significant risk that our use of social media for such purposes may cause us to nonetheless be found in violation of them. Such uses of social media could have a material adverse effect on our business, financial condition and results of operations.

Legislative actions and new accounting pronouncements are likely to impact our future financial position or results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future and as a result we may be required to make changes in our accounting policies. Those changes could adversely affect our reported revenues and expenses, future profitability or financial position. Compliance with new regulations regarding corporate governance and public disclosure may result in additional expenses.

The application of existing or future financial accounting standards, particularly those relating to the way we account for revenues and costs, could have a significant impact on our reported results. In addition, compliance with new regulations regarding corporate governance and public disclosure may result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from science and business activities to compliance activities.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our headquarters are in Bothell, Washington. Our Bothell campus comprises 11 leased buildings of office and warehouse space that we use for laboratory, discovery, research and development and general and administrative purposes, and a biologics manufacturing facility which we own. We also have leased space in Seattle, Washington, South San Francisco, California, Mississauga, Canada, Zug, Switzerland, and in several other European locations used for general and administrative purposes. All of our significant leases include renewal options. We believe that our real estate is currently adequate to meet our needs. As we continue to expand our operations, we may need to lease or purchase additional real estate.

Item 3. Legal Proceedings

The information set forth in Note 14 of the Notes to Consolidated Financial Statements included in Part II Item 8 of this Annual Report on Form 10-K is incorporated by reference into this Item 3.

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

Our Common Stock

Our common stock is traded on the Nasdaq Global Select Market under the symbol "SGEN." As of February 9, 2021, there were 181,164,446 shares of our common stock outstanding, which were held by approximately 60 holders of record.

Dividend Policy

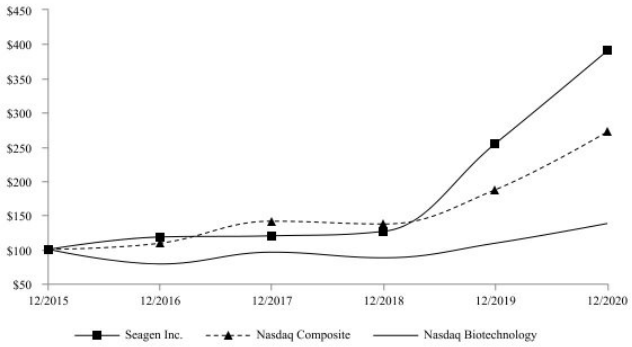
We have not paid any cash dividends on our common stock since our inception. We do not intend to pay any cash dividends in the foreseeable future, but intend to retain all earnings, if any, for use in our business operations.

Sales of Unregistered Securities and Issuer Repurchases of Securities

Other than as previously reported on a Current Report on Form 8-K filed with the Securities and Exchange Commission on September 14, 2020, there were no unregistered sales of equity securities by us during 2020. In addition, we did not repurchase any of our equity securities during 2020.

Stock Performance Graph

The table below shows the cumulative total return to our stockholders during the period from December 31, 2015 through December 31, 2020 in comparison to the indicated indexes. The results assume that $100 was invested on December 31, 2015 in our common stock and each of the indicated indexes, including reinvestment of any dividends.



	December 31,					
	2015	2016	2017	2018	2019	2020
Seagen Inc.	$ 100.00	$ 117.58	$ 119.21	$ 126.25	$ 254.59	$ 390.24
Nasdaq Composite	100.00	108.87	141.13	137.12	187.44	271.64
Nasdaq Biotechnology	100.00	78.65	95.67	87.19	109.08	137.90

This information under "Stock Performance Graph" is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference in any filing of Seagen Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K and irrespective of any general incorporation language in those filings.

Item 6. Selected Financial Data

The following selected financial data should be read in conjunction with our consolidated financial statements and notes to our consolidated financial statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained elsewhere in this Annual Report on Form 10-K. The selected Consolidated Statements of Comprehensive Income (Loss) data for the years ended December 31, 2020, 2019, and 2018, and Consolidated Balance Sheet data as of December 31, 2020 and 2019 have been derived from our audited financial statements appearing elsewhere in this Annual Report on Form 10-K. The selected Consolidated Statements of Comprehensive Income (Loss) data for the years ended December 31, 2017 and 2016 and Consolidated Balance Sheet data as of December 31, 2018, 2017, and 2016 have been derived from our audited financial statements that are not included in this Annual Report on Form 10-K. Historical results are not necessarily indicative of future results.

	Years ended December 31,				
	2020 (a)	2019 (b)	2018 (c)	2017	2016
	(in thousands, except for per share amounts)				
Consolidated Statements of Comprehensive Income (Loss) Data:					
Revenues:					
Net product sales	$ 1,000,598	$ 627,977	$ 476,903	$ 307,562	$ 265,766
Royalty revenues	126,756	138,491	83,440	66,056	67,455
Collaboration and license agreement revenues	1,048,182	150,245	94,357	108,632	84,926
Total revenues	2,175,536	916,713	654,700	482,250	418,147
Costs and expenses:					
Cost of sales	217,720	43,952	88,293	54,118	42,317
Research and development	827,129	719,374	565,309	456,700	379,308
Selling, general and administrative	533,835	373,932	261,096	167,233	139,247
Total costs and expenses	1,578,684	1,137,258	914,698	678,051	560,872
Income (loss) from operations	596,852	(220,545)	(259,998)	(195,801)	(142,725)
Investment and other income, net	18,849	61,895	13,652	36,914	2,614
Income (loss) before income taxes	615,701	(158,650)	(246,346)	(158,887)	(140,111)
Income tax benefit (expense)	(2,031)	—	23,653	33,357	—
Net income (loss)	$ 613,670	$ (158,650)	$ (222,693)	$ (125,530)	$ (140,111)
Net income (loss) per share - basic	$ 3.51	$ (0.96)	$ (1.41)	$ (0.88)	$ (1.00)
Net income (loss) per share - diluted	$ 3.37	$ (0.96)	$ (1.41)	$ (0.88)	$ (1.00)
Shares used in computation of per share amounts - basic	174,834	165,498	157,655	143,174	140,746
Shares used in computation of per share amounts - diluted	182,287	165,498	157,655	143,174	140,746

	December 31,				
	2020	2019	2018	2017	2016
	(a)	(b)	(c)		
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	$ 2,660,250	$ 868,338	$ 459,866	$ 413,171	$ 618,974
Working capital	2,674,246	917,284	428,523	409,932	586,132
Total assets	4,000,906	2,205,866	1,503,329	877,949	838,396
Stockholders' equity	3,488,100	1,876,287	1,273,943	677,569	634,087

(a) In October 2020, we closed the sale of the shares pursuant to the Purchase Agreement, and issued 5,000,000 shares of our common stock to Merck at a purchase price of $200 per share, for proceeds of $1.0 billion. As a result, we recorded $749.9 million in stockholders' equity on our consolidated balance sheet and recognized the $250.1 million premium attributed to the Purchase Agreement in collaboration and license agreement revenues for the year ended December 31, 2020.

(b) In July 2019, we completed an underwritten public offering of 8,214,286 shares of our common stock at a public offering price of $70.00 per share. The offering resulted in net proceeds to us of $548.7 million.

On January 1, 2019, we adopted Accounting Standards Codification, or ASC, Topic 842--Leases. We recognized $35.2 million of operating lease liabilities and $34.7 million of operating lease right-of-use assets on our consolidated balance sheet. We elected the modified retrospective method transition option, which permitted us not to restate the comparative periods presented. For additional information, refer to Note 3 of the Notes to Consolidated Financial Statements included in Part II Item 8 of this Annual Report on Form 10-K.

(c) In March 2018, we acquired Cascadian Therapeutics, Inc., or Cascadian, for a total purchase price of approximately $614.1 million. Cascadian was included in our results of operations, along with the estimated fair values of the assets acquired and liabilities assumed in the acquisition, as of the acquisition date.

In February 2018, we completed an underwritten public offering of 13,269,230 shares of our common stock at a public offering price of $52.00 per share. The offering resulted in net proceeds to us of $658.2 million. The primary use of the net proceeds received from the offering was the fund the Cascadian acquisition.

On January 1, 2018, we adopted ASC Topic 606--Revenue from Contracts with Customers. We recorded a $26.6 million cumulative effect adjustment to decrease the accumulated deficit as of January 1, 2018. We used the modified retrospective method transition option, which permitted us not to restate the comparative periods presented. For additional information, refer to Note 2 of the Notes to Consolidated Financial Statements included in Part II Item 8 of this Annual Report on Form 10-K.

On January 1, 2018, we adopted Accounting Standards Update, or ASU, "ASU 2016-01, Financial Instruments: Overall," which required, among other items, that changes in the fair value of equity securities be recorded in income or loss rather than accumulated other comprehensive income or loss in stockholders' equity. We recognized a $64.1 million cumulative effect adjustment to decrease the accumulated deficit as of January 1, 2018. We used the modified retrospective method transition option, which permitted us not to restate the comparative periods presented. For additional information, refer to the heading "Investments" in Note 1 of the Notes to the Consolidated Financial Statements included in Part II Item 8 of this Annual Report on Form 10-K.

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 contains 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 are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail in "Part I Item 1A—Risk Factors." We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

You should read the following discussion and analysis in conjunction with the Selected Financial Data and our consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K.

Overview

Seagen is a biotechnology company that develops and commercializes targeted therapies to treat cancer. We are commercializing ADCETRIS for the treatment of certain CD30-expressing lymphomas, PADCEV for the treatment of certain metastatic urothelial cancers, and TUKYSA for treatment of certain metastatic HER2-positive breast cancers. We are also advancing a pipeline of novel therapies for solid tumors and blood-related cancers designed to address unmet medical needs and improve treatment outcomes for patients. Many of our programs, including ADCETRIS and PADCEV, are based on our antibody-drug conjugate, or ADC, technology that utilizes the targeting ability of monoclonal antibodies to deliver cell-killing agents directly to cancer cells. In October 2020, we changed our corporate name from Seattle Genetics, Inc. to Seagen Inc., reflecting the global expansion of our operations.

2020 highlights and recent developments

Corporate

- Reported net product sales of $1 billion for full year 2020.
- Entered into oncology collaborations with Merck under which we received $725 million in upfront payments and $1 billion through an equity investment by Merck.
- Continued to make strategic investments in our pipeline, commercial launches, infrastructure, and headcount to support our future growth.

ADCETRIS

- Reported the five-year update of the phase 3 ECHELON-1 clinical trial which showed treatment with ADCETRIS in combination with AVD resulted in superior long-term outcomes when compared to ABVD, which includes bleomycin, in frontline advanced Hodgkin lymphoma.
- Expanded clinical program including initiation of phase 3 trial in relapsed and refractory diffuse large B-cell lymphoma and expanded a trial in frontline Hodgkin lymphoma to evaluate stage I and II patients.
- Expanded indication approved in the European Union and first approval in China for our partner Takeda.

PADCEV

- Commercial launch with Astellas, for patients with previously treated metastatic urothelial cancer, following FDA approval in December 2019.

- Announced positive topline results from EV-301 phase 3 trial showing that PADCEV significantly improved overall survival in previously treated metastatic urothelial cancer patients. Data to support global marketing applications.
- Announced positive topline results from second cohort of EV-201 pivotal trial. Data to support additional indication in the U.S.
- Initiated EV-302 phase 3 trial in first-line metastatic urothelial cancer in combination with pembrolizumab.
- Received breakthrough therapy designation in first-line advanced urothelial cancer for PADCEV in combination with pembrolizumab.

TUKYSA

- Commercial launch following FDA approval for patients with previously treated metastatic HER2-positive breast cancer, including patients with brain metastases in April 2020.
- Received ex-U.S. regulatory approvals in Australia, Canada, Singapore and Switzerland under the Project Orbis initiative of the FDA Oncology Center of Excellence.
- Received marketing authorization in the European Union in February 2021.
- Entered into exclusive license and co-development agreement with Merck to commercialize TUKYSA in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe.

Pipeline

- Announced positive results from tisotumab vedotin pivotal trial in patients with previously treated recurrent or metastatic cervical cancer. Data used to support approval application submitted in the U.S. in February 2021.
- Entered into a global co-development and co-commercialization agreement with Merck for our drug candidate ladiratuzumab vedotin.
- Initiated phase 1 trials of two novel drug candidates, SGN-B6A and SEA-TGT.

Also refer to Part I Item 1 “Business” for more information about our products, pipeline, technologies, research programs, and future plans for our clinical programs, including recent key business achievements.

Outlook

We recognize revenue from ADCETRIS product sales in the U.S. and Canada, and PADCEV and TUKYSA products sales in the U.S. While we anticipate that sales of ADCETRIS will increase in 2021 as compared to 2020, we have experienced and expect continued impacts associated with the COVID-19 pandemic, which appear to be reducing the rate of Hodgkin lymphoma diagnoses, and an increase in gross-to-net deductions that we believe is due to a shift in the locations where ADCETRIS is administered, which has increased the proportion of ADCETRIS sales through the federal 340B drug discount program. We expect that, going forward, our ability to maintain or continue to grow our ADCETRIS sales, if at all, will depend primarily on our ability to establish or demonstrate to the medical community the value of ADCETRIS and its potential advantages compared to existing and future therapeutics in its approved indications, including in the frontline Hodgkin lymphoma indication, and the extent to which physicians make prescribing decisions with respect to ADCETRIS. Other important factors affecting our ADCETRIS sales include the incidence flow of patients eligible for treatment in ADCETRIS’ approved indications, the extent to which coverage and adequate levels of reimbursement for ADCETRIS are available from governments and other third-party payors, the impact of any healthcare reform measures that may be upheld, or adopted in the future, including measures that could result in more rigorous coverage criteria or reduce the price that we receive for ADCETRIS, increasing competition from competing therapies including pembrolizumab in multiple indications, including in the relapsed or refractory classical Hodgkin lymphoma indication, impacts resulting from the evolving effects of the COVID-19 pandemic including lower diagnosis rates, and the potential future approval of ADCETRIS in any additional indications. For these reasons, we cannot assure you that ADCETRIS sales will continue to grow or that we can maintain sales of ADCETRIS at or near current levels. In addition, as a result of these and other factors, our future ADCETRIS product sales can be difficult to accurately predict from period to period.

Our ability to realize the anticipated benefits from our investment in PADCEV is subject to a number of risks and uncertainties, including our and Astellas’ ability to successfully jointly market and commercialize PADCEV in the U.S. in its approved indication, the extent to which we and Astellas are able to obtain regulatory approvals of PADCEV in

additional indications in the U.S., including in the frontline metastatic urothelial cancer setting, and in territories outside the U.S., our ability and Astellas' ability to successfully comply with rigorous post-marketing requirements, including obtaining the FDA's agreement as to the confirmation of clinical benefit of PADCEV based on the results of the EV-301 clinical trial, the acceptance of PADCEV by the medical community and patients, the extent to which physicians make prescribing decisions with respect to PADCEV, the incidence flow of patients eligible for treatment in PADCEV's approved indication, the duration of therapy for patients receiving PADCEV, the extent to which coverage and adequate levels of reimbursement for PADCEV are available from governments and other third-party payors, the impact of any healthcare reform measures that may be adopted in the future, including measures that could potentially result in more rigorous coverage criteria and additional downward pressure on the price that we receive for PADCEV, potential competition from competing therapies, the impact of conducting launch activities virtually during the COVID-19 pandemic and other impacts resulting from the evolving effects of the COVID-19 pandemic including potential negative impacts of reduced cancer diagnosis rates. In addition, as a result of these and other factors, including the lack of significant historical sales data, PADCEV sales are currently difficult to predict from period to period.

Our ability to realize the anticipated benefits of our investment in TUKYSA is subject to a number of risks and uncertainties, including our and Merck's ability to successfully launch, market and commercialize TUKYSA in our respective territories in its approved indication, the extent to which we and Merck are able to obtain regulatory and other required governmental and pricing and reimbursement approvals of TUKYSA in additional territories, the extent to which we and Merck are able to obtain regulatory approvals of TUKYSA in additional indications, including earlier lines of breast cancer and other HER2-positive cancers, the acceptance of TUKYSA by the medical community and patients, competition from other therapies, our and Merck's ability to accurately predict and supply product demand, the extent to which coverage and reimbursement will be available from governments and other third-party payors, our capacity to effectively commercialize a product outside of the U.S., the impact of conducting launch activities virtually during the COVID-19 pandemic and other impacts resulting from the evolving effects of the COVID-19 pandemic including potential negative impacts of reduced cancer diagnosis rates. In addition, as a result of these and other factors, including the lack of significant historical sales data, TUKYSA sales are currently difficult to predict from period to period.

The biopharmaceutical industry and the markets in which we operate are intensely competitive. Many of our competitors are working to develop or have commercialized products similar to those we market or are developing. Drug prices are under significant scrutiny and we expect drug pricing and other health care costs to continue to be subject to intense political and societal pressures on a global basis. For example, in July 2020, then-President Trump announced four Executive Orders related to reducing prescription drug prices and we expect that drug pricing will continue to be subject to close scrutiny by federal, state and foreign governments. In addition to pricing actions and other measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures, our sales and operations could also be affected by other risks of doing business internationally.

We expect that amounts received from our collaboration agreements, including royalties, will continue to be an important source of our revenues and cash flows. These revenues and cash flows will be impacted by future development funding and the achievement of development, clinical and commercial success by our collaborators under our existing collaboration and license agreements, as well as by entering into potential new collaboration and license agreements.

Our ongoing research, development, manufacturing and commercial activities will require substantial amounts of capital and may not ultimately be successful. We expect that we will incur substantial expenses, and we will require significant financial resources and additional personnel in order to advance the development of, to pursue, obtain and maintain regulatory approvals for, and to commercialize our products and product candidates, and expand our pipeline. In addition, we may pursue new operations or continue the expansion of our existing operations, including with respect to our plans to build a commercial infrastructure in Europe and to otherwise continue to expand our operations internationally. As a result, we may need to raise additional capital, and our operating expenses may fluctuate as a result of such activities. We may also incur milestone payment obligations to certain of our licensors as our product candidates progress through clinical trials towards potential commercialization.

We are closely evaluating the impacts of the evolving effects of the COVID-19 pandemic on our ability and the ability of our collaborators to effectively market, sell and distribute our products and to develop our products and product candidates. While our field-based personnel are engaging in limited in-person interactions, they are primarily using electronic communication, such as emails, phone calls and video conferences. Many healthcare professionals that we normally call on are working a greater proportion of their working schedule from home and are facing additional demands on their time during the ongoing COVID-19 pandemic. We are experiencing increased competition for virtual appointments with healthcare professionals and a significant reduction in the number of interactions our sales personnel are having with physicians. We expect the different quality of electronic interactions as compared with in-person interactions, as well as the reduced quantity of interactions during the COVID-19 pandemic, to reduce the effectiveness of our sales personnel, as well as those of our collaborators, which could negatively affect our product sales and those of our collaborators, as well as physician awareness of our products. With respect to PADCEV and TUKYSA specifically, we have not launched a product using primarily virtual communication channels in the past and cannot predict the effects that this approach will ultimately have on demand for PADCEV or TUKYSA. However, we believe that the need to conduct these activities virtually is negatively impacting our ability to connect with key customers, including those familiar with competitive products, and our ability to conduct payor engagements. We face a number of challenges that will limit our ability to fully resume in-person interactions for the foreseeable future, including increasing COVID-19 infection rates in many states, the potential for more severe outbreaks, the need to navigate varying restrictions for entering healthcare facilities and employee childcare obligations during virtual school sessions. In addition, the effects of the COVID-19 pandemic continue to evolve rapidly, and we may subsequently be forced to, or subsequently determine that we should, resume a more restrictive remote work model, whether as a result of further spikes or surges in COVID-19 infection or hospitalization rates or otherwise. Moreover, the long-term effects of the COVID-19 pandemic are also unknown and it is possible that following the pandemic, healthcare institutions could alter their policies with respect to in person visits by pharmaceutical company representatives. COVID-19 related restrictions could also present product distribution challenges as we utilize recently initiated distribution channels for TUKYSA. We also expect that the conversion of medical conferences to a virtual format may reduce our ability to effectively disseminate scientific information about our products, which may result in decreased physician awareness of our products, their approved indications and their efficacy and safety. The evolving effects of the COVID-19 pandemic may also negatively affect our product sales due to challenges in patient access to healthcare settings, significant increases in unemployment and the resulting loss of individual health insurance coverage, and inability to access government healthcare programs due to backlogs, some or all of which appear to be affecting diagnosis rates and may affect side effect management, course of treatment and increase enrollment in our patient support programs. With respect to ADCETRIS specifically, impacts associated with the COVID-19 pandemic appear to be reducing the rate of Hodgkin lymphoma diagnoses. In addition, we have experienced lower than expected levels of our research and development spending, in part as a result of the COVID-19 pandemic. This includes some delays in clinical trial enrollment as well as reduced travel due to the conversion of medical and scientific meetings to virtual format. While we do not at this time anticipate the need to revise our publicly reported projected clinical milestone dates as a result of the effects of the COVID-19 pandemic, there may be some impacts to our clinical study timelines, which, depending upon the duration and severity of the evolving effects of the COVID-19 pandemic, could ultimately delay data availability. In addition, many of our non-essential on-site research activities are currently significantly reduced as a result of the COVID-19 pandemic, which may negatively impact the number of investigational new drug application, or IND, candidates entering our clinical pipeline in future years. The extent to which the risks and evolving effects of the COVID-19 pandemic impact our business, our ability to generate sales of and revenues from our approved products, and our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate duration and severity of the pandemic, government actions, such as travel restrictions, quarantines and social distancing requirements in the U.S. and in other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and in other countries to contain and treat the disease, including the effectiveness and timing of vaccine programs in the U.S. and worldwide.

Because of the above and other factors, our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period to period comparisons of our operating results may not be meaningful and should not be relied upon as being indicative of our future performance.

Financial summary

For 2020, our total revenues increased to $2.2 billion, compared to $916.7 million in 2019. This growth was driven by $975.2 million collaboration and license agreement revenues recognized related to the agreements we entered into with Merck during 2020, the U.S. launches of PADCEV beginning in December 2019 and TUKYSA in April 2020, respectively, as well as higher ADCETRIS net product sales.

For 2020, total costs and expenses increased to $1.6 billion, compared to $1.1 billion in 2019. This primarily reflected higher cost of sales, higher selling, general and administrative expenses, and higher research and development expenses.

As of December 31, 2020, we had $2.7 billion in cash, cash equivalents and investments and $3.5 billion in total stockholders' equity.

Comparability

We adopted ASC Topic 842—Leases on January 1, 2019, resulting in a change to our accounting policy for leases. We recorded a liability to make lease payments and a right-of-use asset representing our right to use the underlying assets for the applicable lease terms in our consolidated balance sheet at January 1, 2019. We used the modified retrospective method transition option. Accordingly, 2018 comparative information has not been adjusted and continues to be reported under previous accounting standards. For additional information, refer to Note 3 of the Notes to Consolidated Financial Statements included in Part II Item 8 of this Annual Report on Form 10-K.

In 2018, we acquired Cascadian for $10.00 per share in cash, or approximately $614.1 million. Cascadian was included in our results of operations as of the acquisition date. Accordingly, the results discussed below were impacted by the timing of this acquisition. For additional information, refer to Note 4 of the Notes to Consolidated Financial Statements included in Part II Item 8 of this Annual Report on Form 10-K.

In addition, the section of this Management's Discussion and Analysis of Financial Condition and Results of Operations generally discusses 2020 and 2019 items and year-to-year comparisons between 2020 and 2019. Discussions of 2018 items and year-to-year comparisons between 2019 and 2018 that are not included in this Annual Report on Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on February 6, 2020.

Critical Accounting Policies

The preparation of financial statements in accordance with generally accepted accounting principles, or GAAP, requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. We believe the following critical accounting policies describe the more significant judgments and estimates used in the preparation of our financial statements.

We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions and conditions.

Revenue Recognition. Our revenues are comprised of ADCETRIS, PADCEV and TUKYSA net product sales, amounts earned under our collaboration and licensing agreements, and royalties. Revenue recognition occurs when a customer obtains control of promised goods or services in an amount that reflects the consideration we expect to receive in exchange for those goods or services. The period between when we transfer control of promised goods or services and when we receive payment is expected to be one year or less, and that expectation is consistent with our historical experience. As such, we do not adjust our revenues for the effects of a significant financing component.

We apply significant judgment to our estimates in the following revenue recognition areas, each as discussed in more detail in the corresponding sections after this list:

- *Net product sales* - sales deductions related to government-mandated rebates and chargebacks, such as for the Medicaid and 340B programs
- *Collaboration and license agreement revenues* - assessing the probability of future reversal of variable consideration and evaluating whether contractual obligations represent distinct performance obligations
- *Royalty revenues* - estimating Takeda's net sales of ADCETRIS to the extent actual information is not available

Net product sales

We sell ADCETRIS, PADCEV and TUKYSA through a limited number of specialty distributors and specialty pharmacies. We and our collaboration partner Astellas jointly promote PADCEV in the U.S. Under the joint promotion in the U.S., we record net sales of PADCEV and are responsible for all distribution through a limited number of specialty distributors. The delivery of our products represents a single performance obligation for these transactions and we record net product sales at the point in time when title and risk of loss pass. The transaction price for net product sales 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. We reflect these accruals as either a reduction in the related account receivable from the distributor or as an accrued liability, depending on the nature of the sales deduction. 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. We have applied a portfolio approach as a practical expedient for estimating net product sales.

Government-mandated rebates and chargebacks: We have entered into a Medicaid Drug Rebate Agreement, or MDRA, with the Centers for Medicare & Medicaid Services. This agreement provides for a rebate based on covered purchases of our products. Medicaid rebates are invoiced to us by the various state Medicaid programs. We estimate Medicaid rebates using the expected value approach, based on a variety of factors, including payor mix and our experience to-date.

We have a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of our products. In addition, we have entered into a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services, which enables certain entities that qualify for government pricing under the Public Health Services Act, or PHS, to receive discounts on their qualified purchases of our products. Under these agreements, distributors process a chargeback to us for the difference between wholesale acquisition cost and the applicable discounted price. We estimate expected chargebacks for FSS and PHS purchases based on the expected value of each entity’s eligibility for the FSS and PHS programs. We also review historical rebate and chargeback information to further refine these estimates.

Distribution fees, product returns and other deductions: Our distributors charge a volume-based fee for distribution services that they perform for us. We allow for the return of product that is within a specified number of days of its expiration date or that is damaged. We estimate product returns based on our experience to-date using the expected value approach. We provide financial assistance to qualifying patients that are underinsured or cannot cover the cost of commercial coinsurance amounts through our patient support programs. Estimated contributions for commercial coinsurance under SeaGen Secure are deducted from gross sales and are based on an analysis of expected plan utilization. These estimates are adjusted as necessary to reflect our actual experience.

Royalty revenues

Royalty revenues primarily reflect amounts earned under the ADCETRIS collaboration with Takeda. These royalties include commercial sales-based milestones and sales royalties that relate predominantly to the license of intellectual property. Sales royalties are based on a percentage of Takeda's net sales of ADCETRIS, with rates that range from the mid-teens to the mid-twenties based on annual net sales tiers. Takeda bears a portion of low single digit third-party royalty costs owed on its sales of ADCETRIS. This amount is included in royalty revenues. Amounts owed to our third-party licensors related to Takeda's sales of ADCETRIS are recorded in cost of sales. These amounts are recognized in the period in which the related sales by Takeda occur. Royalty revenues also reflect amounts from Genentech, Inc., a member of the Roche Group, or Genentech, earned on net sales of Polivy, and amounts from GlaxoSmithKline earned on net sales of Blenrep.

Collaboration and license agreement revenues

We have collaboration and license agreements for our technology with a number of biotechnology and pharmaceutical companies. Under these agreements, we typically receive or are entitled to receive upfront cash payments and progress- and sales-dependent milestones for the achievement by our licensees of certain events, and annual maintenance fees and support fees for research and development services and materials provided under the agreements. We also are entitled to receive royalties on net sales of any resulting products incorporating our technology. Our licensees are solely responsible for research, product development, manufacturing and commercialization of any product candidates under these collaborations, which includes the achievement of the potential milestones. Since we may not take a substantive role or control the research, development or commercialization of any products generated by some of our licensees, we may not able to reasonably estimate when, if at all, any potential future milestone payments or royalties may be payable to us by our licensees. As such, the potential future milestone payments associated with certain of our collaboration and license agreements involve a substantial degree of uncertainty and risk that they may never be received.

Collaboration and license agreements are initially evaluated as to whether the intellectual property licenses granted by us represent distinct performance obligations. If they are determined to be distinct, the value of the intellectual property licenses would be recognized up-front while the research and development service fees would be recognized as the performance obligations are satisfied. Variable consideration is assessed at each reporting period as to whether it is not subject to future reversal of cumulative revenue and, therefore, should be included in the transaction price. Assessing the recognition of variable consideration requires significant judgment. If a contract includes a fixed or minimum amount of research and development support, this also would be included in the transaction price. Changes to collaboration and license agreements, such as the extensions of the research term or increasing the number of targets or technology covered under an existing agreement, are assessed for whether they represent a modification or should be accounted for as a new contract.

We have concluded that the license of intellectual property in certain collaboration and license agreements is not distinct from the perspective of our customers at the time of initial transfer, since we often do not license intellectual property without related technology transfer and research and development support services. Such evaluation requires significant judgment since it is made from the customer's perspective. Our performance obligations under our collaborations may include such things as providing intellectual property licenses, performing technology transfer, performing research and development consulting services, providing reagents, ADCs, and other materials, and notifying the customer of any enhancements to licensed technology or new technology that we discover, among others. We determined our performance obligations under certain collaboration and license agreements as evaluated at contract inception were not distinct and represented a single performance obligation. For those agreements, revenue is recognized using a proportional performance model, representing the transfer of goods or services as activities are performed over the term of the agreement. Upfront payments are also amortized to revenue over the performance period. Upfront payment contract liabilities resulting from our collaborations do not represent a financing component as the payment is not financing the transfer of goods or services, and the technology underlying the licenses granted reflects research and development expenses already incurred by us. For agreements beyond the initial performance period, we have no remaining performance obligations. We may receive license maintenance fees and potential milestones and royalties based on collaborator development and regulatory progress, which are recorded in the period achieved in the case of milestones, and during the period of the related sales for royalties.

When no performance obligations are required of us, or following the completion of the performance obligation period, such amounts are recognized upon transfer of control of the goods or services to the customer. Generally, all amounts received or due other than sales-based milestones and royalties are classified as collaboration and license agreement revenues. Sales-based milestones and royalties are recognized as royalty revenue in the period the related sale occurred.

We generally invoice our collaborators and licensees on a monthly or quarterly basis, or upon the completion of the effort or achievement of a milestone, based on the terms of each agreement. Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods as performance obligations are satisfied. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

Business combinations, including acquired in-process research and development and goodwill. We account for business combinations using the acquisition method, recording the acquisition-date fair value of total consideration over the acquisition-date fair value of net assets acquired as goodwill.

Fair value is typically estimated using an income approach based on the present value of future discounted cash flows. The significant estimates in the discounted cash flow model primarily include the discount rate, rates of future revenue growth and/or profitability of the acquired business. The discount rate considers the relevant risk associated with business-specific characteristics and the uncertainty related to the ability to achieve the projected cash flows. We may record adjustments to the fair values of assets acquired and liabilities assumed within the measurement period (up to one year from the acquisition date).

In-process research and development assets are accounted for as indefinite-lived intangible assets and maintained on the balance sheet until either the underlying project is completed or the asset becomes impaired. If the project is completed, which generally occurs when FDA approval is obtained, the carrying value of the related intangible asset is amortized to cost of sales on a straight-line basis over the estimated useful life of the asset beginning in the period in which the project is completed. We periodically evaluate when facts or circumstances indicate that the carrying value of these assets may not be recoverable. If the asset becomes impaired or is abandoned, the carrying value of the related intangible asset is written down to its fair value and an impairment charge is recorded in the period in which the impairment occurs.

We evaluate indefinite-lived intangible assets and goodwill for impairment annually, as of October 1, or more frequently when events or circumstances indicate that impairment may have occurred. As part of the impairment evaluation, we may elect to perform an assessment of qualitative factors. If this qualitative assessment indicates that it is more likely than not that the fair value of the indefinite-lived intangible asset or the reporting unit (for goodwill) is less than its carrying value, we then would proceed with the quantitative impairment test to compare the fair value to the carrying value and record an impairment charge if the carrying value exceeds the fair value.

Accrued Liabilities. As part of the process of preparing financial statements, we estimate accrued liabilities. This process involves identifying services that have been performed on our behalf and estimating the level of services performed and the associated costs incurred for such services where we have not yet been invoiced or otherwise notified of actual cost. We record these estimates in our consolidated financial statements as of each balance sheet date. Examples of estimated accrued liabilities include amounts due to contract research organizations and other costs in conjunction with clinical trials, amounts due in conjunction with manufacturing our product candidates, third-party royalties that accrue on our sales of our marketed products, and professional service fees, among other items.

In accruing service fees, we estimate the time period over which services will be provided and the level of effort in each period. If the actual timing of the provision of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. In the event that we do not identify costs that have been incurred or we under or overestimate the level of services performed or the costs of such services, our actual liabilities would differ from such estimates. The date on which some services commence, the level of services performed on or before a given date and the cost of such services are often subjective determinations. We make judgments based upon the facts and circumstances known to us at the time.

Long-term Incentive Plans. We have long term incentive plans which provide eligible employees with the opportunity to receive performance-based incentive compensation, which may be comprised of cash, stock options, and/or restricted stock units. The payment of cash and the grant or vesting of equity awards are contingent upon the achievement of pre-determined regulatory milestones. We record compensation expense over the estimated service period for each milestone when we believe the milestone is considered probable, which we assess at each reporting date. Once a milestone is considered probable, we record compensation expense based on the portion of the service period elapsed to date with respect to that milestone, with a cumulative catch-up, net of estimated forfeitures, and recognize any remaining compensation expense, if any, over the remaining estimated service period.

Income Taxes. We have net deferred tax assets which are offset by a valuation allowance due to our determination that it is more likely than not that the deferred tax assets will not be realized. We believe that a valuation allowance is appropriate as we have a history of net operating losses. In the event we were to determine that we would be able to realize our net deferred tax assets in the future, an adjustment to the valuation allowance would be made, a portion of which would increase income (or decrease losses) in the period in which such a determination was made. We follow the guidance related to accounting for uncertainty in income taxes, which requires the recognition of an uncertain tax position when it is more likely than not to be sustainable upon audit by the applicable taxing authority.

Results of Operations - Years Ended December 31, 2020, 2019, and 2018

Net product sales

(dollars in thousands)	2020	2019	2018	Percentage change 2020/2019	Percentage change 2019/2018
ADCETRIS	$ 658,577	$ 627,733	$ 476,903	5 %	32 %
PADCEV	222,436	244	—	NM	NM
TUKYSA	119,585	—	—	NM	NM
Net product sales	$ 1,000,598	$ 627,977	$ 476,903	59 %	32 %

NM: No amount in comparable period or not a meaningful comparison.

Our net product sales grew 59% during 2020 as compared to 2019, primarily driven by recent product launches of PADCEV and TUKYSA. We began commercializing PADCEV and TUKYSA following FDA approvals in December 2019 and April 2020, respectively. ADCETRIS net product sales increased in 2020 from 2019 due to higher sales volumes and the effect of price increases during the current year period.

We expect growth in net product sales in 2021 from 2020 to be primarily driven by sales growth of TUKYSA and PADCEV, and to a lesser extent, ADCETRIS.

Gross-to-net deductions, net of related payments and credits, were as follows:

	December 31, 2020			December 31, 2019			December 31, 2018		
(in thousands)	Rebates and chargebacks	Distribution fees, product returns and other	Total	Rebates and chargebacks	Distribution fees, product returns and other	Total	Rebates and chargebacks	Distribution fees, product returns and other	Total
Balance, beginning of year	$ 38,084	$ 7,519	$ 45,603	$ 26,968	$ 5,604	$ 32,572	$ 14,374	$ 3,521	$ 17,895
Provision related to current year sales	358,238	28,724	386,962	253,702	15,298	269,000	179,394	11,717	191,111
Adjustments for prior period sales	(1,341)	—	(1,341)	(392)	(464)	(856)	440	(478)	(38)
Payments/credits for current year sales	(319,444)	(18,886)	(338,330)	(217,905)	(11,349)	(229,254)	(155,581)	(8,248)	(163,829)
Payments/credits for prior year sales	(31,344)	(1,668)	(33,012)	(24,289)	(1,570)	(25,859)	(11,659)	(908)	(12,567)
Balance, end of year	$ 44,193	$ 15,689	$ 59,882	$ 38,084	$ 7,519	$ 45,603	$ 26,968	$ 5,604	$ 32,572

Government-mandated rebates and chargebacks are the most significant component of our total gross-to-net deductions and the discount percentage has been increasing. These discount percentages increased during 2020 and 2019 as a result of price increases for ADCETRIS that we instituted that exceeded the rate of inflation. The most significant portion of our gross-to-net accrual balances as of December 31, 2020 and 2019 was for ADCETRIS Medicaid rebates. We expect future gross-to-net deductions to fluctuate based on the volume of purchases eligible for government mandated discounts and rebates, as well as changes in the discount percentage which is impacted by potential future price increases, the rate of inflation, and other factors. We expect gross-to-net deductions to increase in 2021 as compared to 2020, driven by anticipated growth in our gross product sales.

Royalty revenues

Royalty revenues primarily reflect royalties earned under the ADCETRIS collaboration with Takeda. These royalties include commercial sales-based milestones and sales royalties. Sales royalties are based on a percentage of Takeda's net sales of ADCETRIS, with rates that range from the mid-teens to the mid-twenties based on annual net sales tiers. Takeda bears third-party royalty costs owed on its sales of ADCETRIS. This amount is included in royalty revenues. Royalty revenues also reflect, to a lesser extent, amounts from Genentech earned on net sales of Polivy beginning in 2019, and amounts from GlaxoSmithKline earned on net sales of Blenrep beginning in August 2020, both of which utilizes technology that we have licensed to them.

				Percentage change	
(dollars in thousands)	2020	2019	2018	2020/2019	2019/2018
Royalty revenues	$ 126,756	$ 138,491	$ 83,440	(8) %	66 %

Royalty revenues decreased in 2020 as compared to 2019 due to Takeda's achievement of a $40.0 million sales-based milestone during 2019, offset in part by 2020 growth in Takeda net sales of ADCETRIS in its territories, as well as higher Roche net sales of Polivy.

We expect that royalty revenues will increase in 2021 as compared to 2020 primarily due to higher royalties from anticipated growth in ADCETRIS sales volume by Takeda, as well as anticipated sales growth of our other licensees.

Collaboration and license agreement revenues

Collaboration and license agreement revenues reflect amounts earned under certain of our license and collaboration agreements. These revenues reflect the earned portion of license fees, payments received by us for technology access and maintenance fees, milestone payments and reimbursement payments for research and development support that we provide to our collaborators.

Collaboration and license agreement revenues by collaborator were as follows:

				Percentage change	
(dollars in thousands)	**2020**	**2019**	**2018**	**2020/2019**	**2019/2018**
Merck	$ 975,150	$ —	$ —	NM	NM
Takeda	32,107	108,175	58,605	(70) %	85 %
Other	40,925	42,070	35,752	(3) %	18 %
Collaboration and license agreement revenues	$ 1,048,182	$ 150,245	$ 94,357	598 %	59 %

NM: No amount in comparable period or not a meaningful comparison.

Collaboration and license agreement revenues from Merck included license revenues of $725.0 million related to the collaboration agreements for LV and TUKYSA that were entered into in 2020, as well as a stock purchase premium paid by Merck of $250.1 million. Refer to Note 11 of the Notes to Consolidated Financial Statements included in Part II Item 8 for additional information.

Collaboration revenues from Takeda fluctuate based on changes in the recognized portion of reimbursement funding under the ADCETRIS collaboration, which are impacted by the activities each party is performing under the collaboration agreement at a given time. For example, when Takeda's level of spending on clinical collaboration activities increases above our own, our earned portion of reimbursement funding generally decreases. Additionally, we receive reimbursement for the cost of drug product supplied to Takeda for its use, the timing of which fluctuates based on Takeda's product supply needs. Collaboration revenues from Takeda can also fluctuate based on the achievement of milestones by Takeda. Collaboration revenues from Takeda in 2020 decreased compared to 2019, primarily as a result of two regulatory milestones achieved in 2019 totaling $37.5 million, which were related to approvals of ADCETRIS in frontline Hodgkin lymphoma, and the completion of the Takeda performance period in November 2019.

Other collaboration revenues declined slightly in 2020 as compared to 2019 due to recognition of $20.0 million license and collaboration agreement revenues from BeiGene, Ltd., or BeiGene, in 2019, as well as development milestones received from GSK and Genentech in 2019, offset in part by two regulatory milestones achieved by GSK and a development milestone achieved by AbbVie in 2020.

We expect our collaboration and license agreement revenues in 2021 to significantly decrease compared to 2020, driven by the amounts recognized related to the Merck Agreements in 2020. Our collaboration and license agreement revenues are impacted by the term and duration of those agreements and by progress-dependent milestones, annual maintenance fees, and reimbursement of materials and support services. Collaboration and license agreement revenues may vary substantially from year to year and quarter to quarter depending on the progress made by our collaborators with their product candidates, the level of support we provide to our collaborators, specifically to Takeda under our ADCETRIS collaboration, the timing of milestones achieved and our ability to enter into potential additional collaboration and license agreements.

Collaboration agreements

We discuss the below arrangements in greater detail under the heading "Corporate Collaborations" in Part I Item 1 of this Annual Report on Form 10-K.

Takeda ADCETRIS collaboration

We have an agreement with Takeda for the global co-development of ADCETRIS and the commercialization of ADCETRIS by Takeda in its territory. We recognize payments received from Takeda, including progress-dependent development and regulatory milestone payments, reimbursement for drug supplied, and net development cost reimbursement payments, as collaboration and license agreement revenues upon transfer of control of the goods or services over the development period. When the performance of development activities under the collaboration results in us making a reimbursement payment to Takeda, that payment reduces collaboration and license agreement revenues. We also recognize royalty revenues based on a percentage of Takeda's net sales of ADCETRIS in its territories, ranging from the mid-teens to the mid-twenties based on annual net sales tiers, as well as sales-based milestones. Takeda bears a portion of third-party royalty costs owed on its sales of ADCETRIS, which is included in royalty revenues.

Astellas PADCEV collaboration

We have a collaboration agreement with Agensys, Inc., which subsequently became an affiliate of Astellas, to jointly research, develop and commercialize ADCs for the treatment of several types of cancer. Under this collaboration, we and Astellas are co-funding all development costs for PADCEV. Cost associated with co-development activities are included in research and development expense. Gross profit share payments owed to Astellas in the U.S. under the joint commercialization agreement are recorded in cost of sales.

Genmab tisotumab vedotin collaboration

We have an agreement with Genmab to develop and commercialize ADCs for the treatment of several types of cancer, under which we previously exercised a co-development option for tisotumab vedotin. In October 2020, we and Genmab entered into a joint commercialization agreement to govern the global commercialization of tisotumab vedotin, if we are successful in obtaining any regulatory approvals of tisotumab vedotin. Costs associated with co-development activities are included in research and development expense.

Merck LV collaboration

In September 2020, we entered into the LV Agreement with a subsidiary of Merck. We are pursuing a broad joint development program evaluating LV as monotherapy and in combination settings, including with Merck’s anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in triple-negative breast cancer, hormone receptor-positive breast cancer and other LIV-1-expressing solid tumors. Under the terms of the LV Agreement, we granted Merck a co-exclusive worldwide development and commercialization license for LV, and agreed to jointly develop and commercialize LV on a worldwide basis. We received an upfront cash payment of $600.0 million, and we are eligible to receive up to $850.0 million in milestone payments upon the initiation of certain clinical trials and regulatory approval in certain major markets, and up to an additional $1.8 billion in milestone payments upon the achievement of specified annual global net sales thresholds of LV. Each company is responsible for 50% of global costs to develop and commercialize LV and will receive 50% of potential future profits. In connection with the LV Agreement, we entered into a stock purchase agreement with Merck in September 2020, pursuant to which we agreed to issue and sell, and Merck agreed to purchase 5,000,000 newly-issued shares of our common stock, at a purchase price of $200 per share, for an aggregate purchase price of $1.0 billion, referred to as the Purchase Agreement. We closed the Purchase Agreement on October 27, 2020 following the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

We recognized license revenue of $850.1 million during the year ended December 31, 2020 associated with the LV and Stock Purchase Agreements, and we recognize such cost sharing proportionately with the performance of the underlying activities, while recording Merck’s reimbursement of our expenses as a reduction of research and development expenses.

Merck TUKYSA collaboration

In September 2020, we entered into the TUKYSA Agreement with a subsidiary of Merck. We granted exclusive rights to commercialize TUKYSA in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. Under the terms of the TUKYSA Agreement, Merck is responsible for marketing applications for approval in its territory, supported by the positive results from the HER2CLIMB clinical trial. We retained commercial rights in, and will record sales in, the U.S., Canada and Europe. Merck is also co-funding a portion of the TUKYSA global development plan, which encompasses several ongoing and planned trials across HER2-positive cancers. We will continue to lead ongoing TUKYSA global development operational execution. Merck will solely fund and conduct

country-specific clinical trials necessary to support anticipated regulatory applications in its territories. We received an upfront cash payment from Merck of $125.0 million and also received $85.0 million in prepaid research and development funding to be applied to Merck's global development cost sharing obligations. We are eligible to receive progress-dependent milestone payments of up to $65.0 million, and are entitled to receive tiered royalties on sales of TUKYSA by Merck that begin in the low twenty percent range and escalate based sales volume by Merck in its territory. We owe Array a portion of any non-royalty payments received from sublicensing TUKSYA rights, as well as a low double-digit royalty based on net sales of TUKYSA by us, and will owe a single-digit royalty based on net sales of TUKYSA by Merck in its territories.

We recognized license revenue of $125.0 million during the year ended December 31, 2020 associated with the TUKYSA Agreement, and we recognize such cost sharing proportionately with the performance of the underlying activities, while recording Merck's reimbursement of our expenses as a reduction of research and development expenses. Sales of TUKYSA drug product supplied is included in collaboration and license agreement revenues. The prepayment received for global development cost-sharing was recorded as a co-development liability in accrued liabilities and other or other long-term liabilities on our consolidated balance sheet as of December 31, 2020. As joint development expenses are incurred, we recognize the portion of Merck's prepayment as a reduction of our research and development expenses on our consolidated statements of net income (loss). As of December 31, 2020, $80.9 million was recorded as the remaining co-development liability.

Other collaboration and license agreements

We have other collaboration and license agreements for our ADC technology with a number of biotechnology and pharmaceutical companies. We typically receive upfront cash payments and progress- and sales-dependent milestones for the achievement by our licensees of certain events, and annual maintenance fees and support fees for research and development services and materials provided under the agreements. These amounts are recognized as revenue over the performance obligation period if the license is determined not to be distinct from other goods and services provided, or, if there is no performance obligation, upon transfer of control of the goods or services to the customer.

As of December 31, 2020, the remaining potential milestone payments to us under our other ADC license and collaboration agreements could total approximately $1.6 billion if all potential product candidates achieved all of their milestone events. Of this amount, approximately $0.9 billion relates to the achievement of development and regulatory milestones, and approximately $0.7 billion relates to the achievement of commercial milestones. Since we do not control the research, development or commercialization of any of the products that would generate these milestones, we are not able to reasonably estimate when, if at all, any potential future milestone payments or royalties may be payable by our collaborators. Successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing it is a significantly lengthy and highly uncertain process which entails a significant risk of failure. In addition, business combinations, changes in a collaborator's business strategy and financial difficulties or other factors could result and have resulted in a collaborator abandoning or delaying development of its product candidates. As such, the potential future milestone payments associated with our ADC collaboration agreements involve a substantial degree of risk and may never be received. Accordingly, we do not expect, and investors should not assume, that we will receive all of the potential milestone payments described above, and it is possible that we may never receive any additional significant milestone payments under these agreements.

Cost of sales

Cost of sales includes manufacturing and distribution costs of product sold, gross profit share with Astellas pursuant to our PADCEV collaboration, amortization of acquired technology license costs, royalties owed on our PADCEV net product sales and global ADCETRIS and TUKSYA net product sales.

				Percentage change	
(dollars in thousands)	2020	2019	2018	2020/2019	2019/2018
Cost of sales	$ 217,720	$ 43,952	$ 88,293	395 %	(50) %

Cost of sales increased in 2020 as compared to 2019, driven by the Astellas gross profit share related to PADCEV net product sales, a payment owed to a third-party technology licensor resulting from the TUKSYA Agreement, amortization expense associated with acquired TUKSYA technology costs, and in-licensing royalties owed on PADCEV and TUKYSA net product sales. The gross profit share with Astellas totaled $104.6 million for the year ended December 31, 2020. We recorded amortization expense of $16.3 million for acquired TUKYSA technology costs during the year ended December 31, 2020, which began following FDA approval of TUKYSA in April 2020.

We expect cost of sales to increase in 2021 as compared to 2020 as a result of the net product sales growth of our commercial-stage drugs. This includes cost of product sales for PADCEV and the gross profit share with Astellas under our collaboration. Growth will also be driven by the full-year 2021 amortization of acquired TUKYSA technology costs. The increase in cost of sales will also reflect expected growth in ADCETRIS net product sales. Cost of sales includes a low-single digit royalty on global net sales of ADCETRIS, a mid-single digit royalty on our net sales of PADCEV, and a low double-digit royalty on global net sales of TUKYSA. Cost of sales for PADCEV and TUKYSA in 2021 will be partially reduced by the use of product inventory that was manufactured prior to FDA approval, and previously charged to research and development expense.

Research and development

				Percentage change	
(dollars in thousands)	2020	2019	2018	2020/2019	2019/2018
Research and clinical development	$ 581,496	$ 497,986	$ 397,429	17 %	25 %
Process sciences and manufacturing	245,633	221,388	167,880	11 %	32 %
Total research and development	$ 827,129	$ 719,374	$ 565,309	15 %	27 %

Certain prior year balances have been reclassified within research and development expenses to conform to current year presentation.

Research and clinical development expenses include personnel, occupancy and laboratory expenses, technology access fees, preclinical translational biology and *in vitro* and *in vivo* studies, IND-enabling pharmacology and toxicology studies, and external clinical trial costs including costs for clinical sites, clinical research organizations, contractors and regulatory activities associated with conducting human clinical trials. The increase in 2020 as compared to 2019 primarily reflected higher employee-related costs and external development costs mainly to support our early- and late-stage pipeline of product candidates.

Process sciences and manufacturing expenses include personnel and occupancy expenses, manufacturing costs for the scale-up and pre-approval manufacturing of drug product used in research and our clinical trials, and costs for drug product supplied to our collaborators. Process sciences and manufacturing expenses also include quality control and assurance activities, and storage and shipment of our product candidates. The increase in 2020 compared to 2019 primarily reflected higher employee-related costs and external development costs primarily to support our early- and late-stage pipeline of product candidates, as well as higher costs for drug product supplied to Takeda.

We utilize our employee and infrastructure resources across multiple research and development projects. We track human resource efforts expended on many of our programs for purposes of billing our collaborators for time incurred at agreed upon rates and for resource planning. We do not account for actual costs on a project basis as it relates to our infrastructure, facility, employee and other indirect costs; however, we do separately track significant third-party costs including clinical trial costs, manufacturing costs and other contracted service costs on a project basis. To that end, the following table shows third-party costs incurred for research, contract manufacturing of our product candidates and clinical and regulatory services, as well as development milestone payments for in-licensed technology for our products

and certain of our clinical-stage product candidates. The table also presents other costs and overhead consisting of third-party costs for our preclinical stage programs, as well as personnel, facilities, manufacturing, and other indirect costs not directly charged to development programs.

				Percentage change		5 years ended
(dollars in thousands)	**2020**	**2019**	**2018**	**2020/2019**	**2019/2018**	**December 31, 2020**
ADCETRIS (brentuximab vedotin)	$ 55,530	$ 45,151	$ 40,435	23 %	12 %	$ 294,082
TUKYSA (tucatinib)	73,142	84,276	40,739	(13) %	107 %	198,157
PADCEV (enfortumab vedotin-ejfv)	35,563	36,186	24,943	(2) %	45 %	123,134
Tisotumab vedotin	28,102	30,423	22,253	(8) %	37 %	86,799
Ladiratuzumab vedotin	14,320	23,178	24,523	(38) %	(5) %	85,225
Other clinical stage programs	35,174	38,103	36,656	(8) %	4 %	271,508
Total third-party costs for clinical stage programs	241,831	257,317	189,549	(6) %	36 %	1,058,905
Other costs and overhead	585,298	462,057	375,760	27 %	23 %	1,888,909
Total research and development	$ 827,129	$ 719,374	$ 565,309	15 %	27 %	$ 2,947,814

Third-party costs for ADCETRIS increased in 2020 as compared to 2019 primarily due to increased activities associated with our ongoing ADCETRIS clinical trials. The cost of drug product supplied to Takeda is charged to research and development expense. We are reimbursed for the drug product, which is included in collaboration and license agreement revenues.

Third-party costs for TUKYSA decreased in 2020 as compared to 2019, primarily due to lower clinical supply expenses. Following the approval of TUKYSA in April 2020, we began capitalizing inventory costs manufactured for commercial sale.

Third-party costs for PADCEV decreased slightly in 2020 as compared to 2019, due to the timing of our ongoing clinical trials.

Third-party costs for tisotumab vedotin decreased in 2020 as compared to 2019, due to the timing of our and Genmab's ongoing clinical trials.

Third-party costs for ladiratuzumab vedotin decreased in 2020 as compared to 2019, primarily due to lower research and clinical development expenses as well as cost-sharing reimbursements received from Merck in 2020 related to the LV Agreement.

Third-party costs for other clinical stage programs were related to multiple earlier-stage development programs and were relatively consistent across 2020 and 2019.

Other costs and overhead include third-party costs of our preclinical programs and costs associated with personnel and facilities. These costs increased in 2020 as compared to 2019 due primarily to due to the addition of new preclinical programs and higher employee-related expenses from headcount growth.

In order to advance our product candidates toward commercialization, the product candidates are tested in numerous preclinical safety, toxicology and efficacy studies. We then conduct clinical trials for those product candidates that take several years or more to complete. The length of time varies substantially based upon the type, complexity, novelty and intended use of a product candidate. We will also need to conduct additional clinical trials in order to expand labeled indications of use for our commercial products. The outcome of our clinical trials is uncertain. The cost of clinical trials may vary significantly as a result of a variety of factors, including the number of patients enrolled, patient site costs, quantity and source of drug supply required, safety and efficacy of the product candidate, and extent of regulatory efforts, among others.

We anticipate that our total research and development expenses in 2021 will increase compared to 2020 primarily due to higher costs for the continued development of our approved products and product candidates.

The risks and uncertainties associated with our research and development projects are discussed more fully in "Part I Item 1A—Risk Factors." As a result of these risks and uncertainties, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, anticipated completion dates, or when and to what extent we will receive cash inflows from the commercialization and sale of our products in any additional approved indications or of any of our product candidates.

Selling, general and administrative

				Percentage change	
(dollars in thousands)	2020	2019	2018	2020/2019	2019/2018
Selling, general and administrative	$ 533,835	$ 373,932	$ 261,096	43 %	43 %

Selling, general and administrative expenses increased in 2020 and 2019 as compared to prior years primarily due to increased field sales personnel and external spend to support our recently commercialized products, and higher infrastructure costs to support our continued growth in the U.S. and Europe.

We anticipate that selling, general and administrative expenses will increase in 2021 as compared to 2020 as we continue our commercial activities in support of our products, and invest in infrastructure to support our continued growth in the U.S. and Europe.

Investment and other income, net

				Percentage change	
(dollars in thousands)	2020	2019	2018	2020/2019	2019/2018
Gain on equity securities	$ 11,604	$ 50,124	$ 7,336	(77)	NM
Investment and other income, net	7,245	11,771	6,316	(38) %	86 %
Total investment and other income, net	$ 18,849	$ 61,895	$ 13,652	(70)	353 %

NM: No amount in comparable period or not a meaningful comparison.

Investment and other income, net includes other non-operating income and loss, such as unrealized holding gains and losses on equity securities (which primarily include common stock holdings in Immunomedics prior to the sale of these securities in April 2020), realized gains and losses on equity and debt securities, and amounts earned on our investments in U.S. Treasury securities.

The gain on equity securities in the year ended December 31, 2020 was primarily driven by a realized gain in April 2020 from the sale of our equity securities, offset in part by an unrealized loss on equity securities during the first quarter of 2020.

Investment income reflects amounts earned on our investments in U.S. Treasury securities. Investment income decreased in 2020 compared to 2019 due to due to lower average yields on our investment portfolio during 2020.

Income taxes

				Percentage change	
(dollars in thousands)	2020	2019	2018	2020/2019	2019/2018
Income tax benefit (expense)	$ (2,031)	$ —	$ 23,653	NM	NM

NM: No amount in comparable period or not a meaningful comparison.

We generated pre-tax income of $615.7 million in 2020 as the result of the Merck agreements entered into during 2020. For the year ended December 31, 2020, we recorded a provision for income taxes of $2.0 million, consisting primarily of current state income taxes. We utilized net operating loss carryforwards to offset the federal tax liability.

We did not generate pre-tax income during 2019 or 2018. In 2018, we recognized a deferred tax liability of $23.7 million on acquired intangible assets in connection with the acquisition of Cascadian. As a result, we recorded an income tax benefit of $23.7 million for the release of valuation allowance on our existing U.S. deferred tax assets as a result of the offset of deferred tax liabilities established for intangible assets from the acquisition.

Liquidity and capital resources

	December 31,		
(dollars in thousands)	**2020**	**2019**	**2018**
Cash, cash equivalents and investments	$ 2,660,250	$ 868,338	$ 459,866
Working capital	2,674,246	917,284	428,523
Stockholders' equity	3,488,100	1,876,287	1,273,943

	Years ended December 31,		
(dollars in thousands)	**2020**	**2019**	**2018**
Cash provided by (used in):			
Operating activities	$ 856,568	$ (163,737)	$ (203,536)
Investing activities	(1,419,012)	(277,729)	(592,630)
Financing activities	846,108	637,842	713,407

The change in net cash from operating activities from 2020 as compared to 2019 primarily was related to the change in our net income (loss), working capital fluctuations and changes in our non-cash expenses, all of which are highly variable. The increase in cash provided by operating activities was primarily driven by $975.2 million in collaboration and license agreement revenues recognized related to the agreements we entered into with Merck during 2020.

The change in net cash from investing activities from 2020 as compared to 2019 reflected differences between the proceeds received from sale and maturity of our investments and amounts reinvested, and the difference for purchases of property, plant, and equipment.

The change in net cash from financing activities included proceeds from issuances of common stock, the exercise of options to purchase shares of our common stock, and common stock sales under our employee stock purchase plan for all years presented.

We primarily have financed our operations through the issuance of our common stock, collections from commercial sales of our products, amounts received pursuant to license and collaboration agreements, and royalty revenues. To a lesser degree, we also have financed our operations through investment income. These financing and revenue sources have allowed us to maintain adequate levels of cash and investments.

Our cash, cash equivalents, and investments are held in a variety of non-interest bearing bank accounts and interest-bearing instruments subject to investment guidelines allowing for holdings in U.S. government and agency securities, corporate securities, taxable municipal bonds, commercial paper and money market accounts. Our investment portfolio is structured to provide for investment maturities and access to cash to fund our anticipated working capital needs. However, if our liquidity needs should be accelerated for any reason in the near term, or investments do not pay at maturity, we may be required to sell investment securities in our portfolio prior to their scheduled maturities, which may result in a loss. As of December 31, 2020, we had $2.7 billion held in cash, cash equivalents, and investments.

At our currently planned spending rates, we believe that our existing financial resources, together with product and royalty revenues, and the fees, milestone payments and reimbursements we expect to receive under our existing collaboration and license agreements, will be sufficient to fund our operations for at least the next twelve months.

We expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees, and support our development, commercialization, invest in our facilities, and expand globally, which may require us to raise additional capital. Further, we actively evaluate various strategic transactions on an ongoing basis, including licensing or otherwise acquiring complementary products, technologies or businesses, and we may require significant additional capital in order to complete or otherwise provide funding for such transactions. We may seek additional capital through some or all of the following methods: corporate collaborations, licensing arrangements, and public or private debt or equity financings. We do not know whether additional capital will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If we are unable to raise additional funds when we need them, our business and operations may be adversely affected.

Commitments

The following table reflects our future minimum contractual commitments as of December 31, 2020:

(dollars in thousands)	Total	2021	2022	2023	2024	2025	Thereafter
Operating leases	$ 88,330	$ 16,337	$ 15,650	$ 15,030	$ 11,147	$ 7,510	$ 22,656
Supply and other agreements	366,126	141,130	84,384	61,680	44,988	33,816	128
Total	$ 454,456	$ 157,467	$ 100,034	$ 76,710	$ 56,135	$ 41,326	$ 22,784

We have entered into leases for our office and laboratory facilities expiring in 2021 through 2029 that contain rate escalations and options for us to extend the leases. Operating lease obligations in the table above do not assume the exercise by us of any extension options.

Supply and other agreements primarily include non-cancelable obligations under our manufacturing, license and collaboration agreements. Further, a substantial portion of those non-cancelable obligations include minimum payments related to manufacturing our product candidates for use in our clinical trials and for commercial operations in the case of ADCETRIS.

Some of our manufacturing, license and collaboration agreements provide for periodic maintenance fees over specified time periods, profit share payments, and/or payments by us upon the achievement of development and regulatory milestones. Some of our licensing agreements obligate us to pay royalties based on net sales of products utilizing licensed technology. Such royalties and profit share payments are dependent on future product sales and are not provided for in the table above as they are dependent on events that have not yet occurred. Future milestone payments for research and pre-clinical stage development programs have not been included in the above table as the event triggering such payment or obligation has not yet occurred, which consisted of up to approximately $2.1 billion in total potential future milestone payments to third parties under our collaboration and license agreements with these parties. These milestone payments generally become due and payable only upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones. These contingent payments have not been included in the above table as the event triggering such payment or obligation has not yet occurred.

Recent accounting pronouncements

See the section “Recent accounting pronouncements” in Note 1 to the Notes to Consolidated Financial Statements in Part II Item 8 of this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. We currently have holdings in U.S. Treasury securities. A summary of our investment securities follows:

	December 31,	
(dollars in thousands)	**2020**	**2019**
Short-term investments	$ 2,000,996	$ 536,493
Long-term investments	100,830	57,283
Total	$ 2,101,826	$ 593,776

We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of $9.1 million in the fair value of our investments as of December 31, 2020. In addition, a hypothetical decrease of 10% in the effective yield of our investments would reduce our expected investment income by $0.3 million over the next twelve months based on our investment balance at December 31, 2020.

Foreign Currency Risk

Most of our revenues and expenses are denominated in U.S. dollars and as a result, we have not experienced significant foreign currency transaction gains and losses to date. Our commercial sales in Canada are denominated in Canadian Dollars. We also had other transactions denominated in foreign currencies during the year ended December 31, 2020, primarily related to contract manufacturing and ex-U.S. clinical trial activities, and we expect to continue to do so. Our royalties from Takeda are derived from their sales of ADCETRIS in multiple countries and in multiple currencies that are converted into U.S. dollars for purposes of determining the royalty owed to us. Our limited foreign currency exposure is to fluctuations in the Euro, British Pound, Canadian Dollar, Swiss Franc, and Danish Krone. We do not anticipate that foreign currency transaction gains or losses will be significant at our current level of operations. However, transaction gains or losses may become significant in the future as we continue to expand our operations internationally. We have not engaged in foreign currency hedging to date; however, we may do so in the future.

Item 8. Financial Statements and Supplementary Data

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Seagen Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Seagen Inc. and its subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of comprehensive income (loss), of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2020, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Changes in Accounting Principles

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019 and the manner in which it accounts for revenue from contracts with customers and the manner in which it accounts for investments in equity securities in 2018.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

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

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 (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 (iii) 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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters 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.

Government-mandated rebates - Medicaid

As described in Note 1 to the consolidated financial statements, the Company records product sales 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 are offset against applicable accruals. As disclosed by management, amounts accrued for rebates and chargebacks as of December 31, 2020 are $44.2 million, with the most significant portion of the accrual balance related to ADCETRIS Medicaid rebates. Management estimates Medicaid rebates using the expected value approach, based on a variety of factors, including payor mix and experience to-date. Management also reviews historical rebate information to further refine these estimates.

The principal considerations for our determination that performing procedures relating to government-mandated rebates – Medicaid is a critical audit matter are (i) the significant judgment by management when determining the rebate estimate and (ii) the high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating audit evidence related to management's estimate and significant assumptions related to payor mix and estimated purchases covered by the various state Medicaid programs.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the various state Medicaid programs, including controls over the assumptions used to estimate the rebate. These procedures also included, among others, (i) testing management's process for determining the rebate estimate; (ii) evaluating the appropriateness of management's model; (iii) testing the completeness and accuracy of the underlying data used by management; and (iv) evaluating the significant assumptions used by management including payor mix and estimated purchases covered by the various state Medicaid programs. Evaluating management's assumptions involved evaluating whether the assumptions were reasonable considering (i) the consistency of the historical covered purchases and rebate processing times; (ii) expansion of state Medicaid programs; (iii) comparing assumptions to other industry data; (iv) testing of actual rebate claims processed by the Company; and (v) whether these assumptions were consistent with evidence obtained in other areas of the audit.

/s/ PricewaterhouseCoopers LLP

Seattle, Washington
February 11, 2021

We have served as the Company's auditor since 1998.

Seagen Inc.
Consolidated Balance Sheets
(In thousands, except par value)

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 558,424	$ 274,562
Short-term investments	2,000,996	536,493
Accounts receivable, net	324,988	236,001
Inventories	116,136	85,932
Prepaid expenses and other current assets	61,840	43,653
Total current assets	3,062,384	1,176,641
Property and equipment, net	196,700	155,491
Operating lease right-of-use assets	61,480	65,230
Long-term investments	100,830	57,283
Intangible assets, net	283,680	300,025
Goodwill	274,671	274,671
Other non-current assets	21,161	176,525
Total assets	$ 4,000,906	$ 2,205,866
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 78,067	$ 52,292
Accrued liabilities and other	310,071	207,065
Total current liabilities	388,138	259,357
Long-term liabilities:		
Operating lease liabilities, long-term	61,884	67,607
Other long-term liabilities	62,784	2,615
Total long-term liabilities	124,668	70,222
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000 shares authorized; none issued	—	—
Common stock, $0.001 par value, 250,000 shares authorized; 180,902 shares issued and outstanding at December 31, 2020 and 171,994 shares issued and outstanding at December 31, 2019	181	172
Additional paid-in capital	4,356,922	3,359,124
Accumulated other comprehensive income	565	229
Accumulated deficit	(869,568)	(1,483,238)
Total stockholders' equity	3,488,100	1,876,287
Total liabilities and stockholders' equity	$ 4,000,906	$ 2,205,866

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

Seagen Inc.
Consolidated Statements of Comprehensive Income (Loss)
(In thousands, except per share amounts)

	Years ended December 31,		
	2020	2019	2018
Revenues:			
Net product sales	$ 1,000,598	$ 627,977	$ 476,903
Royalty revenues	126,756	138,491	83,440
Collaboration and license agreement revenues	1,048,182	150,245	94,357
Total revenues	2,175,536	916,713	654,700
Costs and expenses:			
Cost of sales	217,720	43,952	88,293
Research and development	827,129	719,374	565,309
Selling, general and administrative	533,835	373,932	261,096
Total costs and expenses	1,578,684	1,137,258	914,698
Income (loss) from operations	596,852	(220,545)	(259,998)
Investment and other income, net	18,849	61,895	13,652
Income (loss) before income taxes	615,701	(158,650)	(246,346)
Income tax (expense) benefit	(2,031)	—	23,653
Net income (loss)	$ 613,670	$ (158,650)	$ (222,693)
Net income (loss) per share - basic	$ 3.51	$ (0.96)	$ (1.41)
Net income (loss) per share - diluted	$ 3.37	$ (0.96)	$ (1.41)
Shares used in computation of per share amounts - basic	174,834	165,498	157,655
Shares used in computation of per share amounts - diluted	182,287	165,498	157,655
Comprehensive income (loss):			
Net income (loss)	$ 613,670	$ (158,650)	$ (222,693)
Other comprehensive income:			
Unrealized (loss) gain on securities available-for-sale, net of income tax provision of $0, $0, and $0, respectively	(186)	204	293
Foreign currency translation gain (loss), net of income tax provision of $0, $0, and $0, respectively	522	65	(50)
Total other comprehensive income	336	269	243
Comprehensive income (loss)	$ 614,006	$ (158,381)	$ (222,450)

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

Seagen Inc.
Consolidated Statements of Stockholders' Equity
(In thousands)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balances at December 31, 2017	144,395	$ 144	$ 1,806,159	$ 63,836	$ (1,192,570)	$ 677,569
Net loss	—	—	—	—	(222,693)	(222,693)
Other comprehensive income	—	—	—	243	—	243
Cumulative effects of accounting changes	—	—	—	(64,119)	90,675	26,556
Issuance of common stock for stock option exercises and employee stock purchase plan	2,006	2	55,163	—	—	55,165
Restricted stock vested during the period, net	592	1	(1)	—	—	—
Issuance of common stock	13,269	13	658,229	—	—	658,242
Share-based compensation	—	—	78,861	—	—	78,861
Balances at December 31, 2018	160,262	160	2,598,411	(40)	(1,324,588)	1,273,943
Net loss	—	—	—	—	(158,650)	(158,650)
Other comprehensive income	—	—	—	269	—	269
Issuance of common stock for stock option exercises and employee stock purchase plan	2,621	3	89,148	—	—	89,151
Restricted stock vested during the period, net	897	1	(1)	—	—	—
Issuance of common stock	8,214	8	548,683	—	—	548,691
Share-based compensation	—	—	122,883	—	—	122,883
Balances at December 31, 2019	171,994	172	3,359,124	229	(1,483,238)	1,876,287
Net income	—	—	—	—	613,670	613,670
Other comprehensive income	—	—	—	336	—	336
Issuance of common stock for stock option exercises and employee stock purchase plan	2,466	2	96,255	—	—	96,257
Restricted stock vested during the period, net	1,442	2	(2)	—	—	—
Issuance of common stock	5,000	5	749,845	—	—	749,850
Share-based compensation	—	—	151,700	—	—	151,700
Balances at December 31, 2020	180,902	$ 181	$ 4,356,922	$ 565	$ (869,568)	$ 3,488,100

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

Seagen Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Years ended December 31,		
	2020	2019	2018
Operating activities:			
Net income (loss)	$ 613,670	$ (158,650)	$ (222,693)
Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities			
Share-based compensation	147,233	127,349	78,861
Depreciation and amortization	36,045	23,759	25,308
Amortization of intangible assets	16,345	15	724
Amortization of right-of-use-assets	10,994	9,740	—
Amortization of premiums, accretion of discounts, and (gains) losses on debt securities	3,104	(4,916)	(2,530)
Gain on equity securities	(11,604)	(50,124)	(7,336)
(Gain) loss on disposals of property and equipment	(26)	1,853	—
Deferred income taxes	(2,053)	—	(23,653)
Changes in operating assets and liabilities:			
Accounts receivable, net	(88,727)	(89,720)	(45,233)
Inventories	(30,204)	(32,693)	6,739
Prepaid expenses and other assets	(22,231)	2,459	(14,567)
Lease liabilities	(11,271)	(6,660)	—
Deferred revenue	—	(33,600)	(33,913)
Other liabilities	195,293	47,451	34,757
Net cash provided (used) by operating activities	856,568	(163,737)	(203,536)
Investing activities:			
Purchases of securities	(2,483,336)	(992,976)	(512,334)
Proceeds from maturities of securities	952,000	786,000	398,722
Proceeds from sales of securities	194,733	—	140,352
Purchases of property and equipment	(82,409)	(70,753)	(21,219)
Acquisition of Cascadian Therapeutics, Inc., net of cash acquired	—	—	(598,151)
Net cash used by investing activities	(1,419,012)	(277,729)	(592,630)
Financing activities:			
Net proceeds from issuance of common stock	749,850	548,691	658,242
Proceeds from exercise of stock options and employee stock purchase plan	96,258	89,151	55,165
Net cash provided by financing activities	846,108	637,842	713,407
Effect of exchange rate changes on cash and cash equivalents	198	—	—
Net increase (decrease) in cash and cash equivalents	283,862	196,376	(82,759)
Cash and cash equivalents at beginning of year	274,562	78,186	160,945
Cash and cash equivalents at end of year	$ 558,424	$ 274,562	$ 78,186

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

Seagen Inc.
Notes to Consolidated Financial Statements

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1. Organization and Summary of Significant Accounting Policies

Organization

We are a biotechnology company that develops and commercializes targeted therapies to treat cancer. We are commercializing ADCETRIS®, or brentuximab vedotin, for the treatment of certain CD30-expressing lymphomas, PADCEV®, or enfortumab vedotin-ejfv, for the treatment of certain metastatic urothelial cancers, and TUKYSA®, or tucatinib, for treatment of certain metastatic HER2-positive breast cancers. We are also advancing a pipeline of novel therapies for solid tumors and blood-related cancers designed to address unmet medical needs and improve treatment outcomes for patients. Many of our programs, including ADCETRIS and PADCEV, are based on our antibody-drug conjugate, or ADC, technology that utilizes the targeting ability of monoclonal antibodies to deliver cell-killing agents directly to cancer cells. In October 2020, we changed our corporate name from Seattle Genetics, Inc. to Seagen Inc., reflecting the global expansion of our operations.

Basis of presentation

The accompanying consolidated financial statements reflect the accounts of Seagen Inc. and its wholly-owned subsidiaries (collectively "Seagen," "we," "our," or "us"). The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. All intercompany transactions and balances have been eliminated. We acquired Cascadian Therapeutics, Inc., or Cascadian, in March 2018, as further described in Note 4. Management has determined that we operate in one segment: the development and sale of pharmaceutical products on our own behalf or in collaboration with others.

Use of estimates

The preparation of financial statements in accordance with GAAP requires us to make estimates, assumptions, and judgments that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates. Estimates include those used for revenue recognition, valuation of investments, inventory valuation, business combinations, accrued liabilities (including those related to the long-term incentive plans, clinical trials and contingencies), stock option valuation, and valuation allowance for deferred tax assets.

Reclassifications

We combined cost of sales with cost of royalty revenues during the current year and reclassified the prior years cost of royalty revenues on our consolidated statements of comprehensive income (loss), to conform to the current year presentation. This reclassification had no effect on our net cash used by operating activities or our consolidated statements of comprehensive income (loss).

Cash and cash equivalents

We consider all highly liquid investments with maturities of three months or less at the date of acquisition to be cash equivalents.

Non-cash activities

We had $6.0 million and $11.1 million of accrued capital expenditures as of December 31, 2020 and 2019, respectively. Accrued capital expenditures have been treated as a non-cash investing activity and, accordingly, have not been included in the consolidated statement of cash flows until such amounts have been paid in cash. During the years ended December 31, 2020 and 2019, we recorded $7.2 million and $40.3 million, respectively, of right-of-use assets in exchange for lease liabilities, which has been treated as a non-cash operating activity. See Note 3 for additional information.

Investments

We held certain equity securities that we acquired in connection with strategic agreements, which were reported at estimated fair value. Changes in the fair value of equity securities are recorded in income or loss. The cost of equity securities for purposes of computing gains and losses is based on the specific identification method. We adopted Accounting Standards Update, or ASU, "ASU 2016-01, Financial Instruments: Overall" on January 1, 2018, which addressed certain aspects of recognition, measurement, presentation and disclosure of financial instruments, including that changes in the fair value of equity securities be recorded in income or loss rather than accumulated other comprehensive income or loss in stockholders' equity. We used the modified retrospective method transition option and recognized a $64.1 million cumulative effect of initially applying this ASU as an adjustment to decrease the opening accumulated deficit at January 1, 2018.

We invest our available cash primarily in debt securities. These debt securities are classified as available-for-sale, which are reported at estimated fair value with unrealized gains and losses included in accumulated other comprehensive income and loss in stockholders' equity. Realized gains, realized losses and declines in the value of debt securities judged to be other-than-temporary are included in investment and other income, net. The cost of debt securities for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Amortization of premiums and accretion of discounts on debt securities are included in investment and other income, net. Interest and dividends earned are included in investment and other income, net. We classify investments in debt securities maturing within one year of the reporting date, or where management's intent is to use the investments to fund current operations or to make them available for current operations, as short-term investments.

If the estimated fair value of a debt security is below its carrying value, we evaluate whether it is more likely than not that we will sell the security before its anticipated recovery in market value and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. We also evaluate whether or not we intend to sell the investment. If the impairment is considered to be other-than-temporary, the security is written down to its estimated fair value. In addition, we consider whether credit losses exist for any securities. A credit loss exists if the present value of cash flows expected to be collected is less than the amortized cost basis of the security. Other-than-temporary declines in estimated fair value and credit losses are included in investment and other income, net.

Fair value of financial instruments

The recorded amounts of certain financial instruments, including cash and cash equivalents, interest receivable, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. Investments that are classified as available-for-sale are recorded at estimated fair value. The estimated fair value for securities held is determined using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.

Leases

We adopted Accounting Standards Codification, or ASC, Topic 842--Leases on January 1, 2019, resulting in a change to our accounting policy for leases. We recorded a liability to make lease payments and a right-of-use asset representing our right to use the underlying assets for the applicable lease terms in our consolidated balance sheet. We used the modified retrospective method transition option. Accordingly, 2018 comparative information has not been adjusted and continues to be reported under previous accounting standards.

We elected the "package of practical expedients", which permitted us not to reassess our prior conclusion about lease identification, lease classification and initial direct cost. We also elected the practical expedient to not separate lease and non-lease components for our real estate leases, and elected the short-term lease recognition exemption for our short-term leases, which allows us not to recognize lease liabilities and right-of-use assets on our consolidated balance sheet for leases with an original term of twelve months or less.

The adoption of the standard had a material impact on our consolidated balance sheet, did not have an impact on our consolidated statement of comprehensive income (loss), and there was no cumulative-effect adjustment to the opening accumulated deficit in the period of adoption. See Note 3 for additional information.

We determine if an arrangement is a lease at inception date. All of our leases are classified as operating leases. Operating lease liabilities and the corresponding right-of-use assets are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The operating lease right-of-use asset also excludes lease incentives and initial direct costs incurred. As our existing leases do not contain an implicit interest rate, we estimate our incremental borrowing rate based on information available at commencement date in determining the present value of future payments. We include options to extend the lease in our lease liability and right-of-use asset when it is reasonably certain that we will exercise that option. Our lease agreements do not contain any material residual value guarantees or material restrictive covenants. Variable lease cost primarily includes building operating expenses as charged to us by our landlords.

Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. For our short-term leases, we recognize lease payments as an expense on a straight-line base over the lease term.

Inventories

We consider regulatory approval of product candidates to be uncertain. Accordingly, we charge manufacturing costs to research and development expense until such time as a product has received regulatory approval for commercial sale. Production costs for our marketed products are capitalized into inventory. Inventory that is deployed for clinical, research or development use is charged to research and development expense when it is no longer available for commercial sales. Production costs for our other product candidates continue to be charged to research and development expense.

We value our inventories at the lower of cost or market value. Cost is determined on a specific identification basis. Inventory includes the cost of materials, third-party contract manufacturing and overhead associated with the production of our commercialized products. In the event that we identify excess, obsolete or unsalable inventory, its value is written down to net realizable value.

Property and equipment

Property and equipment are stated at cost. Land is not depreciated, while all other property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, which are generally as follows:

	Years
Building	30
Laboratory and manufacturing equipment	5-15
Furniture and fixtures	5
Computers, software and office equipment	3

Leasehold improvements are amortized over the shorter of the remaining term of the applicable lease or the useful life of the asset. Gains and losses from the disposal of property and equipment are reflected in income or loss at the time of disposition and have not been significant. Expenditures for additions and improvements to our facilities are capitalized and expenditures for maintenance and repairs are charged to expense as incurred.

Business combinations, including acquired in-process research and development and goodwill

We account for business combinations using the acquisition method, recording the acquisition-date fair value of total consideration over the acquisition-date fair value of net assets acquired as goodwill.

Fair value is typically estimated using an income approach based on the present value of future discounted cash flows. The significant estimates in the discounted cash flow model primarily include the discount rate, and rates of future revenue and expense growth and/or profitability of the acquired business. The discount rate considers the relevant risk associated with business-specific characteristics and the uncertainty related to the ability to achieve the projected cash flows. We may record adjustments to the fair values of assets acquired and liabilities assumed within the measurement period (up to one year from the acquisition date).

In-process research and development assets are accounted for as indefinite-lived intangible assets and maintained on the balance sheet until either the underlying project is completed or the asset becomes impaired. If the project is completed, which generally occurs when FDA approval is obtained, the carrying value of the related intangible asset is amortized to cost of sales on a straight-line basis over the estimated useful life of the asset beginning in the period in which the project is completed. We periodically evaluate when facts or circumstances indicate that the carrying value of these assets may not be recoverable. If the asset becomes impaired or is abandoned, the carrying value of the related intangible asset is written down to its fair value and an impairment charge is recorded in the period in which the impairment occurs.

We evaluate indefinite-lived intangible assets and goodwill for impairment annually, as of October 1, or more frequently when events or circumstances indicate that impairment may have occurred. As part of the impairment evaluation, we may elect to perform an assessment of qualitative factors. If this qualitative assessment indicates that it is more likely than not that the fair value of the indefinite-lived intangible asset or the reporting unit (for goodwill) is less than its carrying value, we then would proceed with the quantitative impairment test to compare the fair value to the carrying value and record an impairment charge if the carrying value exceeds the fair value.

Acquisition-related costs, including banking, legal, accounting, valuation, and other similar costs, are expensed in the period in which the costs are incurred. The results of operations of the acquired business are included in the consolidated financial statements from the acquisition date.

Intangible assets, net

Our intangible assets are primarily comprised of acquired TUKYSA technology from the acquisition of Cascadian Therapeutics, Inc. in 2018. Upon FDA approval and commercial launch of TUKYSA in April 2020, we classified in-process research and development costs related to the acquired TUKYSA technology as finite-lived intangible assets. Prior to 2020, our finite-lived intangible assets consisted of certain in-licensed ADCETRIS technology. Amortization expense of $16.3 million related to acquired TUKYSA technology costs for the year ended December 31, 2020, was included in cost of sales in our consolidated statements of comprehensive income (loss). The gross carrying value and accumulated amortization of our finite-lived intangible assets was $305.7 million and $22.0 million respectively as of December 31, 2020, and gross carrying value and accumulated amortization of our finite-lived intangible assets was $5.7 million and $5.6 million respectively as of December 31, 2019. The weighted average useful life of our finite-lived intangible assets was 12 years as of December 31, 2020, and estimated future amortization expense related to acquired TUKYSA technology costs is $23.1 million for each of the years ending December 31, 2021 through December 31, 2025.

Impairment of long-lived assets (other than acquired in-process research and development and goodwill)

We assess the impairment of long-lived assets, including intangible assets and property and equipment, whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. When such events occur, we determine whether there has been an impairment in value by comparing the asset's carrying value with its fair value, as measured by the anticipated undiscounted net cash flows of the asset. If an impairment in value exists, the asset is written down to its estimated fair value. We have not recognized any impairment losses through December 31, 2020 as there have been no events warranting an impairment analysis. Our long-lived assets are primarily located in the U.S.

Revenue recognition - Net product sales

We adopted ASC Topic 606--Revenue from Contracts with Customers on January 1, 2018, resulting in a change to our accounting policy for revenue recognition. We used the modified retrospective method transition option and recognized the cumulative effect of initially applying ASC Topic 606 as an adjustment to decrease the opening accumulated deficit at January 1, 2018. See Note 2 for additional information.

We sell ADCETRIS, PADCEV and TUKYSA through a limited number of specialty distributors and specialty pharmacies. We and our collaboration partner Astellas jointly promote PADCEV in the U.S. Under the joint promotion in the U.S., we record net sales of PADCEV and are responsible for all distribution through a limited number of specialty distributors. The delivery of our products represents a single performance obligation for these transactions and we record net product sales at the point in time when title and risk of loss pass. The transaction price for net product sales 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. We reflect these accruals as either a reduction in the related account receivable from the distributor or as an accrued liability, depending on the nature of the sales deduction. 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. We have applied a portfolio approach as a practical expedient for estimating net product sales.

Government-mandated rebates and chargebacks: We have entered into a Medicaid Drug Rebate Agreement, or MDRA, with the Centers for Medicare & Medicaid Services. This agreement provides for a rebate based on covered purchases of our products. Medicaid rebates are invoiced to us by the various state Medicaid programs. We estimate Medicaid rebates using the expected value approach, based on a variety of factors, including payor mix and our experience to-date.

We have a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of our products. In addition, we have entered into a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services, which enables certain entities that qualify for government pricing under the Public Health Services Act, or PHS, to receive discounts on their qualified purchases of our products. Under these agreements, distributors process a chargeback to us for the difference between wholesale acquisition cost and the applicable discounted price. We estimate expected chargebacks for FSS and PHS purchases based on the expected value of each entity's eligibility for the FSS and PHS programs. We also review historical rebate and chargeback information to further refine these estimates.

Distribution fees, product returns and other deductions: Our distributors charge a volume-based fee for distribution services that they perform for us. We allow for the return of product that is within a specified number of days of its expiration date or that is damaged. We estimate product returns based on our experience to-date using the expected value approach. We provide financial assistance to qualifying patients that are underinsured or cannot cover the cost of commercial coinsurance amounts through our patient support programs. Estimated contributions for commercial coinsurance under SeaGen Secure are deducted from gross sales and are based on an analysis of expected plan utilization. These estimates are adjusted as necessary to reflect our actual experience.

Revenue recognition - Royalty revenues

Royalty revenues primarily reflect amounts earned under the ADCETRIS collaboration with Takeda. These royalties include commercial sales-based milestones and sales royalties that relate predominantly to the license of intellectual property. Sales royalties are based on a percentage of Takeda's net sales of ADCETRIS, with rates that range from the mid-teens to the mid-twenties based on annual net sales tiers. Takeda bears a portion of low single digit third-party royalty costs owed on its sales of ADCETRIS. This amount is included in royalty revenues. Amounts owed to our third-party licensors related to Takeda's sales of ADCETRIS are recorded in cost of sales. These amounts are recognized in the period in which the related sales by Takeda occur. Royalty revenues also reflect amounts from Genentech, Inc., a member of the Roche Group, or Genentech, earned on net sales of Polivy, and amounts from GlaxoSmithKline earned on net sales of Blenrep.

Revenue recognition - Collaboration and license agreement revenues

We have collaboration and license agreements for our technology with a number of biotechnology and pharmaceutical companies. Under these agreements, we typically receive or are entitled to receive upfront cash payments and progress- and sales-dependent milestones for the achievement by our licensees of certain events, and annual maintenance fees and support fees for research and development services and materials provided under the agreements. We also are entitled to receive royalties on net sales of any resulting products incorporating our technology. Our licensees are solely responsible for research, product development, manufacturing and commercialization of any product candidates under these collaborations, which includes the achievement of the potential milestones. Since we may not take a substantive role or control the research, development or commercialization of any products generated by some of our licensees, we may not able to reasonably estimate when, if at all, any potential future milestone payments or royalties may be payable to us by our licensees. As such, the potential future milestone payments associated with certain of our collaboration and license agreements involve a substantial degree of uncertainty and risk that they may never be received.

Collaboration and license agreements are initially evaluated as to whether the intellectual property licenses granted by us represent distinct performance obligations. If they are determined to be distinct, the value of the intellectual property licenses would be recognized up-front while the research and development service fees would be recognized as the performance obligations are satisfied. Variable consideration is assessed at each reporting period as to whether it is not subject to future reversal of cumulative revenue and, therefore, should be included in the transaction price. Assessing the recognition of variable consideration requires significant judgment. If a contract includes a fixed or minimum amount of research and development support, this also would be included in the transaction price. Changes to collaboration and license agreements, such as the extensions of the research term or increasing the number of targets or technology covered under an existing agreement, are assessed for whether they represent a modification or should be accounted for as a new contract.

We have concluded that the license of intellectual property in certain collaboration and license agreements is not distinct from the perspective of our customers at the time of initial transfer, since we often do not license intellectual property without related technology transfer and research and development support services. Such evaluation requires significant judgment since it is made from the customer's perspective. Our performance obligations under our collaborations may include such things as providing intellectual property licenses, performing technology transfer, performing research and development consulting services, providing reagents, ADCs, and other materials, and notifying the customer of any enhancements to licensed technology or new technology that we discover, among others. We determined our performance obligations under certain collaboration and license agreements as evaluated at contract inception were not distinct and represented a single performance obligation. For those agreements, revenue is recognized using a proportional performance model, representing the transfer of goods or services as activities are performed over the term of the agreement. Upfront payments are also amortized to revenue over the performance period. Upfront payment contract liabilities resulting from our collaborations do not represent a financing component as the payment is not financing the transfer of goods or services, and the technology underlying the licenses granted reflects research and development expenses already incurred by us. For agreements beyond the initial performance period, we have no remaining performance obligations. We may receive license maintenance fees and potential milestones and royalties based on collaborator development and regulatory progress, which are recorded in the period achieved in the case of milestones, and during the period of the related sales for royalties.

When no performance obligations are required of us, or following the completion of the performance obligation period, such amounts are recognized upon transfer of control of the goods or services to the customer. Generally, all amounts received or due other than sales-based milestones and royalties are classified as collaboration and license agreement revenues. Sales-based milestones and royalties are recognized as royalty revenue in the period the related sale occurred.

We generally invoice our collaborators and licensees on a monthly or quarterly basis, or upon the completion of the effort or achievement of a milestone, based on the terms of each agreement. Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods as performance obligations are satisfied. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

Research and development expenses

Research and development, or R&D, expenses consist of salaries, benefits and other headcount-related costs of our R&D staff, preclinical activities, clinical trials and related manufacturing costs, lab supplies, contract and outside service fees and facilities and overhead expenses for research, development and preclinical studies focused on drug discovery, development and testing. R&D activities are expensed as incurred.

Clinical trial expenses are a significant component of research and development expenses, and we outsource a significant portion of these costs to third parties. Third-party clinical trial expenses include investigator fees, site costs, clinical research organization costs, and costs for central laboratory testing and data management. Costs associated with activities performed under co-development collaborations are reflected in R&D expense. In-licensing fees, milestones, maintenance fees and other costs to acquire technologies utilized in R&D for product candidates that have not yet received regulatory approval and that are not expected to have alternative future use are expensed when incurred. Non-refundable advance payments for goods or services that will be used or rendered for future R&D activities are capitalized and recognized as expense as the related goods are delivered or the related services are performed. This results in the temporary deferral of recording expense for amounts incurred for research and development activities from the time payments are made until the time goods or services are provided.

Advertising

Advertising costs are expensed as incurred. We incurred $59.3 million, $33.5 million, and $26.6 million in advertising expenses during 2020, 2019, and 2018, respectively.

Concentration of credit risk

Cash, cash equivalents and investments are invested in accordance with our investment policy. The policy includes guidelines for the investment of cash reserves and is reviewed periodically to minimize credit risk. Most of our investments are in U.S. Treasury securities and are not federally insured. We have accounts receivable from the sale of our products from a small number of distributors, and from our collaborators. We do not require collateral on amounts due from our distributors or our collaborators and are therefore subject to credit risk.

Allowance for doubtful accounts

We estimate an allowance for doubtful accounts based on our assessment of the collectability of customer accounts. We regularly review the allowance by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. As of December 31, 2020 and 2019, there was no allowance for doubtful accounts, and we recognized no bad debt expense during the years ending December 31, 2020, 2019, and 2018.

Geographic and customer information

Substantially all of our assets and revenues are related to operations in the U.S.; however, we have multiple subsidiaries in foreign jurisdictions, including several subsidiaries in Europe. We sell our products through a limited number of distributors and specialty pharmacies.

The following table presents each major distributor or collaborator that comprised more than 10% of total revenue:

	Years ended December 31,		
	2020	2019	2018
Distributor A	18 %	26 %	28 %
Distributor B	15 %	21 %	22 %
Distributor C	10 %	18 %	20 %
Collaborator B	45 %	— %	— %
Collaborator A	7 %	27 %	21 %

The following table presents each major distributor or collaborator that accounted for more than 10% of accounts receivable:

	December 31,	
	2020	2019
Distributor A	32 %	24 %
Distributor B	25 %	19 %
Distributor C	16 %	16 %
Collaborator A	13 %	33 %

Major suppliers

The use of a relatively small number of contract manufacturers to supply drug necessary for our commercial and clinical operations create a concentration of risk for us. While primarily one source of supply is utilized for certain components of ADCETRIS, PADCEV, TUKYSA and each of our clinical product candidates, other sources are available should we need to change suppliers. For PADCEV, in particular, we rely on Astellas for both commercial and clinical supply as Astellas oversees the manufacturing supply chain. As a form of reducing near-term risk, we also endeavor to maintain reasonable levels of drug supply inventory across the supply chain. A change in suppliers or disruption at one of our suppliers, however, could cause a delay or interruption in delivery of drug or clinical trials. Such an event would adversely affect our business.

Income taxes

We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the differences between the financial statement and tax bases of assets and liabilities using tax rates in effect for the year in which the differences are expected to reverse. We have provided a valuation allowance against substantially all our deferred tax assets for all periods presented. A valuation allowance is recorded when it is more likely than not that the net deferred tax asset will not be realized. We follow the guidance related to accounting for uncertainty in income taxes, which requires the recognition of an uncertain tax position when it is more likely than not to be sustainable upon audit by the applicable taxing authority.

Share-based compensation

We use the graded-vesting attribution method for recognizing compensation expense for our stock options and restricted stock units, or RSUs. Compensation expense is recognized over the requisite service periods on awards ultimately expected to vest and reduced for forfeitures that are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. For performance-based stock options and RSUs, we record compensation expense over the estimated service period once the achievement of the performance-based milestone is considered probable. At each reporting date, we assess whether achievement of a milestone is considered probable, and if so, record compensation expense based on the portion of the service period elapsed to date with respect to that milestone, with a cumulative catch-up, net of estimated forfeitures. We will recognize remaining compensation expense with respect to a milestone, if any, over the remaining estimated service period.

Long-term incentive plans

We have established Long-Term Incentive Plans, or LTIPs. The LTIPs provide eligible employees with the opportunity to receive performance-based incentive compensation, which may be comprised of cash, stock options, and/or RSUs. The payment of cash and the grant and/or vesting of equity are contingent upon the achievement of pre-determined regulatory milestones. We record compensation expense over the estimated service period for each milestone subject to the achievement of the milestone being considered probable in accordance with the provisions of ASC Topic 450--Contingencies. At each reporting date, we assess whether achievement of a milestone is considered probable and, if so, record compensation expense based on the portion of the service period elapsed to date with respect to that milestone, with a cumulative catch-up, net of estimated forfeitures. We recognize compensation expense with respect to a milestone over the remaining estimated service period.

The total estimate of unrecognized compensation expense could change in the future for several reasons, including the addition or termination of employees, the recognition of LTIP compensation expense, or the addition, termination, or modification of an LTIP.

Comprehensive income (loss)

Comprehensive income (loss) is the change in stockholders' equity from transactions and other events and circumstances other than those resulting from investments by stockholders and distributions to stockholders. Our comprehensive income (loss) is comprised of net income (loss), unrealized gains and losses on available-for-sale securities, net of income tax provision and foreign currency translation adjustments, net of income tax provision.

Loss contingencies

We are involved in various legal proceedings in the normal course of business. A loss contingency is recorded if it is probable that an asset has been impaired or a liability has been incurred and the amount of the loss can be reasonably estimated. We evaluate, among other factors, the probability of an unfavorable outcome and our ability to make a reasonable estimate and the amount of the ultimate loss. Loss contingencies that are determined to be reasonably possible, but not probable, are disclosed but not recorded. Legal fees incurred as a result of our involvement in legal procedures are expensed as incurred.

Certain risks and uncertainties

Our revenues are derived from net product sales, royalties, and from collaboration and license agreements. Our products are subject to regulation by the FDA in the U.S. and other regulatory agencies outside the U.S. as well as competition by other pharmaceutical companies. Our collaboration and license agreement revenues are derived from a relatively small number of agreements. Each of these agreements can be terminated by our collaborators at their discretion. We are also subject to risks common to companies in the pharmaceutical industry, including risks and uncertainties related to commercial success and acceptance of our products and our potential future products by patients, physicians and payers, competition from other products, regulatory approvals, regulatory requirements, business combinations and product or product candidate acquisition and in-licensing transactions, and protection of intellectual property. Also, drug development is a lengthy process characterized by a relatively low rate of success. We may commit substantial resources toward developing product candidates that never result in further development, achieve regulatory approvals or achieve commercial success. Likewise, we have committed and expect to continue to commit substantial resources towards additional clinical development of our products in an effort to continue to expand our products' labeled indications of use, and there can be no assurance that we and/or our partners will obtain and maintain the necessary regulatory approvals to market our products for any additional indications.

Guarantees

In the normal course of business, we indemnify our directors, certain employees and other parties, including distributors, collaboration partners, lessors and other parties that perform certain work on behalf of, or for us to take licenses to our technologies. We have agreed to hold these parties harmless against losses arising from our breach of representations or covenants, intellectual property infringement or other claims made against these parties in performance of their work with us. These agreements typically limit the time within which the party may seek indemnification by us and the amount of the claim. It is not possible to prospectively determine the maximum potential amount of liability under these indemnification agreements. Further, each potential claim would be based on the unique facts and circumstances of the claim and the particular provisions of each agreement.

Recent accounting pronouncements adopted

In June 2016, Financial Accounting Standards Board, or FASB, issued "ASU 2016-13, Financial Instruments: Credit Losses," as clarified in ASU 2019-04 and ASU 2019-05. The objective of the standard is to provide information about expected credit losses on financial instruments at each reporting date and to change how other-than-temporary impairments on investment securities are recorded. We adopted this standard on January 1, 2020 using the modified retrospective transition method. The adoption of this ASU had no material impact on our current or previously reported financial condition, results of operations, cash flows, and financial statement disclosures.

In August 2018, FASB issued "ASU 2018-15, Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract." The objective of the standard is to align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. We adopted this standard on January 1, 2020 on a prospective basis. The adoption of this ASU did not have a material impact on our financial condition, results of operations, cash flows, and financial statement disclosures. Capitalized implementation costs are included in prepaid expenses and other current assets or other non-current assets.

In November 2018, FASB issued "ASU 2018-18, Clarifying the Interaction between Topic 808 and Topic 606." The objective of the standard is to clarify the interaction between ASC Topic 808--Collaborative Arrangements and ASC Topic 606--Revenue from Contracts with Customers. Currently, ASC Topic 808 does not provide comprehensive recognition or measurement guidance for collaborative arrangements, and the accounting for those arrangements is often based on an analogy to other accounting literature or an accounting policy election. Similarly, aspects of ASC Topic 606 have resulted in uncertainty in practice about the effect of the revenue standard on the accounting for collaborative arrangements. We adopted this standard on January 1, 2020 on a retrospective basis to contracts that were not completed. The adoption of this ASU did not change the way we previously accounted for any of our collaboration arrangements under ASC Topic 808, thus had no impact on our current or previously reported financial condition, results of operations, cash flows, and financial statement disclosures.

In December 2019, the FASB issued "ASU 2019-12, Simplifying the Accounting for Income Taxes." The objective of the standard is to improve areas of GAAP by removing certain exceptions permitted by ASC Topic 740-- Income Taxes and clarifying existing guidance to facilitate consistent application. The standard is effective for us beginning on January 1, 2021. We are currently evaluating the new standard to determine the potential impact on our financial condition, results of operations, cash flows, or financial statement disclosures.

2. Revenue from contracts with customers

The following table presents our disaggregated revenue for the years presented:

	Years ended December 31,		
(dollars in thousands)	**2020**	**2019**	**2018**
ADCETRIS	$ 658,577	$ 627,733	$ 476,903
PADCEV	222,436	244	—
TUKYSA	119,585	—	—
Net product sales	$ 1,000,598	$ 627,977	$ 476,903
Royalty revenues	$ 126,756	$ 138,491	$ 83,440
Merck	$ 975,150	$ —	$ —
Takeda	32,107	108,175	58,605
Other	40,925	42,070	35,752
Collaboration and license agreement revenues	$ 1,048,182	$ 150,245	$ 94,357
Total revenues	$ 2,175,536	$ 916,713	$ 654,700

Substantially all of our product revenues during the years ended December 31, 2020, 2019, and 2018 were recorded in the U.S. Royalty revenues primarily reflect royalties earned under the ADCETRIS collaboration with Takeda.

In 2019, other collaboration and license agreement revenues included $20.0 million from BeiGene, Ltd., or BeiGene. BeiGene is a related party due to a common shareholder that has a representative or representatives serving on each company's respective Board of Directors.

Contract balances and performance obligations

We had no contract assets or liabilities as of December 31, 2020 and 2019. We recognized collaboration and license agreement revenues of $0, $33.6 million and $34.5 million during the years ended December 31, 2020, 2019, and 2018, respectively, that were included in deferred revenue as of the beginning of the respective years.

On January 1, 2018, we adopted ASC Topic 606 applying the modified retrospective method transition option to all contracts that were not completed as of January 1, 2018. We recorded the following cumulative effect as of January 1, 2018:

(dollars in thousands)	
Collaboration and license agreement revenues	$ 10,281
Royalty revenues	22,230
Cost of royalty revenues	$ (5,955)
Accumulated deficit – (debit) credit	$ 26,556

3. Operating leases

We have operating leases for our office and laboratory facilities with terms that expire from 2021 through 2029. Upon adoption of ASC Topic 842--Leases on January 1, 2019, we recognized $35.2 million of operating lease liabilities and $34.7 million of operating lease right-of-use assets for our existing leases on our consolidated balance sheet. During the years ended December 31, 2020 and 2019, we recorded $7.2 million and $40.3 million, respectively, of right-of-use assets in exchange for lease liabilities, which has been treated as a non-cash operating activity. All of our significant leases include options for us to extend the lease term. None of our options to extend the rental term of any existing leases were considered reasonably certain as of December 31, 2020.

Supplemental operating lease information was as follows:

	Years ended December 31,	
(dollars in thousands, except term and rate)	**2020**	**2019**
Operating lease cost	$ 15,013	$ 13,590
Variable lease cost	3,937	2,958
Total lease cost	$ 18,950	$ 16,548
Cash paid for amounts included in measurement of lease liabilities	$ 14,265	$ 10,197
Weighted average remaining lease term (in years)	6.16	7.04
Weighted average discount rate	5.2 %	5.4 %

Rent expense attributable to non-cancelable operating leases totaled approximately $16.6 million, $14.6 million, and $8.7 million for the years ended December 31, 2020, 2019, and 2018, respectively.

Operating lease liabilities were recorded in the following captions of our consolidated balance sheet as follows:

	December 31,	
(dollars in thousands)	2020	2019
Accrued liabilities and other	$ 12,749	$ 9,445
Operating lease liabilities, long-term	61,884	67,607
Total	$ 74,633	$ 77,052

As of December 31, 2020, future minimum lease payments under the lease agreements were as follows:

(dollars in thousands)	
Years ending December 31,	
2021	$ 16,337
2022	15,650
2023	15,030
2024	11,147
2025	7,510
Thereafter	22,656
Total future minimum lease payments	88,330
Less: imputed interest	(13,697)
Total	$ 74,633

4. Acquisition of Cascadian

In 2018, we acquired all issued and outstanding shares of Cascadian, a clinical-stage biopharmaceutical company based in Seattle, Washington, for $10.00 per share in cash, or approximately $614.1 million, which was funded by an underwritten public offering as further described in Note 15. The acquisition of Cascadian expanded our late-stage pipeline, providing global rights to TUKYSA.

The acquisition of Cascadian was accounted for as a business combination. During the year ended December 31, 2018, we incurred $8.5 million in acquisition-related costs, which were recorded in selling, general and administrative expenses.

The purchase price allocation of the assets acquired and liabilities assumed based on their estimated fair values as of the acquisition date was as follows:

(dollars in thousands)	
Cash and cash equivalents	$ 15,919
Short-term and long-term investments	66,491
Prepaid expenses and other assets	2,215
Property and equipment	566
In-process research and development	300,000
Goodwill	274,671
Accounts payable and accrued liabilities	(22,139)
Deferred tax liability	(23,653)
Total purchase price	$ 614,070

The amount allocated to in-process research and development was based on the present value of future discounted cash flows, which was based on significant estimates. These estimates included the number of potential patients and market price of a future TUKYSA-based regimen, costs required to conduct clinical trials and potentially commercialize TUKYSA, as well as estimates for probability of success and the discount rate. Goodwill primarily was attributed to TUKYSA's potential application in other treatment settings, intangible assets that do not qualify for separate recognition, and synergies with our existing pipeline and capabilities. Goodwill is not expected to be deductible for tax purposes.

5. Fair Value

We have certain assets that are measured at fair value on a recurring basis according to a fair value hierarchy that prioritizes the inputs, assumptions and valuation techniques used to measure fair value. The three levels of the fair value hierarchy are:

Level 1:	Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
Level 2:	Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly.
Level 3:	Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The determination of a financial instrument's level within the fair value hierarchy is based on an assessment of the lowest level of any input that is significant to the fair value measurement. We consider observable data to be market data which is readily available, regularly distributed or updated, reliable and verifiable, not proprietary, and provided by independent sources that are actively involved in the relevant market.

The following table summarized the type of assets measured at fair value on a recurring basis by level within the fair value hierarchy:

	Fair value measurement using:			
(dollars in thousands)	Quoted prices in active markets for identical assets (Level 1)	Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
December 31, 2020				
Short-term investments—U.S. Treasury securities	$ 2,000,996	$ —	$ —	$ 2,000,996
Long-term investments—U.S. Treasury securities	100,830	—	—	100,830
Total	$ 2,101,826	$ —	$ —	$ 2,101,826
December 31, 2019				
Short-term investments—U.S. Treasury securities	$ 536,493	$ —	$ —	$ 536,493
Long-term investments—U.S. Treasury securities	57,283	—	—	57,283
Other non-current assets—equity securities	163,936	—	—	163,936
Total	$ 757,712	$ —	$ —	$ 757,712

Our short- and long-term investments portfolio predominantly contains investments in U.S. Treasury and other U.S. government-backed securities. We review our portfolio based on the underlying risk profile of the securities and also regularly review the securities in an unrealized loss position and evaluate the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. During the years ended December 31, 2020 and 2019, we recognized no year-to-date credit loss related to our short- and long-term investments, and had no allowance for credit loss recorded as of December 31, 2020.

Our debt securities consisted of the following:

(dollars in thousands)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
December 31, 2020				
U.S. Treasury securities	$ 2,101,801	$ 259	$ (234)	$ 2,101,826
Contractual maturities (at date of purchase):				
Due in one year or less	$ 1,791,399			$ 1,791,239
Due in one to two years	310,402			310,587
Total	$ 2,101,801			$ 2,101,826
December 31, 2019				
U.S. Treasury securities	$ 593,565	$ 236	$ (25)	$ 593,776
Contractual maturities (at date of purchase):				
Due in one year or less	$ 466,439			$ 466,547
Due in one to two years	127,126			127,229
Total	$ 593,565			$ 593,776

6. Investment and Other Income, Net

Investment and other income, net consisted of the following:

	Years ended December 31,		
(dollars in thousands)	2020	2019	2018
Gain on equity securities	$ 11,604	$ 50,124	$ 7,336
Investment and other income, net	7,245	11,771	6,316
Total investment and other income, net	$ 18,849	$ 61,895	$ 13,652

Gain on equity securities includes the realized and unrealized holding gains and losses on our equity securities. In 2020, we sold our all our common stock holdings for $174.7 million.

7. Inventories

Inventories consisted of the following:

	December 31,	
(dollars in thousands)	2020	2019
Raw materials	$ 99,049	$ 78,285
Finished goods	17,087	7,647
Total	$ 116,136	$ 85,932

8. Property and equipment

Property and equipment consisted of the following:

(dollars in thousands)	December 31, 2020	December 31, 2019
Leasehold improvements	$ 204,918	$ 154,606
Laboratory and manufacturing equipment	78,724	68,226
Building	23,341	23,341
Computers, software and office equipment	45,141	37,154
Furniture and fixtures	15,825	11,758
Land	4,771	4,771
	372,720	299,856
Less: accumulated depreciation and amortization	(176,020)	(144,365)
Total	$ 196,700	$ 155,491

Depreciation and amortization expenses on property and equipment totaled $36.0 million, $23.8 million, and $25.3 million for the years ended December 31, 2020, 2019, and 2018, respectively. Leasehold improvements included $24.5 million and $62.2 million of construction in process at December 31, 2020 and 2019, respectively.

9. Accrued liabilities

Accrued liabilities consisted of the following:

(dollars in thousands)	December 31, 2020	December 31, 2019
Employee compensation and benefits	$ 96,902	$ 74,835
Clinical trial and related costs	69,756	37,418
Contract manufacturing	20,765	13,866
Gross-to-net deductions and third-party royalties	52,565	37,662
Operating lease liability, current	12,749	9,445
Collaborator contract liability – short-term	30,130	—
Professional services and other	27,204	33,839
Total	$ 310,071	$ 207,065

10. Income taxes

Our pre-tax income (loss) by jurisdiction consisted of the following:

(dollars in thousands)	Years ended December 31, 2020	2019	2018
U.S.	$ 613,054	$ (160,189)	$ (226,626)
Foreign	2,647	1,539	(19,720)
Total	$ 615,701	$ (158,650)	$ (246,346)

A reconciliation of the federal statutory income tax rate to the effective income tax rate is as follows:

	Years ended December 31,		
	2020	2019	2018
Statutory federal income tax rate	21.0 %	(21.0)%	(21.0)%
Tax credits	(5.4)	(11.0)	(6.0)
Foreign rate differential	—	—	(8.0)
State income taxes and other	1.5	(4.7)	(3.7)
Valuation allowance	(8.4)	37.1	44.0
Stock compensation	(8.4)	(6.4)	(3.2)
Non-deductible asset basis	—	6.0	—
Worthless stock deduction	—	—	(12.1)
Effective tax rate	0.3 %	0.0 %	(10.0)%

For the year ended December 31, 2020, we recorded a provision for income taxes of $2.0 million, consisting primarily of $3.7 million of current state taxes offset by a net $1.7 million deferred foreign tax benefit primarily related to the release of a valuation allowance on our foreign deferred tax asset for net operating losses. We utilized net operating loss carryforwards to reduce any federal tax liability, and we incurred state tax liabilities of $3.7 million due to certain states with current limitations on the utilization of net operating losses.

In 2019, we did not record any income tax expense or benefit due to a tax loss position. In 2018, we recognized a deferred tax liability of $23.7 million on acquired intangible assets in connection with the acquisition of Cascadian. As a result, we recorded an income tax benefit of $23.7 million for the release of valuation allowance on our existing U.S. deferred tax assets as a result of the offset of deferred tax liabilities established for intangible assets from the acquisition.

The foreign rate differential in the table above reflects the effect of operations in jurisdictions with tax rates that differ from the rate in the U.S. The change in foreign rate differential from 2018 to 2019 was primarily due to the one-time impact of foreign entity restructuring in 2018. As of December 31, 2020, unremitted earnings of our foreign subsidiaries will be retained indefinitely by the foreign subsidiaries for continuing investment. If foreign earnings were to be repatriated to the U.S., we could be subject to additional state income and withholding taxes.

Our net deferred tax assets consisted of the following:

(dollars in thousands)	December 31, 2020	December 31, 2019
Deferred tax assets:		
Net operating loss carryforwards	$ 228,041	$ 331,124
Foreign net operating loss carryforwards	8,341	3,527
Tax credit carryforwards	224,233	193,552
Share-based compensation	33,315	34,869
Allowance and accruals	29,355	26,625
Operating lease liabilities	16,596	18,597
Inventory	19,402	3,815
Capitalized research and development	4,139	4,732
Depreciation	—	9,430
Other	—	1,133
Total deferred tax assets	563,422	627,404
Less: valuation allowance	(489,519)	(536,316)
Total deferred tax assets, net of valuation allowance	73,903	91,088
Deferred tax liability:		
Right-of-use assets	(13,647)	(17,125)
Intangibles and amortization	(46,018)	(50,725)
Depreciation	(10,215)	—
Unrealized gain on available-for-sale securities	—	(20,064)
Other	(1,970)	(3,174)
Net deferred tax assets	$ 2,053	$ —

Our deferred tax assets primarily consist of net operating loss (NOL) carryforwards, tax credit carryforwards, share-based compensation, allowance and accruals, operating lease liabilities, inventory, and capitalized research and development expense. Realization of deferred tax assets is dependent upon a number of factors, including future earnings, the timing and amount of which is uncertain. The assessment regarding whether a valuation allowance is required considers the evaluation of both positive and negative evidence when concluding whether it is more likely than not that deferred tax assets are realizable. Based upon a review of available evidence, we determined that it is not more likely than not that the U.S. deferred tax assets will be realized, and therefore the deferred tax assets have been fully offset by a valuation allowance. During the year ended December 31, 2020, we released $2.1 million of valuation allowance on our foreign NOL carryforward deferred tax asset.

At December 31, 2020, we had gross federal NOL carryforwards of $971.0 million, of which $391.2 million may be carried forward indefinitely and $579.8 million of which expire from 2021 to 2037 if not utilized, gross state NOL carryforwards of $367.7 million, gross foreign NOL carryforwards of $42.3 million and tax credit carryforwards of $247.3 million expiring from 2021 to 2040.

Utilization of the NOL and tax credit carryforwards may be subject to a substantial annual limitation in the event of a change in ownership as set forth in Section 382 of the Internal Revenue Code of 1986, as amended. We have evaluated ownership changes through the year ended December 31, 2019 and believe that it is likely that utilization of its NOLs would not be limited under Section 382 as of December 31, 2019. It is possible that there has been or may be a change in ownership after this date, which would limit our ability to utilize our NOLs. Any limitation may result in the expiration of the NOLs and tax credit carryforwards before utilization.

The valuation allowance decreased by $46.8 million in 2020, increased by $58.5 million in 2019, and increased by $113.3 million in 2018, which was mostly related to the changes in our deferred tax asset balances. The 2020 decrease in the valuation allowance is primarily due to the current year net operating loss utilization, partially offset by tax credit generation. The 2019 increase in the valuation allowance is related to the loss, tax credits generated, and other activity. The 2018 increase in the valuation allowance included a $143.3 million increase related to the loss, tax credits and other activity in 2018, offset by a $23.7 million decrease for release of valuation allowance related to the deferred tax assets and liabilities acquired from Cascadian and a $6.3 million decrease due to the adoption of ASC Topic 606.

The financial statement recognition of the benefit for a tax position is dependent upon the benefit being more likely than not to be sustainable upon audit by the applicable taxing authority. If this threshold is met, the tax benefit is then measured and recognized at the largest amount that is greater than 50% likely of being realized upon ultimate settlement. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	Years ended December 31,		
(dollars in thousands)	2020	2019	2018
Balance at January 1	$ 24,018	$ 20,706	$ 18,172
Increase (decrease) related to prior year tax positions	(4,008)	—	108
Increase related to current year tax positions	3,068	3,312	2,426
Balance at December 31	$ 23,078	$ 24,018	$ 20,706

We do not anticipate any significant changes to our unrecognized tax positions or benefits during the next twelve months. Interest and penalties related to the settlement of uncertain tax positions, if any, will be reflected in income tax expense. Tax years 2001 to 2020 remain subject to future examination for federal and foreign income taxes.

11. Collaboration and license agreements

We have collaboration and license agreements with a number of pharmaceutical and biotechnology companies. Revenues recognized under these agreements are disclosed in Note 2.

These agreements generally may be terminated due to material and uncured breaches, insolvency of either party, mutual written consent, unilateral decision of one or either party upon prior written notice, expiration of payment obligations, cessation of development or commercialization of the products, and/or challenges to patents which are subject to the related agreement. Each agreement is discussed in more detail in the following sections.

Takeda ADCETRIS collaboration

The Takeda ADCETRIS collaboration provides for the global co-development of ADCETRIS and the commercialization of ADCETRIS by Takeda in its territory. We have commercial rights for ADCETRIS in the U.S. and its territories and in Canada. Takeda has commercial rights in the rest of the world. Under the collaboration, we and Takeda can each conduct development activities and equally co-fund the cost of certain mutually agreed development activities. Costs associated with co-development activities are included in research and development expense.

We recognize payments received from Takeda, including progress-dependent development and regulatory milestone payments, reimbursement for drug supplied, and net development cost reimbursement payments, as collaboration and license agreement revenues upon transfer of control of the goods or services over the development period. When the performance of development activities under the collaboration results in us making a reimbursement payment to Takeda, that payment reduces collaboration and license agreement revenues. In addition, we recognize royalty revenues, where royalties are based on a percentage of Takeda's net sales of ADCETRIS in its licensed territories, with percentages ranging from the mid-teens to the mid-twenties based on annual net sales tiers, and sales-based milestones. Takeda bears a portion of third-party royalty costs owed on its sales of ADCETRIS, which is included in royalty revenues.

Astellas PADCEV collaboration

We have a collaboration agreement with Agensys, Inc., which subsequently became an affiliate of Astellas, to jointly research, develop and commercialize ADCs for the treatment of several types of cancer. The collaboration encompasses combinations of our ADC technology with fully-human antibodies developed by Astellas to proprietary cancer targets. Under this collaboration, we and Astellas are co-funding all development costs for PADCEV. We rely on Astellas to supply PADCEV for commercial sales and for our clinical trials, and Astellas oversees the manufacturing supply chain for PADCEV. Costs associated with co-development activities are included in research and development expense and amounted to $99.3 million, $76.8 million, and $54.9 million for the years ended December 31, 2020, 2019, and 2018, respectively.

In 2018, we and Astellas entered into a joint commercialization agreement to govern the global commercialization of PADCEV:

- In the U.S., we and Astellas jointly promote PADCEV. We record sales of PADCEV in the U.S. and are responsible for all U.S. distribution activities. The companies each bear the costs of their own sales organizations in the U.S., equally share certain costs associated with commercializing PADCEV in the U.S., and equally share in any profits realized in the U.S. We and Astellas launched PADCEV in the U.S. in December 2019. Gross profit share payments owed to Astellas in the U.S. are recorded in cost of sales and totaled $104.6 million during the year ended December 31, 2020.
- Outside the U.S., we have commercialization rights in all countries in North and South America, and Astellas has commercialization rights in the rest of the world, including Europe, Asia, Australia and Africa. The agreement is intended to provide that we and Astellas will effectively equally share in costs incurred and any profits realized in all of these markets. Cost and profit sharing in Canada, the United Kingdom, Germany, France, Spain and Italy will be based on product sales and costs of commercialization. In the remaining markets, the commercializing party will bear costs and will pay the other party a royalty rate applied to net sales of the product based on a rate intended to approximate an equal profit share for both parties.

Either party may opt out of co-development and profit-sharing under the collaboration agreement in return for receiving milestones and royalties from the continuing party. Astellas or its affiliates are responsible for manufacturing PADCEV for development and commercial use. However, we are responsible for packaging and labeling in countries in which we sell PADCEV. In addition, if the parties determine that a second source is required, we will be responsible for establishing such second source whether internally or through a third party.

Genmab tisotumab vedotin collaboration

We have an agreement with Genmab to develop and commercialize ADCs for the treatment of several types of cancer, under which we previously exercised a co-development option for tisotumab vedotin. In October 2020, we and Genmab entered into a joint commercialization agreement to govern the global commercialization of tisotumab vedotin, if we are successful in obtaining any regulatory approvals of tisotumab vedotin:

- In the U.S., we and Genmab will co-promote tisotumab vedotin. We will record sales of tisotumab vedotin in the U.S. and are responsible for leading U.S. distribution activities. The companies will each hire and maintain 50% of the sales representatives and medical science liaisons, equally share those and certain other costs associated with commercializing tisotumab vedotin in the U.S., and equally share in any profits realized in the U.S.
- Outside the U.S., we have commercialization rights in the rest of the world except for Japan, where Genmab has commercialization rights. In Europe, China, and Japan, we and Genmab equally share 50% of the costs associated with commercializing tisotumab vedotin as well as any profits realized in these markets. In markets outside the U.S. other than Europe, China, and Japan, aside from certain costs specified in the agreement, we are solely responsible for all costs associated with commercializing tisotumab vedotin and will pay Genmab a royalty based on a percentage of aggregate net sales ranging from the mid-teens to mid-twenties.

In February 2021, a BLA for tisotumab vedotin was submitted to the FDA seeking accelerated approval for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Costs associated with co-development activities are included in research and development expense and amounted $50.1 million, $48.5 million, and $33.8 million for the years ended December 31, 2020, 2019, and 2018, respectively. Either party may opt out of co-development and profit-sharing under the collaboration agreement in return for receiving milestones and royalties from the continuing party. Either party may also opt out of co-development and profit-sharing under the collaboration agreement in return for receiving milestones and royalties from the continuing party. The opt out provisions of the collaboration agreement may also be applied to the joint commercialization agreement. In addition, Genmab may elect to opt out of co-promotion of tisotumab vedotin in the United States by providing us with prior written notice.

Merck LV and TUKYSA license and collaboration agreements, and stock purchase agreement

In September 2020, we entered into two license and collaboration agreements, and a stock purchase agreement, with subsidiaries of Merck.

Under one of the license and collaboration agreements, referred to as the LV Agreement, we are pursuing a broad joint development program evaluating ladiratuzumab vedotin, or LV, as monotherapy and in combination settings, including with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in triple-negative breast cancer, hormone receptor-positive breast cancer and other LIV-1-expressing solid tumors. Pursuant to the LV Agreement, we granted to Merck a co-exclusive worldwide development and commercialization license for LV, and agreed to jointly develop and commercialize LV on a worldwide basis. We received an upfront cash payment of $600.0 million, and we are eligible to receive up to $850.0 million in milestone payments upon the initiation of certain clinical trials and regulatory approval in certain major markets, and up to an additional $1.75 billion in milestone payments upon the achievement of specified annual global net sales thresholds of LV. Each company is responsible for 50% of global costs to develop and commercialize LV and will receive 50% of potential future profits.

In connection with the LV Agreement, we entered into a stock purchase agreement with Merck, referred to as the Purchase Agreement, pursuant to which Merck purchased 5,000,000 newly-issued shares of our common stock, at a purchase price of $200 per share, for an aggregate purchase price of $1.0 billion. The fair market value of 5,000,000 shares of our common stock was $749.9 million, based on the closing price of the last trading day prior to the Purchase Agreement being executed. We recorded the fair market value of the shares issued in stockholders' equity on our consolidated balance sheet upon closing of the sale of shares pursuant to the Purchase Agreement in October 2020. We accounted for the associated premium of $250.1 million as a freestanding equity-linked instrument under ASC 815, and determined it to be variable consideration attributable to the total transaction price related to the LV license. Accordingly, we recognized the premium in collaboration and license agreement revenues for the year ended December 31, 2020, upon closing of the sale of shares pursuant to the Purchase Agreement.

Under the other license and collaboration agreement, referred to as the TUKYSA Agreement, we granted Merck exclusive rights to commercialize TUKYSA in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. Pursuant to the TUKYSA Agreement, Merck is responsible for marketing applications for approval in its territory, supported by the positive results from the HER2CLIMB clinical trial. We retained commercial rights in the U.S., Canada and Europe, where we will record sales. Merck is also co-funding a portion of the TUKYSA global development plan, which encompasses several ongoing and planned trials across HER2-positive cancers. We will continue to lead ongoing TUKYSA global development operational execution. Merck will solely fund and conduct country-specific clinical trials necessary to support anticipated regulatory applications in its territories. We received an upfront cash payment from Merck of $125.0 million and also received $85.0 million in prepaid research and development funding to be applied to Merck's global development cost sharing obligations. We are eligible to receive progress-dependent milestone payments of up to $65.0 million, and are entitled to receive tiered royalties on sales of TUKYSA by Merck that begin in the low twenty percent range and escalate based sales volume by Merck in its territory. We owe a portion of any non-royalty payments received from sublicensing TUKSYA rights to a technology licensor, as well as a low double-digit royalty based on net sales of TUKYSA by us, and will owe a single-digit royalty based on net sales of TUKYSA by Merck in its territories.

We determined that these agreements are within the scope of ASC 808. Pursuant to ASC 808, we considered other authoritative guidance for distinct units of account related to these agreements, including ASC 606. Our performance obligations within the scope of ASC 606 consisted of the delivery of the LV license and transfer of regulatory information to enable the LV collaboration, the delivery of the TUKYSA license and transfer of regulatory materials for use by Merck in its territory, and supply of commercial TUKYSA inventory to Merck for use in its territory. The LV license and TUKYSA license are functional intellectual property and distinct from the other promises made under the contract. Since we also determined that Merck can benefit from the LV license and the TUKYSA licenses at the time of conveyance, the related performance obligations were satisfied at that point in time. Therefore, we recognized license revenue related to the upfront payments under ASC 606 in collaboration and license agreement revenues during the year ended December 31, 2020.

Potential development, regulatory, and sales-based milestones, and royalties, will be accounted for as variable transaction price related to the LV or TUKYSA licenses under ASC 606. Given the uncertain nature of these payments, we determined they were fully constrained as of December 31, 2020 and not included in the transaction price. We will re-evaluate the transaction price at each reporting period as uncertain events are resolved or other changes in circumstances occur.

We and Merck share equally in LV global development costs, and Merck is co-funding a portion of the TUKYSA global development plan. We consider the collaborative activities associated with the global development and commercialization of LV, and the global development of TUKYSA, to be units of account within the scope of ASC 808. We recognize development cost sharing proportionately with the performance of the underlying activities, and record Merck's reimbursement of our expenses as a reduction of research and development expenses. Reimbursements from Merck for the LV Agreement and TUKYSA Agreement were not material during the year ended December 31, 2020. Merck's remaining prepayment of $80.9 million towards the TUKYSA global development plan was recorded as a co-development liability in accrued liabilities and other or other long-term liabilities on our consolidated balance sheet as of December 31, 2020. As joint development expenses are incurred, we recognize the portion of Merck's prepayment as a reduction of our research and development expenses on our consolidated statements of comprehensive income (loss). Sales of TUKYSA drug product supplied to Merck will be included in collaboration and license agreement revenues.

Other collaboration and license agreements

We have other collaboration and license agreements for our technology with a number of biotechnology and pharmaceutical companies. Under these agreements, we have granted research and commercial licenses to use our technology, most often in conjunction with the licensee's technology. In certain agreements, we also have agreed to conduct limited development activities and to provide other materials, supplies and services to our licensees during a specified term of the agreement. We typically receive upfront cash payments and progress- and sales-dependent milestones for the achievement by our licensees of certain events, and annual maintenance fees and support fees for research and development services and materials provided under the agreements. These amounts are recognized as revenue over the performance obligation period if the license is determined to not be distinct from other goods and services provided, or, if there is no performance obligation, upon transfer of control of the goods or services to the customer. We also are entitled to receive royalties on net sales of any resulting products incorporating our ADC technology. Our licensees are solely responsible for research, product development, manufacturing and commercialization of any product candidates under these agreements, which includes the achievement of the potential milestones. For agreements beyond the initial performance period, we have no remaining performance obligations. We may receive license maintenance fees and potential milestones and royalties based on collaborator development and regulatory progress, which are recorded in the period achieved in the case of milestones, and during the period of the related sales for royalties.

12. In-license agreements

We have in-licensed antibodies, targets and enabling technologies from pharmaceutical and biotechnology companies and academic institutions for use in ADCETRIS, its pipeline programs and ADC technology. Under the terms of two exclusive license agreements, we are required to pay royalties in the low single digits on net sales of ADCETRIS. In addition, we owed royalties in the low single digits on net sales of ADCETRIS under the terms of other non-exclusive licenses, which expired in 2018.

We are a party to a license agreement in which we were granted an exclusive license to develop, manufacture and commercialize TUKYSA. We pay the licensor a portion of any non-royalty payments received from sublicensing TUKSYA rights, a low double-digit royalty based on net sales of TUKSYA by us, and a single-digit royalty based on net sales of TUKYSA by our sublicensees. The term of the license agreement expires on a country-by-country basis upon the later of the expiration of the last valid claim covering TUKYSA within that country or 10 years after the first commercial sale of TUKYSA within that country.

Under the terms of in-license agreements related to our pipeline programs, we would potentially owe development, regulatory, and sales-based milestones, and royalties on net sales, as defined, of certain approved products.

13. Commitments and contingencies

We have certain non-cancelable obligations under various agreements, including supply agreements relating to the manufacture of ADCETRIS, PADCEV, TUKYSA, and our product candidates that contain annual minimum purchase commitments and other firm commitments when a binding forecast is provided. As of December 31, 2020, our future obligations related to supply and other agreements were as follows:

(dollars in thousands)	
Years ending December 31,	
2021	$ 141,130
2022	84,384
2023	61,680
2024	44,988
2025	33,816
Thereafter	128
Total	$ 366,126

Non-cancelable obligations under these agreements do not include payments that are contingent upon achievement of certain progress-dependent milestones or royalties based on net sales of commercial products. These amounts have been excluded from the table because the events triggering the obligations have not yet occurred.

See Note 3 for our future obligations related to operating leases as of December 31, 2020.

14. Legal matters

We are engaged in multiple legal disputes with Daiichi Sankyo Co. Ltd., or Daiichi Sankyo.

Dispute over ownership of intellectual property

We are in a dispute with Daiichi Sankyo regarding the ownership of certain technology used by Daiichi Sankyo in its cancer drug ENHERTU and certain product candidates. We believe that the linker and other ADC technology used in ENHERTU and these drug candidates are improvements to our ADC technology, the ownership of which we contend was assigned to us under the terms of a 2008 collaboration agreement between us and Daiichi Sankyo. On November 12, 2019, we submitted an arbitration demand to the American Arbitration Association seeking, among other remedies, a declaration that we are the owner of the intellectual property rights under dispute, monetary damages, and a running royalty. On April 27, 2020, the arbitrator confirmed the dispute should be resolved in arbitration. The arbitration is progressing with a hearing date scheduled starting June 14, 2021.

On November 4, 2019, Daiichi Sankyo filed a declaratory judgment action in the United States District Court for the District of Delaware, alleging that we are not entitled to the intellectual property rights under dispute, in an attempt to have the dispute adjudicated in federal court. On March 25, 2020, a District of Delaware magistrate judge issued a stay of Daiichi Sankyo's court action pending determination by the arbitrator of whether the suit should be heard in court or arbitration. On April 8, 2020, Daiichi Sankyo filed objections to the magistrate judge's order. On October 27, 2020, the presiding District Court Judge overruled Daiichi Sankyo's objections and affirmed the magistrate judge's stay, and subsequently ordered the case to be administratively closed on November 13, 2020.

Patent infringement

On October 19, 2020, we filed a complaint in the United States District Court for the Eastern District of Texas to commence an action for infringement of our U.S. Patent No. 10,808,039, or the '039 Patent, by Daiichi Sankyo's importation into, offer for sale, sale, and use in the United States of the cancer drug ENHERTU. This action is seeking, among other remedies, a judgment that Daiichi Sankyo infringed one or more valid and enforceable claims of the '039 Patent, monetary damages and a running royalty. Daiichi Sankyo (as well as Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, LP, or AstraZeneca) subsequently filed an action on November 13, 2020 in the U.S. District Court for the District of Delaware seeking a declaratory judgment that ENHERTU does not infringe the '039 Patent. Daiichi Sankyo, Inc. and AstraZeneca also filed two Petitions for Post-Grant Review on December 23, 2020 and January 22, 2021 with the U.S. Patent Office seeking to have claims of the '039 Patent cancelled as unpatentable.

As a result of these disputes, we have incurred and will continue to incur litigation expenses. In addition, from time to time, we may become involved in other lawsuits, claims and proceedings relating to the conduct of our business, including those pertaining to the defense and enforcement of our patent or other intellectual property rights and our contractual rights. These proceedings are costly and time consuming, and they may subject us to claims which may result in liabilities or require us to take or refrain from certain actions. Additionally, successful challenges to our patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction and may allow third parties to use our proprietary technologies without a license from us or our collaborators.

15. Stockholders' equity

In October 2020, we closed the sale of the shares pursuant to the Purchase Agreement, and issued 5,000,000 shares of our common stock to Merck at a purchase price of $200 per share, for proceeds of $1.0 billion. As a result, we recorded $749.9 million in stockholders' equity on our consolidated balance sheet and recognized the $250.1 million premium attributed to the Purchase Agreement in collaboration and license agreement revenues for the year ended December 31, 2020.

In July 2019, we completed an underwritten public offering of 8,214,286 shares of our common stock at a public offering price of $70.00 per share. The offering resulted in net proceeds to us of $548.7 million, after deducting underwriting discounts, commissions, and other offering expenses. The primary use of the net proceeds was to fund our ADCETRIS and PADCEV commercialization efforts and our research and development efforts, as well as general corporate purposes, including working capital.

In February 2018, we completed an underwritten public offering of 13,269,230 shares of our common stock at a public offering price of $52.00 per share. The offering resulted in net proceeds to us of $658.2 million, after deducting underwriting discounts, commissions, and other offering expenses. The primary use of the net proceeds was to fund the acquisition of Cascadian.

At December 31, 2020, shares of common stock reserved for future issuance are as follows:

(in thousands)	
Stock options and RSUs outstanding	10,917
Shares available for future grant under the 2007 Equity Incentive Plan	8,624
Employee stock purchase plan shares available for future issuance	986
Total	20,527

16. Net income (loss) per share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares and potentially dilutive common shares outstanding during the period. Potentially dilutive common shares include incremental common shares resulting the assumed vesting of restricted stock units and the assumed exercise of outstanding stock options, calculated using the treasury stock method.

The following table shows the calculation of basic and diluted net income (loss) per share:

	Years ended December 31,		
(dollars in thousands, except per share amounts)	**2020**	**2019**	**2018**
Net income (loss)	$ 613,670	$ (158,650)	$ (222,693)
Weighted average common shares outstanding - basic	174,834	165,498	157,655
Effect of potentially dilutive common shares	7,453	—	—
Weighted average common shares outstanding - diluted	182,287	165,498	157,655
Net income (loss) per share - basic	$ 3.51	$ (0.96)	$ (1.41)
Net income (loss) per share - diluted	$ 3.37	$ (0.96)	$ (1.41)

We excluded the potential shares of common stock from the computation of diluted net income (loss) per share because their effect would have been antidilutive. The following table presents the weighted average number of shares that have been excluded for all periods presented:

	Years ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
Stock options and RSUs	356	12,774	13,439

17. Share-based compensation

2007 Equity Incentive Plan

Our 2007 Equity Incentive Plan, or the 2007 Plan, provides for the issuance of our common stock to employees, including our officers, directors and consultants and affiliates. The 2007 Plan was amended and restated in 2020 to reserve an additional 6,000,000 shares thereunder, such that an aggregate of 39,000,000 shares of our common stock were authorized for issuance as of December 31, 2020, and to extend the term of the 2007 Plan through May 2030 unless it is terminated earlier pursuant to its terms. Under the 2007 Plan, we may issue stock options (including incentive stock options and nonstatutory stock options), restricted stock, RSUs, stock appreciation rights and other similar types of awards. We have only issued options to purchase shares of common stock and RSUs under the 2007 Plan, including options and RSUs with time-based or performance-based vesting requirements. Performance-based vesting occurs upon achievement of pre-determined regulatory milestones, sales-based milestones, or market-based performance metrics.

Incentive stock options under the 2007 Plan may be granted only to our employees. The exercise price of an incentive stock option or a nonstatutory stock option may not be less than 100% of the fair market value of the common stock on the date the option is granted and the options generally have a maximum term of ten years from the date of grant. Generally, options granted to employees under the 2007 Plan vest 25% one year after the grant date and thereafter ratably each month over the following thirty-six months. Generally, RSUs granted to employees vest 25% each year beginning one year after the grant date. Option and RSU grants to non-employee members of our board of directors vest over one year. The vesting of performance-based awards generally includes vesting upon achievement of pre-determined milestones or metrics and, in some cases, vesting upon achievement of pre-determined milestones or metrics in addition to the passage of time.

The 2007 Plan provides for (i) the full acceleration of vesting of equity awards upon a change in control if the successor company does not assume, substitute or otherwise replace the equity awards upon the change in control; and (ii) the full acceleration of vesting of any equity awards if at the time of, immediately prior to or within twelve months after a change in control of the Company, the holder of such equity awards is involuntarily terminated without cause or is constructively terminated by the successor company that assumed, substituted or otherwise replaced such stock awards in connection with the change in control.

Share-based compensation expense

We recorded total share-based compensation expense of $147.2 million, $127.3 million, and $78.9 million for 2020, 2019, and 2018, respectively, including share-based compensation expense associated with our LTIPs. Share-based compensation included in research and development expenses was $72.7 million, $64.7 million, and $40.4 million for 2020, 2019, and 2018, respectively, and share-based compensation included in sales, general, and administrative expenses was $74.5 million, $62.6 million, and $38.5 million for 2020, 2019, and 2018, respectively. We recognized a tax benefit of $55.7 million related to share-based compensation expense for 2020. No tax benefit was recognized for 2019 and 2018 since there is no taxable income for those years and a valuation allowance is available to offset all potential tax benefits associated with its deferred tax assets.

Valuation assumptions

We calculate the fair value of each option award on the date of grant using the Black-Scholes option pricing model. The following weighted-average assumptions were used for the periods indicated:

	2007 Plan Years ended December 31,			Employee Stock Purchase Plan Years ended December 31,		
	2020	2019	2018	2020	2019	2018
Risk-free interest rate	0.3 %	1.5 %	2.8 %	1.3 %	2.2 %	1.7 %
Expected lives (in years)	5.7	5.6	5.6	0.5	0.5	0.5
Expected dividend	0 %	0 %	0 %	0 %	0 %	0 %
Expected volatility	44 %	44 %	42 %	47 %	43 %	36 %

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for the expected life of the award. Our computation of expected life was determined based on our historical experience with similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and expectations of future employee behavior. A forfeiture rate is estimated at the time of grant to reflect the amount of awards that are granted but are expected to be forfeited by the award holder prior to vesting. The estimated forfeiture rate applied to these amounts is derived from historical stock award forfeiture behavior. We have never paid cash dividends and do not currently intend to pay cash dividends. Our computation of expected volatility is based on the historical volatility of our stock price.

The fair value of RSUs is determined based on the closing price of our common stock on the date of grant.

Stock option activity

A summary of stock option activity is as follows:

	Shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Balance at December 31, 2019	9,560,510	$ 47.62		
Granted	871,939	$ 159.69		
Exercised	(2,258,503)	$ 35.77		
Forfeited/expired	(292,693)	$ 69.50		
Balance at December 31, 2020	7,881,253	$ 62.60	6.05	$ 887,226
Expected to vest	7,668,287	$ 61.31	5.98	$ 873,149
Options exercisable	5,236,758	$ 46.10	4.98	$ 675,746

The weighted average grant-date fair values of options granted with exercise prices equal to market were $64.66, $30.51, and $30.77 for the years ended December 31, 2020, 2019, and 2018, respectively.

The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the underlying options and the quoted price of our common stock for all options that were in-the-money at December 31, 2020. The aggregate intrinsic value of options exercised was $271.0 million during 2020, $128.4 million during 2019, and $73.3 million during 2018, determined as of the date of option exercise. As of December 31, 2020, there was approximately $52.4 million of total unrecognized compensation cost related to unvested options, as adjusted for expected forfeitures. That cost is expected to be recognized over a weighted-average period of 1.22 years. We utilize newly issued shares to satisfy option exercises.

RSU activity

A summary of RSU activity, excluding performance-based RSUs, is as follows:

	Share equivalent	Weighted-average grant date fair value
Non-vested at December 31, 2019	2,991,562	$ 68.66
Granted	816,486	$ 159.51
Vested	(1,201,084)	$ 60.90
Forfeited	(249,458)	$ 78.08
Non-vested at December 31, 2020	2,357,506	$ 105.50

The weighted average grant-date fair values of RSUs granted were $159.51, $75.58, and $70.78 for the years ended December 31, 2020, 2019, and 2018, respectively. The total fair value of RSUs that vested during 2020, 2019, and 2018 (measured on the date of vesting) was $187.1 million, $67.1 million, and $42.4 million, respectively. As of December 31, 2020, there was approximately $144.7 million of total unrecognized compensation cost related to non-vested RSU awards, as adjusted for expected forfeitures. That cost is expected to be recognized over a weighted-average period of 1.60 years. We utilize newly issued shares for RSUs that vest.

LTIP and performance-based awards activity

We have various LTIPs, which contain performance-based equity compensation, and have granted other performance-based awards to certain executive officers.

During 2020, an LTIP milestone was achieved related to FDA approval of TUKYSA based on our HER2CLIMB trial, which triggered vesting of performance-based stock awards previously granted to eligible participants, and an RSU grant to eligible participants. The vesting of the previously granted performance-based stock awards related to this LTIP is included in the table below. The second tranche grant upon milestone achievement and time-based vesting of these awards is included in the "*RSU activity*" table above.

During 2019, an LTIP milestone was achieved related to the FDA approval of PADCEV based on our EV-201 trial, which triggered a cash payment to eligible participants and an RSU grant to certain eligible participants. The vesting of grants made under that LTIP is time-based and is included in the *"RSU activity"* table above.

During 2018, an LTIP milestone was achieved related to the FDA approval of an ADCETRIS indication, which triggered a cash payment to eligible participants and commenced vesting of stock options related to that LTIP. The vesting for that LTIP is time-based and is included in the *"Stock option activity"* table above.

A summary of activity related to our performance-based RSUs and LTIPs is as follows:

	Share equivalent	Weighted-average grant date fair value
Non-vested at December 31, 2019	616,643	$ 95.05
Granted	365,070	$ 151.93
Vested	(240,667)	$ 58.14
Forfeited	(62,469)	$ 96.89
Non-vested at December 31, 2020	678,577	$ 132.80

As of December 31, 2020, the estimated unrecognized compensation cost related to all LTIPs and performance-based awards was approximately $74 million.

Employee Stock Purchase Plan

Under the current terms of the Amended and Restated 2000 Employee Stock Purchase Plan, or the Employee Stock Purchase Plan, employees can purchase shares of our common stock based on a percentage of their compensation subject to certain limits. Shares are purchased at the lower of 85 percent of the fair market value of our common stock on either the first day or the last day of each six-month offering period. Share issuance activity under the Employee Stock Purchase Plan is disclosed in our consolidated statements of stockholders' equity. In May 2019, our stockholders approved an increase of 1,000,000 shares in the number of shares of common stock authorized for issuance under the Employee Stock Purchase Plan.

18. Employee benefit plan

We have a 401(k) Plan for all of our U.S. employees. Eligible employees may contribute through payroll deductions, and we may match the employees' 401(k) contributions, at our discretion and not to exceed a prescribed annual limit. Under this matching program, we contributed $18.0 million in 2020, $11.9 million in 2019, and $7.7 million in 2018.

19. Quarterly financial data (unaudited)

The unaudited quarterly financial information should be read in conjunction with our financial statements and related notes included elsewhere in this report. We believe that the following unaudited information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period. The following table contains selected unaudited financial data for each of the indicated periods:

	Three months ended			
(dollars in thousands, except per share data)	**March 31,**	**June 30,**	**September 30,**	**December 31,**
		2020		
Total revenues	$ 234,514	$ 277,998	$ 1,061,731	$ 601,293
Net income (loss)	$ (168,402)	$ (21,190)	$ 636,167	$ 167,095
Net income (loss) per share - basic	$ (0.98)	$ (0.12)	$ 3.65	$ 0.93
Net income (loss) per share - diluted	$ (0.98)	$ (0.12)	$ 3.50	$ 0.90
		2019		
Total revenues	$ 195,199	$ 218,447	$ 213,263	$ 289,804
Net income (loss)	$ (13,329)	$ (79,238)	$ (91,913)	$ 25,830
Net income (loss) per share - basic	$ (0.08)	$ (0.49)	$ (0.55)	$ 0.15
Net income (loss) per share - diluted	$ (0.08)	$ (0.49)	$ (0.55)	$ 0.14

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

a. *Evaluation of disclosure controls and procedures.* Our Chief Executive Officer and our Chief Financial Officer have evaluated our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this annual report. Based on that evaluation, they have concluded that, as of the end of the period covered by this annual report, our disclosure controls and procedures were, in design and operation, effective at the reasonable assurance level.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met.

b. *Changes in internal control over financial reporting.* There have not been any changes in our internal control over financial reporting during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

c. *Management's Annual Report on Internal Control over Financial Reporting.* Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 2013 framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its evaluation under the framework in *Internal Control—Integrated Framework,* our management concluded that our internal control over financial reporting was effective as of December 31, 2020.

The effectiveness of our internal control over financial reporting as of December 31, 2020 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included in Item 8 in this Annual Report on Form 10-K.

Item 9B. Other Information

Amendment to Senior Executive Annual Bonus Plan

To reflect market practice among peer companies and further align pay with performance, the Compensation Committee of our Board of Directors, or the Compensation Committee, amended our Senior Executive Annual Bonus Plan, or the Plan, on February 9, 2021 to (a) provide for the use of guidelines established by the Compensation Committee to partially determine a participant's individual performance percentage for any Plan year and (b) change the relative weight of the corporate and individual performance factors for our executive officers other that the CEO from 60% corporate performance and 40% individual performance to 50% corporate performance and 50% individual performance. All other material terms of the Plan remain unchanged. Under the Plan, which is administered by the Compensation Committee, executives at the Vice President level or higher are eligible to receive an annual performance-based cash bonus for each calendar year based on the achievement of specified Company goals and, as applicable, an assessment of individual performance. The above description of the amendments to the Plan is only a brief summary of such amendments, does not purport to be complete, and is qualified in its entirety by reference to the Plan, as amended, which is filed as Exhibit 10.66 to this Annual Report on Form 10-K.

PART III

The information required by Part III is omitted from this report because we will file a definitive proxy statement within 120 days after the end of our 2020 fiscal year pursuant to Regulation 14A for our 2021 Annual Meeting of Stockholders, or the 2021 Proxy Statement, and the information to be included in the 2021 Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance

1. The information required by this Item concerning our executive officers and our directors and nominees for director, including information with respect to our audit committee and audit committee financial expert, may be found under the section entitled "Proposal No. 1—Election of Directors" appearing in the 2021 Proxy Statement. Such information is incorporated herein by reference.
2. The information required by this Item concerning our code of ethics may be found under the section entitled "Proposal No. 1—Election of Directors—Corporate Governance—Code of Conduct and Business Ethics" appearing in the 2021 Proxy Statement. Such information is incorporated herein by reference.
3. The information required by this Item concerning compliance with Section 16(a) of the Securities Exchange Act of 1934 may be found in the section entitled "Delinquent Section 16(a) Reports" appearing in the 2021 Proxy Statement. Such information is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item may be found under the sections entitled "Proposal No. 1—Election of Directors—Director Compensation" and "Compensation of Executive Officers" appearing in the 2021 Proxy Statement. Such information is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

1. The information required by this Item with respect to security ownership of certain beneficial owners and management may be found under the section entitled "Security Ownership of Certain Beneficial Owners and Management" appearing in the 2021 Proxy Statement. Such information is incorporated herein by reference.
2. The information required by this Item with respect to securities authorized for issuance under our equity compensation plans may be found under the sections entitled "Equity Compensation Plan Information" appearing in the 2021 Proxy Statement. Such information is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

1. The information required by this Item concerning related party transactions may be found under the section entitled "Certain Relationships and Related Party Transactions" appearing in the 2021 Proxy Statement. Such information is incorporated herein by reference.
2. The information required by this Item concerning director independence may be found under the section entitled "Proposal No. 1—Election of Directors—Corporate Governance—Director Independence" appearing in the 2021 Proxy Statement. Such information is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item may be found under the section entitled "Proposal No. 3—Ratification of Appointment of Independent Registered Public Accounting Firm" appearing in the 2021 Proxy Statement. Such information is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

1. The following documents are filed as part of this report:
   a. Financial Statements and Report of Independent Registered Public Accounting Firm
   b. Financial Statement Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.
   c. Exhibits are incorporated herein by reference or are filed with this report as indicated below (numbered in accordance with Item 601 of Regulation S-K).
2. Exhibits

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
2.1**	Agreement and Plan of Merger, dated January 30, 2018, among Seagen Inc. (f.k.a. Seattle Genetics, Inc.), Valley Acquisition Sub, Inc. and Cascadian Therapeutics, Inc.	8-K	000-32405	2.1	1/31/2018
3.1	Fourth Amended and Restated Certificate of Incorporation of Seagen Inc. (f.k.a. Seattle Genetics, Inc.).	10-Q	000-32405	3.1	11/7/2008
3.2	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seagen Inc. (f.k.a. Seattle Genetics, Inc.).	8-K	000-32405	3.3	5/26/2011
3.3	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seagen Inc. (f.k.a Seattle Genetics, Inc.).	8-K	000-32405	3.1	10/8/2020
3.4	Amended and Restated Bylaws of Seagen Inc. (f.k.a. Seattle Genetics, Inc.).	8-K	000-32405	3.1	1/16/2020
4.1	Description of Securities of Seagen Inc.	10-K	000-32405	4.1	2/6/2020
4.2+	Specimen Stock Certificate.	—	—	—	—
4.3	Investor Rights Agreement dated July 8, 2003 among Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and certain of its stockholders.	10-Q	000-32405	4.3	11/7/2008
4.4	Registration Rights Agreement, dated September 10, 2015, by and between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and the persons listed on Schedule A attached thereto.	8-K	000-32405	10.1	9/11/2015
10.1†	Collaboration Agreement between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Millennium Pharmaceuticals, Inc. (a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited) dated December 14, 2009.	10-K	000-32405	10.1	2/6/2020
10.2†	Collaboration and License Agreement dated January 7, 2007 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Agensys, Inc.	10-Q	000-32405	10.1	5/8/2007
10.3†	Amendment to the Collaboration and License Agreement between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Agensys, Inc. dated effective November 20, 2009.	10-K	000-32405	10.49	3/12/2010
10.4†	Joint Commercialization Agreement dated October 20, 2018 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Agensys, Inc.	10-Q	000-32405	10.1	7/16/2019
10.5†	License and Collaboration Agreement, effective October 7, 2011, between Genmab A/S and Seagen Inc. (f.k.a. Seattle Genetics, Inc.).	10-Q/A	000-32405	10.3	4/13/2018
10.6+††	Joint Commercialization Agreement dated October 19, 2020 between Genmab A/S and Seagen Inc. (f.k.a. Seattle Genetics Inc.).	—	—	—	—

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.7	License Agreement dated March 30, 1998 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Bristol-Myers Squibb Company.	10-K/A	000-32405	10.1	11/26/2010
10.8	Amendment Letter to the Bristol-Myers Squibb Company License Agreement dated July 29, 1999 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Bristol-Myers Squibb Company.	10-K/A	000-32405	10.2	11/26/2010
10.9	Amendment Agreement to the Bristol-Myers Squibb Company License Agreement dated July 26, 2000 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Bristol-Myers Squibb Company.	S-1/A	333-50266	10.7	12/5/2000
10.10†	Amendment to License Agreement to the Bristol-Myers Squibb Company License Agreement dated December 18, 2015 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Bristol-Myers Squibb Company.	10-K	000-32405	10.4	2/19/2016
10.11	License Agreement dated September 20, 1999 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and the University of Miami.	10-K/A	000-32405	10.6	11/26/2010
10.12	Amendment No. 1 to the University of Miami License Agreement dated August 4, 2000 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and the University of Miami.	10-K/A	000-32405	10.7	11/26/2010
10.13†	Letter Agreement Regarding Royalty between the University of Miami and Seagen Inc. (f.k.a. Seattle Genetics, Inc.) dated April 11, 2016.	10-Q	000-32405	10.1	7/26/2016
10.14	License Agreement between Cascadian Therapeutics, Inc. and Array BioPharma Inc. dated December 11, 2014.	10-Q	000-32405	10.1	4/26/2018
10.15	Amendment No. 1 to License Agreement dated April 23, 2020 between Cascadian Therapeutics, Inc. and Array Biopharma Inc.	10-Q	000-32405	10.5	7/31/2020
10.16+††	Commercial Supply Agreement dated December 1, 2010 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and SAFC, an operating division of Sigma-Aldrich, Inc.	—	—	—	—
10.17+††	First Amendment to Commercial Supply Agreement effective as of January 20, 2014 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and SAFC, an operating division of Sigma-Aldrich, Inc.	—	—	—	—
10.18+††	Second Amendment to Commercial Supply Agreement effective as of December 2, 2016 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and SAFC, an operating division of Sigma-Aldrich, Inc.	—	—	—	—
10.19†	Third Amendment to Commercial Supply Agreement effective as of July 1, 2019 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and SAFC, an operating division of Sigma-Aldrich, Inc.	10-Q	000-32405	10.2	10/30/2019
10.20	Development and Supply Agreement dated February 23, 2004 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Abbott Laboratories.	10-K	000-32405	10.15	2/27/2015
10.21†	First Amendment to Development and Supply Agreement dated April 17, 2008 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Abbott Laboratories, Inc.	10-Q	000-32405	10.1	8/8/2008
10.22†	Second Amendment to Development and Supply Agreement dated June 15, 2009 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Abbott Laboratories, Inc.	10-Q	000-32405	10.4	11/4/2011

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.23†	Third Amendment to Development and Supply Agreement dated November 5, 2009 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Abbott Laboratories, Inc.	10-Q	000-32405	10.5	11/4/2011
10.24†	Fourth Amendment to Development and Supply Agreement dated April 18, 2010 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Abbott Laboratories, Inc.	10-Q	000-32405	10.6	11/4/2011
10.25†	Fifth Amendment to Development and Supply Agreement dated August 24, 2010 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Abbott Laboratories, Inc.	10-Q	000-32405	10.7	11/4/2011
10.26+††	Sixth Amendment to Development and Supply Agreement dated November 18, 2010 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Abbott Laboratories, Inc.	—	—	—	—
10.27†	Seventh Amendment to Development and Supply Agreement dated January 2, 2013 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Abbott Laboratories, Inc.	10-K	000-32405	10.42	2/27/2013
10.28†	Eighth Amendment to Development and Supply Agreement dated July 7, 2015 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and AbbVie Inc. (formerly part of Abbott Laboratories, Inc.).	10-Q	000-32405	10.2	7/30/2015
10.29†	Ninth Amendment to Development and Supply Agreement, effective as of August 28, 2016 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and AbbVie Inc. (formerly part of Abbott Laboratories, Inc.).	10-Q	000-32405	10.1	10/27/2016
10.30†	Tenth Amendment to Development and Supply Agreement, effective as of December 26, 2016 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and AbbVie, Inc. (formerly part of Abbott Laboratories, Inc.).	10-K	000-32405	10.29	2/21/2017
10.31††	Eleventh Amendment to Development and Supply Agreement effective July 12, 2018 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and AbbVie Inc. (formerly part of Abbott Laboratories, Inc.).	10-K	000-32405	10.29	2/6/2020
10.32†	Twelfth Amendment to Development and Supply Agreement, effective as of April 25, 2019 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and AbbVie, Inc. (formerly part of Abbott Laboratories, Inc.).	10-Q	000-32405	10.2	7/16/2019
10.33††	Commercial Supply Agreement dated June 13, 2019 between Seagen Inc. (f.k.a Seattle Genetics, Inc.) and Esteve Quimica, S.A.	10-Q	000-32405	10.1	7/31/2020
10.34††	Amendment No. 1 to Commercial Supply Agreement dated April 14, 2020 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Esteve Quimica, S.A.	10-Q	000-32405	10.2	7/31/2020
10.35††	Commercial Supply Agreement dated February 20, 2020 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Corden Plankstadt.	10-Q	000-32405	10.3	7/31/2020
10.36††	Commercial Supply Agreement dated April 2, 2020 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Sterling Pharma Solutions Limited.	10-Q	000-32405	10.4	7/31/2020
10.37††	License and Collaboration Agreement related to ladiratuzumab vedotin dated September 13, 2020 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Merck Sharp & Dohme Corp.	10-Q	000-32405	10.1	10/30/2020
10.38††	Stock Purchase Agreement dated September 13, 2020 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Merck Sharp & Dohme Corp.	10-Q	000-32405	10.2	10/30/2020
10.39	Lease Agreement dated December 1, 2000 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and WCM 132-302, LLC.	S-1/A	333-50266	10.21	1/4/2001

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.40	First Amendment to Lease dated May 28, 2003 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and B&N 141-302, LLC.	10-Q	333-50266	10.1	8/12/2003
10.41†	Second Amendment to Lease dated July 1, 2008 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and B&N 141-302, LLC.	10-Q	000-32405	10.1	11/7/2008
10.42†	Third Amendment to Lease dated May 9, 2011 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and B&N 141-302, LLC.	10-Q	000-32405	10.2	8/5/2011
10.43†	Fourth Amendment to Lease dated October 24, 2017 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and SNH Medical Office Properties Trust, as successor in interest to B&N 141-302, LLC.	10-K	000-32405	10.12	02/15/2018
10.44†	Office Lease dated May 9, 2011 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and WCM Highlands II, LLC.	10-Q	000-32405	10.1	8/5/2011
10.45†	First Amendment to Office Lease dated October 24, 2017 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and SNH Medical Office Properties Trust, as successor in interest to WCM Highlands II, LLC.	10-K	000-32405	10.14	2/15/2018
10.46†	Purchase Agreement, dated June 16, 2017, between BMR-3450 Monte Villa Parkway, LLC and ZymoGenetics, Inc	10-Q	000-32405	10.1	11/6/2017
10.47	Assignment and Assumption of Purchase Agreement, dated July 30, 2017, between ZymoGenetics, Inc. and Seagen Inc. (f.k.a. Seattle Genetics, Inc.).	10-Q	000-32405	10.2	11/6/2017
10.48*	Form of Indemnification Agreement between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and each of its officers and directors.	S-1/A	333-50266	10.29	1/4/2001
10.49*	Amended and Restated Employment Agreement dated October 25, 2018, between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Clay Siegall.	10-Q	000-32405	10.1	10/26/2018
10.50*	Amended and Restated Employment Agreement dated October 25, 2018, between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Todd Simpson.	10-Q	000-32405	10.2	10/26/2018
10.51*	Amended and Restated Employment Agreement dated October 25, 2018, between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Vaughn Himes.	10-Q	000-32405	10.4	10/26/2018
10.52*	Amended and Restated Employment Agreement dated October 25, 2018, between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Roger Dansey.	10-Q	000-32405	10.3	10/26/2018
10.53*	Amended and Restated Employment Agreement dated October 25, 2018, between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Jean Liu.	10-Q	000-32405	10.6	10/26/2018
10.54*	Amended and Restated Employment Agreement dated April 15, 2020 between Seagen Inc. (f.k.a. Seattle Genetics, Inc.) and Charles Romp.	10-Q	000-32405	10.7	7/31/2020
10.55*	Amended and Restated 1998 Stock Option Plan, effective as of August 5, 2009.	10-Q	000-32405	10.1	8/10/2009
10.56*	2000 Directors' Stock Option Plan, as amended February 5, 2010.	10-K	000-32405	10.13	3/12/2010
10.57*	Amended and Restated 2007 Equity Incentive Plan, effective as of May 18, 2012.	10-Q	000-32405	10.1	8/8/2012
10.58*	Amended and Restated 2007 Equity Incentive Plan, effective as of May 16, 2014.	10-Q	000-32405	10.1	8/8/2014

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.59*	Amended and Restated 2007 Equity Incentive Plan, effective as of May 20, 2016.	10-Q	000-32405	10.4	7/26/2016
10.60*	Amended and Restated 2007 Equity Incentive Plan, effective as of May 18, 2018.	10-Q	000-32405	10.2	7/26/2018
10.61*	Amended and Restated 2007 Equity Incentive Plan, effective as of May 15, 2020.	10-Q	000-32405	10.6	7/31/2020
10.62*	Long Term Incentive Plan for ECHELON-1, effective as of May 9, 2016.	10-Q	000-32405	10.2	7/26/2016
10.63*	Long Term Incentive Plan for EV and TV, effective as of September 29, 2017.	10-Q	000-32405	10.4	11/6/2017
10.64*	Long Term Incentive Plan for Tucatinib, effective as of October 24, 2018.	10-Q	000-32405	10.7	10/26/2018
10.65*	Senior Executive Annual Bonus Plan, as amended February 4, 2019.	10-K	000-32405	10.69	02/07/2019
10.66+*	Senior Executive Annual Bonus Plan, as amended February 9, 2021.	—	—	—	—
10.67*	Amended and Restated 2000 Employee Stock Purchase Plan, effective as of May 20, 2019.	S-8	333-232397	99.1	6/27/2019
10.68*	Rules of the Amended and Restated 2007 Equity Incentive Plan for Restricted Stock Unit Awards Granted to French Grantees effective as of March 13, 2020.	10-Q	000-32405	10.3	4/30/2020
10.69*	Form Notice of Grant and Stock Option Agreement under the Amended and Restated 1998 Stock Option Plan.	10-K	000-32405	10.11	3/15/2005
10.70*	Form Notice of Grant and Stock Option Agreement under the 2000 Directors' Stock Option Plan.	10-K	000-32405	10.12	3/15/2005
10.71*	Form Stock Option Agreement for employees under 2007 Equity Incentive Plan.	10-K	000-32405	10.44	3/13/2009
10.72*	Form of Notice of Stock Option Grant and Stock Option Agreement for non-employee directors under the Amended and Restated 2007 Equity Incentive Plan.	10-Q	000-32405	10.4	8/5/2011
10.73*	Form of Stock Unit Grant Notice and Stock Unit Agreement for employees under the Amended and Restated 2007 Equity Incentive Plan.	8-K	000-32405	10.1	8/30/2011
10.74*	Form of Stock Unit Grant Notice and Stock Unit Agreement for non-employee directors under the Amended and Restated 2007 Equity Incentive Plan.	10-K	000-32405	10.33	2/28/2014
10.75*	Form of Stock Option Agreement for Long Term Incentive Plan for ECHELON-1 under the Amended and Restated 2007 Equity Incentive Plan.	10-Q	000-32405	10.3	7/26/2016
10.76*	Form of Notice of Stock Option Grant and Stock Option Agreement for non-employee directors under the Amended and Restated 2007 Equity Incentive Plan (approved May 18, 2018).	10-Q	000-32405	10.3	7/26/2018
10.77*	Form of Stock Unit Grant Notice and Stock Unit Agreement for non-employee directors under the Amended and Restated 2007 Equity Incentive Plan (approved May 18, 2018).	10-Q	000-32405	10.4	7/26/2018
10.78*	Form of Stock Option Agreement for Non-US Participants under the Amended and Restated 2007 Equity Incentive Plan (approved May 18, 2018).	10-Q	000-32405	10.5	7/26/2018
10.79*	Form of Stock Unit Grant Notice and Stock Unit Agreement for non-US participants under the Amended and Restated 2007 Equity Incentive Plan (approved May 18, 2018).	10-Q	000-32405	10.6	7/26/2018

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.80*	Form of Performance-Based Stock Option Agreement for employees under the Amended and Restated 2007 Equity Incentive Plan (approved May 18, 2018).	10-Q	000-32405	10.7	7/26/2018
10.81*	Form of Time-Based Stock Option Agreement for employees under the Amended and Restated 2007 Equity Incentive Plan (approved May 18, 2018).	10-Q	000-32405	10.8	7/26/2018
10.82*	Form of Performance-Based Stock Unit Grant Notice and Stock Unit Agreement for employees under the Amended and Restated 2007 Equity Incentive Plan (approved May 18, 2018).	10-Q	000-32405	10.9	7/26/2018
10.83*	Form of Time-Based Stock Unit Grant Notice and Stock Unit Agreement for employees under the Amended and Restated 2007 Equity Incentive Plan (approved May 18, 2018).	10-Q	000-32405	10.10	7/26/2018
10.84*	Form of Stock Option Agreement for U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved August 30, 2018).	10-Q	000-32405	10.8	10/26/2018
10.85*	Form of Stock Option Agreement for non-US Participants under the Amended and Restated 2007 Equity Incentive Plan (approved August 30, 2018).	10-Q	000-32405	10.9	10/26/2018
10.86*	Form of Performance-Based Stock Unit Agreement for U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved August 30, 2018).	10-Q	000-32405	10.10	10/26/2018
10.87*	Form of Stock Unit Grant Notice and Stock Unit Agreement for US Participants under the Amended and Restated 2007 Equity Incentive Plan (approved October 24, 2018).	10-Q	000-32405	10.11	10/26/2018
10.88*	Form of Stock Unit Grant Notice and Stock Unit Agreement for non-US Participants under the Amended and Restated 2007 Equity Incentive Plan (approved October 24, 2018).	10-Q	000-32405	10.12	10/26/2018
10.89*	Form of Performance-Based Stock Unit Grant Notice and Stock Unit Agreement under the Amended and Restated 2007 Equity Incentive Plan (approved August 26, 2019).	10-Q	000-32405	10.1	10/30/2019
10.90*	Form of Stock Option Agreement for U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved December 19, 2019).	10-K	000-32405	10.80	2/6/2020
10.91*	Form of Stock Option Agreement for Non-US Participants under the Amended and Restated 2007 Equity Incentive Plan (approved December 19, 2019).	10-K	000-32405	10.81	2/6/2020
10.92*	Form of Time-Based Stock Unit Grant Notice and Stock Unit Agreement for employees under the Amended and Restated 2007 Equity Incentive Plan (approved December 19, 2019).	10-K	000-32405	10.82	2/6/2020
10.93*	Form of Stock Unit Grant Notice and Stock Unit Agreement for non-US Participants under the Amended and Restated 2007 Equity Incentive Plan (approved December 19, 2019).	10-K	000-32405	10.83	2/6/2020
10.94*	Form of Performance-Based Stock Unit Agreement for U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved December 19, 2019).	10-K	000-32405	10.84	2/6/2020
10.95*	Form of Stock Unit Grant Notice for US Participants Long Term Incentive Plan for EV and TV (approved December 19, 2019).	10-K	000-32405	10.85	2/6/2020

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.96*	Form of Stock Unit Grant Notice for Non-US Participants Long Term Incentive Plan for EV and TV (approved December 19, 2019).	10-K	000-32405	10.86	2/6/2020
10.97*	Form of Performance-Based Stock Unit Notice and Stock Unit Agreement for U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved December 24, 2019).	10-K	000-32405	10.87	2/6/2020
10.98*	Form of Performance-Based Stock Unit Notice and Stock Unit Agreement for Non-U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved December 24, 2019).	10-K	000-32405	10.88	2/6/2020
10.99*	Form of Stock Option Agreement for U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved March 13, 2020).	10-Q	000-32405	10.1	4/30/2020
10.100*	Form of Stock Option Agreement for Non-U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved March 13, 2020).	10-Q	000-32405	10.2	4/30/2020
10.101*	Form of Stock Unit Grant Notice and Stock Unit Agreement for French Grantees under the Amended and Restated 2007 Equity Incentive Plan (approved March 13, 2020).	10-Q	000-32405	10.4	4/30/2020
10.102*	Form of Performance-Based Stock Unit Grant Notice and Stock Unit Agreement under the Amended and Restated 2007 Equity Incentive Plan (approved August 16, 2020).	10-Q	000-32405	10.3	10/30/2020
21.1+	Subsidiaries of Seagen Inc.	—	—	—	—
23.1+	Consent of Independent Registered Public Accounting Firm	—	—	—	—
31.1+	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).	—	—	—	—
31.2+	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).	—	—	—	—
32.1+	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.	—	—	—	—
32.2+	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.	—	—	—	—
101	The following financial statements from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Income (Loss), (iii) Consolidated Statements of Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags.	—	—	—	—
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	—	—	—	—

+	Filed herewith.
†	Pursuant to a request for confidential treatment, portions of this Exhibit have been redacted from the publicly filed document and have been furnished separately to the Securities and Exchange Commission as required by Rule 24b-2 under the Securities Exchange Act of 1934.
††	Certain confidential information contained in this Exhibit, marked by asterisks in the Exhibit, has been omitted pursuant to Item 601(b)(2) of Regulation S-K.
*	Indicates a management contract or compensatory plan or arrangement.
**	Schedules have been omitted pursuant to Item 601(b)(2) of Regulations S-K. The registrant will furnish copies of any such schedules to the Securities and Exchange Commission upon request.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

SEAGEN INC.

Date: February 11, 2021 By: /S/ CLAY B. SIEGALL
Clay B. Siegall
President & Chief Executive Officer
(Principal Executive Officer)

Date: February 11, 2021 By: /S/ TODD E. SIMPSON
Todd E. Simpson
Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ CLAY B. SIEGALL Clay B. Siegall	Director, President & CEO (Principal Executive Officer)	February 11, 2021
/S/ TODD E. SIMPSON Todd E. Simpson	Chief Financial Officer (Principal Financial and Accounting Officer)	February 11, 2021
/S/ FELIX J. BAKER Felix J. Baker	Director	February 11, 2021
/S/ DAVID W. GRYSKA David W. Gryska	Director	February 11, 2021
/S/ MARC E. LIPPMAN Marc E. Lippman	Director	February 11, 2021
/S/ TED LOVE Ted Love	Director	February 11, 2021
/S/ JOHN A. ORWIN John A. Orwin	Director	February 11, 2021
/S/ Alpna Seth Alpna Seth	Director	February 11, 2021
/S/ NANCY A. SIMONIAN Nancy A. Simonian	Director	February 11, 2021
/S/ DANIEL G. WELCH Daniel G. Welch	Director	February 11, 2021

EXHIBIT 4.2

ZQ|CERT#|COY|CLS|RGSTRY|ACCT#|TRANSTYPE|RUN#|TRANS#

COMMON STOCK

PAR VALUE $0.001

COMMON STOCK

Seagen®

Certificate Number
ZQ00000000

Shares

SEAGEN INC.

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

THIS CERTIFIES THAT

MR SAMPLE & MRS SAMPLE &
MR SAMPLE & MRS SAMPLE

SEE REVERSE FOR CERTAIN DEFINITIONS

CUSIP 81181C 10 4

is the owner of

ZERO HUNDRED THOUSAND
ZERO HUNDRED AND ZERO

THIS CERTIFICATE IS TRANSFERABLE IN CITIES DESIGNATED BY THE TRANSFER AGENT, AVAILABLE ONLINE AT www.computershare.com

FULLY-PAID AND NON-ASSESSABLE SHARES OF COMMON STOCK OF

Seagen Inc. (hereinafter called the "Company"), transferable on the books of the Company in person or by duly authorized attorney, upon surrender of this Certificate properly endorsed. This Certificate and the shares represented hereby, are issued and shall be held subject to all of the provisions of the Certificate of Incorporation, as amended, and the By-Laws, as amended, of the Company (copies of which are on file with the Company and with the Transfer Agent), to all of which each holder, by acceptance hereof, assents. This Certificate is not valid unless countersigned and registered by the Transfer Agent and Registrar.

Witness the facsimile seal of the Company and the facsimile signatures of its duly authorized officers.

President and CEO

Secretary and EVP, Leg Affairs

SEAGEN INC. CORPORATE SEAL July 15, 1997 DELAWARE

DATED DD-MMM-YYYY

COUNTERSIGNED AND REGISTERED:
COMPUTERSHARE TRUST COMPANY, N.A.
TRANSFER AGENT AND REGISTRAR,

By _____
AUTHORIZED SIGNATURE

SECURITY INSTRUCTIONS ON REVERSE

Printed by DATA BUSINESS FORMS

1234567

Seagen®

PO BOX 505006, Louisville, KY 40233-5006

MR A SAMPLE
DESIGNATION (IF ANY)
ADD 1
ADD 2
ADD 3
ADD 4

	CUSIP/IDENTIFIER	XXXXXX XX X
	Holder ID	XXXXXXXXXX
	Insurance Value	1,000,000.00
	Number of Shares	123456
	DTC	12345678 12345678901234

Certificate Numbers	Num/No.	Denom.	Total
1234567890/1234567890	1	1	1
1234567890/1234567890	2	2	2
1234567890/1234567890	3	3	3
1234567890/1234567890	4	4	4
1234567890/1234567890	5	5	5
1234567890/1234567890	6	6	6
Total Transaction			7

SEAGEN INC.

THE COMPANY WILL FURNISH WITHOUT CHARGE TO EACH STOCKHOLDER WHO SO REQUESTS, A SUMMARY OF THE POWERS, DESIGNATIONS, PREFERENCES AND RELATIVE, PARTICIPATING, OPTIONAL OR OTHER SPECIAL RIGHTS OF EACH CLASS OF STOCK OF THE COMPANY AND THE QUALIFICATIONS, LIMITATIONS OR RESTRICTIONS OF SUCH PREFERENCES AND RIGHTS, AND THE VARIATIONS IN RIGHTS, PREFERENCES AND LIMITATIONS DETERMINED FOR EACH SERIES, WHICH ARE FIXED BY THE CERTIFICATE OF INCORPORATION OF THE COMPANY, AS AMENDED, AND THE RESOLUTIONS OF THE BOARD OF DIRECTORS OF THE COMPANY, AND THE AUTHORITY OF THE BOARD OF DIRECTORS TO DETERMINE VARIATIONS FOR FUTURE SERIES. SUCH REQUEST MAY BE MADE TO THE OFFICE OF THE SECRETARY OF THE COMPANY OR TO THE TRANSFER AGENT. THE BOARD OF DIRECTORS MAY REQUIRE THE OWNER OF A LOST OR DESTROYED STOCK CERTIFICATE, OR HIS LEGAL REPRESENTATIVES, TO GIVE THE COMPANY A BOND TO INDEMNIFY IT AND ITS TRANSFER AGENTS AND REGISTRARS AGAINST ANY CLAIM THAT MAY BE MADE AGAINST THEM ON ACCOUNT OF THE ALLEGED LOSS OR DESTRUCTION OF ANY SUCH CERTIFICATE.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM	- as tenants in common	UNIF GIFT MIN ACT	- ..... (Cust) Custodian ..... (Minor) under Uniform Gifts to Minors Act ..... (State)
TEN ENT	- as tenants by the entireties		
JT TEN	- as joint tenants with right of survivorship and not as tenants in common	UNIF TRF MIN ACT	- ..... (Cust) Custodian (until age .....) ..... (Minor) under Uniform Transfers to Minors Act ..... (State)

Additional abbreviations may also be used though not in the above list.

For value received, _____ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

_____

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING POSTAL ZIP CODE, OF ASSIGNEE)

_____

_____

_____ Shares

of the common stock represented by the within Certificate, and do hereby irrevocably constitute and appoint

_____ Attorney

to transfer the said stock on the books of the within-named Company with full power of substitution in the premises.

Dated: _____ 20 _____

Signature: _____

Signature: _____

Notice: The signature to this assignment must correspond with the name as written upon the face of the certificate, in every particular, without alteration or enlargement, or any change whatever.

Signature(s) Guaranteed: Medallion Guarantee Stamp

THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (Banks, Stockbrokers, Savings and Loan Associations and Credit Unions) WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM, PURSUANT TO S.E.C. RULE 17Ad-15.

SECURITY INSTRUCTIONS

THIS IS WATERMARKED PAPER. DO NOT ACCEPT WITHOUT NOTING WATERMARK. HOLD TO LIGHT TO VERIFY WATERMARK.



The IRS requires that the named transfer agent ("we") report the cost basis of certain shares or units acquired after January 1, 2011. If your shares or units are covered by the legislation, and you requested to sell or transfer the shares or units using a specific cost basis calculation method, then we have processed as you requested. If you did not specify a cost basis calculation method, then we have defaulted to the first in, first out (FIFO) method. Please consult your tax advisor if you need additional information about cost basis.

If you do not keep in contact with the issuer or do not have any activity in your account for the time period specified by state law, your property may become subject to state unclaimed property laws and transferred to the appropriate state.

12345678

Execution Version
CONFIDENTIAL

[*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

Exhibit 10.6{*}

JOINT COMMERCIALIZATION AGREEMENT

by and between

GENMAB A/S

and

SEAGEN INC.

Dated as of October 19, 2020

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[*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

JOINT COMMERCIALIZATION AGREEMENT

THIS JOINT COMMERCIALIZATION AGREEMENT (this "Agreement") is made as of October 19, 2020 (the "Effective Date"), by and between GENMAB A/S, a Danish corporation ("Genmab"), and SEAGEN INC. (f/k/a SEATTLE GENETICS, INC.), a Delaware corporation ("SGI"). Genmab and SGI are sometimes referred to herein, individually, as a "Party" and, collectively, as the "Parties."

RECITALS

WHEREAS, Genmab and SGI entered into a License and Collaboration Agreement, dated as of October 7, 2011 (as amended from time to time, the "Collaboration Agreement"), to, among other things, collaborate on the development and commercialization of Collaboration Products (as defined in the Collaboration Agreement);

WHEREAS, the Parties and their Affiliates are jointly developing the Product (as defined below) as a Collaboration Product pursuant to the Collaboration Agreement; and

WHEREAS, upon obtaining Regulatory Approval in relevant jurisdictions, the Parties have agreed to Commercialize the Product, and have allocated to each Party the right to lead Commercialization in certain Major Markets (as defined below) and other territories, with Genmab having certain rights to co-Promote (as defined below) the Product in the United States, in each case, on the terms and subject to the conditions contained in this Agreement, which terms and conditions amend and further define the terms of the Collaboration Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

ARTICLE 1
DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings:

1.1 "Adverse Event" means any unfavorable and unintended medical occurrence in a human patient or subject who is administered the Product, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease temporally associated with the use of the Product, whether or not considered related to the Product.

1.2 "Affiliate" of a Person means any other Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Person. As used in this definition of Affiliate, the term "control" means the direct or indirect ownership of fifty percent (50%) or more of the stock having the right to vote for directors thereof or the ability to otherwise control the management thereof.

1.3 "Allowable Expenses" means, with respect to the Product for any period (or until expiration of the applicable Royalty Term as specified below), subject to the provisions of this

[*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

Agreement, the following expenses that are incurred by a Party or any of its Affiliates and are directly attributable or reasonably allocable to Commercialization activities, Medical Affairs Activities, or other relevant activities indicated below for the Product during such period with respect to the Major Markets (or, with respect to the Territory for Sections [*], and as otherwise indicated below), in each case, determined in accordance with the Collaboration Accounting Standards:

1.3.1 [*];

1.3.2 [*];

1.3.3 [*];

1.3.4 to the extent that the Parties have agreed to Manufacturing of the Product internally by a Party, itself or through an Affiliate, in each case, pursuant to Section 6.3 or Section 6.4 (as applicable), [*]; provided, that such [*] has been approved by the JFT and is included in the Global Manufacturing Plan; provided, further, that the [*];

1.3.5 [*];

1.3.6 [*];

1.3.7 [*];

1.3.8 [*];

1.3.9 [*];

1.3.10 [*];

1.3.11 [*];

1.3.12 [*]; and

1.3.13 [*];

provided, that, in each of Sections [*], such expenses shall be included within Allowable Expenses for the Product only to the extent consistent with the budget included in the applicable Approved Plan (as adjusted pursuant to this Agreement). The components of Allowable Expenses shall be calculated in accordance with the applicable definition thereof and the applicable terms of this Agreement, including the Collaboration Accounting Standards, and shall be determined and charged as provided in Section 5.1. If any cost or expense is directly attributable or reasonably allocable to more than one activity, such cost or expense shall only be counted as an Allowable Expense with respect to one of such activities. Where appropriate, the Parties, through the JFT, may agree that certain Allowable Expenses shall be determined and charged on the basis of a specified annual charge or as a percentage of Net Sales. For clarity, Allowable Expenses shall exclude (i) any expenses that are deductible in the definition of Net Sales, (ii) any Indirect Taxes that are reasonably recoverable from a Governmental Authority, (iii) any expenses treated as

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Development Costs under this Agreement or "Joint Development Costs" (as defined in the Collaboration Agreement) thereunder, and (iv) any Commercial Packaging and Labeling Costs and Manufacturing Costs for Product for the Royalty Territory.

1.4 "Applicable Law" means any law or statute, any rule or regulation issued by a Governmental Authority (including courts and Regulatory Authorities), as well as and any judicial, governmental, or administrative order, judgment, decree or ruling, in each case, as applicable to the subject matter and the Parties at issue (including the marketing, sale, and promotion of pharmaceutical products for human use), including GxP and any other rules, regulations, guidelines, or other requirements of Regulatory Authorities. For example, (a) in the United States, Applicable Law includes the FFDCA, the Public Health Service Act, the Prescription Drug Marketing Act, the Federal False Claims Act (31 U.S.C. §3729 et seq.), the Federal Health Care Program Anti-Kickback Law (42 U.S.C. §§1320a-7b), and all rules and regulations promulgated under any the foregoing, (b) in the EU, Applicable Law includes the Directive 2001/83/EC on the Community code relating to medicinal products for human use, as well as the requirements for authorization of the manufacturing or importation of such products, the related national implementing laws and regulations of individual EU member states, provisions of the national laws and industry and professionals codes in individual EU member states governing anti-bribery and anti-kickback practices, and (c) Applicable Law includes foreign equivalents of the foregoing. In addition, Applicable Law includes any law, rule, regulation, ordinance, directive, interpretation, judgment, or decision of any Governmental Authority in relation to data protection; privacy; restrictions on, or requirements in respect of, the processing of personal data of any kind, including the Regulation (EU) 2016/679 and the Health Insurance Portability and Accountability Act of 1996 (collectively, "Data Protection Laws").

1.5 "Approved Plans" means the Global Development Plan (including the Global Regulatory Plan incorporated therein), the Commercialization Plans, the Medical Affairs Plans, and the Global Manufacturing Plan, in each case, as amended from time to time, and as approved in accordance with the terms hereof, including any corresponding budgets incorporated therein, as the context requires. For clarity, references herein to the "applicable Approved Plan(s)" shall be deemed to be followed by the phrase "(if any)," and such references shall not limit the activities of SGI in the Royalty Territory if such activities are not subject to an Approved Plan.

1.6 "Approved Subcontractors" means any Third Party subcontractor (including for clarity any CSO) engaged by a Party or its Affiliate to perform activities under this Agreement that is either (i) set forth on Schedule 1.6 or (ii) approved by a Committee to perform specific obligations of the subcontracting Party under this Agreement (including under the Global Development Plan).

1.7 "Biosimilar Product" means, (a) in respect of the Product as sold in the United States, a biological product approved under the Public Health Service Act 351(k) that is highly similar to the Product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between such product and the Product in terms of safety, purity and potency; (B) in respect of the Product as sold in the EU, a biological product approved under Article 10(4) of Directive 2001/83/EC and Section 4, Part II, Annex I to such Directive based on the demonstration of the similar nature of such biological medicinal product and the Product; and (C) in respect of the Product as sold outside the United States and

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outside of the EU, a biological product approved under a similar regulatory pathway as in the United States or in the EU, if such pathway exists in such territory.

1.8 "BLA" means a Biologics License Application submitted to FDA, and all supplements and amendments that may be submitted with respect to the foregoing.

1.9 "Business Day" means a day that is not a Saturday, Sunday or a day on which banking institutions in New York, New York or Copenhagen, Denmark are required by Applicable Law to remain closed.

1.10 "Centralized Procedure" means, to the extent compulsory or permitted for the Regulatory Approval of a pharmaceutical product in Iceland, Liechtenstein, Norway, or any country in the EU, the procedure administrated by the EMA which results in a single Regulatory Approval granted by the European Commission (excluding any pricing or reimbursement approval) that is valid in all countries in the EU and, following recognition, in Iceland, Liechtenstein and Norway.

1.11 [*].

1.12 "China" means, for purposes of this Agreement, the People's Republic of China, including the Hong Kong Special Administrative Region, the Macau Special Administrative Region, and the Taiwan Region.

1.13 "Clinical Supply" means, with respect to the Product, Product intended or used for the purpose of Development or obtaining Regulatory Approval of the Product in accordance with the Global Development Plan.

1.14 "Clinical Supply Agreement" means the Tisotumab Vedotin Clinical Supply Agreement, by and between Genmab and SGI, dated as of March 15, 2018, as amended.

1.15 "Clinical Trial" means a Phase I Clinical Trial, a Phase II Clinical Trial, a Phase III Clinical Trial, a Phase III-B Study, or a Phase IV Study, as the case may be, as such terms are defined in the Collaboration Agreement. For clarity, "Clinical Trials" do not include any investigator-initiated trials or investigator-sponsored research, which shall be considered Medical Affairs Activities.

1.16 "CMC Development" means the Development activities related to the composition, manufacture, and specification of the drug substance and the drug product (including Combination Products in a single formulation) intended to assure the proper identification, quality, purity and strength of the drug, including site transfer (as conducted pursuant to and in accordance with this Agreement), test method development and stability testing, process development, process improvements (i.e., improving product robustness or manufacturing efficiencies), drug substance development, process validation, process scale-up, formulation development, delivery system development, QA and QC development.

1.17 "CMC Development Costs" means, with respect to the Product, the [*] and [*] that are incurred by a Party or any of its Affiliates on or after the Effective Date that are directly attributable or reasonably allocable to CMC Development activities undertaken directly or

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indirectly by such Party or any of its Affiliates with respect to the Product anywhere in the Territory, in each case, determined in accordance with the Collaboration Accounting Standards; provided, that the costs incurred by a Party or any of its Affiliates directly attributable or reasonably allocable to the establishment (but not the ongoing supply costs) of site(s) for the Manufacture of Product shall [*].

1.18 "Collaboration" means the collaboration between Genmab and SGI and their respective Affiliates for the Development, Manufacturing, and Commercialization of the Product pursuant to this Agreement and the Collaboration Agreement.

1.19 "Collaboration Accounting Standards" means (a) in the case of SGI, U.S. generally accepted accounting principles (GAAP), and (b) in the case of Genmab, International Financial Reporting Standards (IFRS), in each case ((a) and (b)), as consistently applied by such Party and its Affiliates.

1.20 "Combination Product" means, solely with respect to Net Sales of a Product in or reasonably allocable to the Royalty Territory, any product or therapy containing (a) as a single formulation, (i) the Product and (ii) one or more other active pharmaceutical ingredients (that are not the Product) (the "Other Components"), or (b) in a single package or container or intended and approved for marketing as a coordinated use, where the Product and the Other Component(s) are both sold by the relevant Selling Party, two or more products or therapies as components including (i) the Product, and (ii) one or more Other Components.

1.21 "Combined Major Market Plans" means the Combined Major Market Commercialization Plan, and the Combined Major Market Medical Affairs Plan, individually or collectively, as the context requires.

1.22 "Commercial Packaging and Labeling Costs" means the [*] and [*] incurred by a Party or its Affiliates that are directly attributable or reasonably allocable to Packaging and Labeling of Commercial Supply (including safety stock) conducted by or on behalf of a Party or its Affiliates and calculated in accordance with the Collaboration Accounting Standards.

1.23 "Commercial Supply" means, with respect to the Product, Product intended or used for the purpose of Commercializing (including Launching and maintaining safety stock) the Product in accordance with the Commercialization Plans (for clarity, whether such Product was Manufactured prior to, on, or after the date on which Regulatory Approval was obtained for the Product). For clarity, Clinical Supply shall not constitute Commercial Supply.

1.24 "Commercialization" means, with respect to the Product, any and all activities to establish and maintain commercial sales for the Product which are undertaken pursuant to an Approved Plan or by SGI with respect to the Royalty Territory. These activities shall include: (a) the pre-Launch marketing and other Launch and Launch preparation activities for the Product, including conducting training of Sales Representatives and any other personnel conducting Commercialization activities, (b) the marketing, Promotion, offering for sale and selling of the Product, (c) importing and exporting the Product for commercial sale, (d) Manufacturing the Product for commercial sale (except for CMC Development activities and Manufacturing performed prior to the First Regulatory Approval, including inventory build to support the first

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Launch, each of which shall be considered Development activities), (e) Sales and Distribution activities, (f) market access and health economics and outcomes research ("HEOR") activities, and (g) Hospital and Organized Customer Activities, in each case ((a) through (g)), in accordance with the applicable Approved Plan. For the avoidance of doubt, as used herein, "Commercialization" shall not include Manufacture of the Product other than Manufacturing for commercial sale following the First Regulatory Approval. When used as a verb, "Commercialize" means to engage in Commercialization.

1.25 "Commercialization Costs" means those [*] and [*] incurred by a Party or its Affiliates for Commercialization activities conducted by or on behalf of such Party or its Affiliates on or after the Effective Date that are directly attributable or reasonably allocable to Commercialization activities for the Product for the Major Markets, in each case, determined in accordance with the Collaboration Accounting Standards, but only to the extent consistent with the applicable Commercialization Plan and the budget included for such activities; provided, that where appropriate, the Parties, through the JCC, may agree that [*]. Notwithstanding the foregoing, Commercialization Costs do not include (i) [*], (ii) [*], or (iii) [*]. For clarity, Commercialization Costs shall exclude [*].

1.26 "Commercialization Plan" means the Combined Major Market Commercialization Plan, the SGI Major Market Commercialization Plan, and the Genmab Major Market Commercialization Plan, or any one or more of them, as the context requires.

1.27 "Commercially Reasonable Efforts" means (a) with respect to the efforts to be [*] by a Party to [*] other than with respect to [*], the [*] and [*] that such Party and its Affiliates would [*] to [*] a [*] under [*], and (b) with respect to the [*] of the Product under this Agreement, the level of efforts and [*] substantially [*] to those efforts and [*] by a Party and its Affiliates for [*] of [*] and at a [*] in its [*], taking into account commercially relevant factors such as [*]. Commercially Reasonable Efforts shall be determined on a [*] and [*] basis for the Product and it is anticipated that the [*] of [*] may be [*] for [*], and may [*], reflecting [*] in the [*] of the Product and the market(s) and indication(s) involved. In addition, the Parties recognize that (i) one or more market(s) or indication(s) may not represent a commercially reasonable opportunity, and therefore may not merit the allocation of any [*], and (ii) the use of Commercially Reasonable Efforts may result in ceasing Commercialization of the Product for one or more market(s) or indication(s). Further, to the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder or under the Collaboration Agreement, the impact of such performance failure will [*].

1.28 "Committee" means any of the Joint Steering Committee, the Joint Development Committee, the Joint Commercialization Committee, the Joint Medical Affairs Team, the Joint Chemistry, Manufacturing & Controls Team, or the Joint Finance Team, individually or collectively, as the context requires.

1.29 "Control" and "Controlled by" mean, with respect to any information or intellectual property right, possession by a Party or any of its Affiliates of the ability to grant the right to access or use, or to grant a license or a sublicense to, such information or intellectual property right as provided for herein or in the Collaboration Agreement without violating the terms of any agreement or other arrangement with any Third Party.

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1.30 "Core Data Sheet" means a document setting forth material information relating to safety, efficacy, indications, dosing, pharmacology and other information concerning the Product that will serve as a global reference document and, subject to Section 8.1.6(a), the basis for local labeling for use in regulatory filings and discussions with Regulatory Authorities in the Territory.

1.31 "Corporate Names" means (a) in the case of SGI, the trademarks "Seagen" and "Seattle Genetics" and the SGI corporate logo or such other names and logos as SGI may designate in writing from time to time and (b) in the case of Genmab, the trademark "Genmab" and the Genmab corporate logos or such other names and logos as Genmab may designate in writing from time to time, in each case ((a) and (b)), together with any variations and derivatives thereof.

1.32 "CSO" means a contract sales force organization.

1.33 "CVO Activities" means, with respect to the Product: (a) meetings with or presentations to (in-person or otherwise) physicians, administrators, or other professionals identified in an applicable Medical Affairs Plan that are conducted in a hospital setting or with Payors, in each case, with respect to clinical value and outcomes (CVO), and (b) clinical value and outcomes activities conducted with any hospital, health system, Payor, or any other Person.

1.34 "Detail" means a face-to-face meeting (including a virtual face-to-face meeting or group presentation, if in accordance with an applicable Approved Plan or otherwise approved by the JCC), including any such meeting conducted in a hospital or physician's office (a) with one or more physicians and other persons included in other medical professional categories identified in the applicable Commercialization Plan (such individuals, "Target Prescribers") (where, in the case of group presentations, each such physician or other person participating in a group presentation shall be counted as a separate Detail), in each case, who are permitted under the Applicable Law of the country in which they work to prescribe the applicable Product, in which such meeting key Product attributes are orally presented consistent with the terms of this Agreement. As of the Effective Date and so long as the Product has obtained Regulatory Approval for only one Disease in the United States (or other country or region in a Major Market), "Details" for purposes of this Agreement include only Primary Position Details; provided, that in connection with the Launch of the Product for a second or subsequent Disease in the United States (or other country or region in a Major Market), the Parties may determine to include Secondary Position Details as "Details" hereunder, in which case the Parties shall also review and determine the terms and conditions applicable to Primary Position Details and Secondary Position Details under this Agreement. For the avoidance of doubt, (i) a mere Sample drop without discussion with the professional about the Product shall not be considered a Detail, and (ii) any contact between a Sales Representative and a Payor (as distinguished from calls on individual HCPs who may be affiliated with a Payor in connection with their professional prescribing decisions) shall not be considered a Detail. "Detail," when used as a verb, and "Detailing" shall have correlative meanings.

1.35 "Development" means all research, non-clinical and clinical drug development activities and processes, including toxicology, pharmacology, project management and other non-clinical efforts, statistical analysis, delivery system development, the performance of Clinical Trials (including the Manufacturing of Product for use in Clinical Trials) and other activities, in each case, which are reasonably necessary to prepare submissions for, and obtain or maintain, Regulatory Approval of the Product, including lifecycle management studies and other activities.

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For the avoidance of doubt, as used herein "Development" shall include CMC Development and Manufacturing of the Product prior to the First Regulatory Approval.

1.36 "Development Costs" means, with respect to the Product, (a) [*] and [*] that are incurred by a Party or any of its Affiliates on or after the Effective Date that are directly attributable or reasonably allocable to Development activities undertaken directly or indirectly by or on behalf of such Party or any of its Affiliates with respect to the Product pursuant to the Global Development Plan anywhere in the Territory, (b) [*] and [*] incurred by a Party or any of its Affiliates with respect to [*] of the Product Manufactured prior to the First Regulatory Approval, and (c) [*], in each case ((a) through (c)), determined in accordance with the Collaboration Accounting Standards and as set forth in an applicable Approved Plan. For clarity, "Development Costs" shall include: (i) [*]; (ii) [*] and [*] incurred in connection with the planning and conduct of any Clinical Trials, including [*] therefor; (iii) [*] and [*] for research, non-clinical or clinical purposes prior to the First Regulatory Approval, and (iv) [*] in connection with Manufacturing for Clinical Supply, in each case ((i)-(iv)), determined in accordance with the Collaboration Accounting Standards and set forth in an applicable Approved Plan. Development Costs shall exclude [*] and [*] incurred in connection with the planning and conduct of investigator-initiated trials or investigator-sponsored research, which shall be considered [*].

1.37 "Disease" means a disease condition for which the Product has received Regulatory Approval to treat having a distinct histology (e.g., carcinoma) or affected organ (e.g., lung).

1.38 "Dollars" or "$" means the legal tender of the United States.

1.39 "Drug Regulatory Approval Application" or "DAA" means an application for Regulatory Approval required before commercial sale or use of the Product in a regulatory jurisdiction, including a BLA filed with the FDA, an MAA filed with EMA in the EU or the Regulatory Authority of a country in the European Economic Area, or any foreign equivalents thereof.

1.40 "EFTA" means the European Free Trade Association, as its membership may be constituted from time to time, and any successor thereto.

1.41 "EMA" means the European Medicines Agency and any successor agency(ies) thereto.

1.42 "EU" means the European Union, as its membership may be constituted from time to time, and any successor thereto.

1.43 "EU14" means [*].

1.44 "Europe" means the United Kingdom, each member state of EU and the EFTA as of the Effective Date (whether or not such countries remain member states of the EU or EFTA), and each member state of the EU and the EFTA from time to time, including the countries set forth on Schedule 1.44.

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1.45 "European Commission" means the executive body of the EU that is responsible for, among other things, granting marketing authorization for medicinal products through the Centralized Procedure.

1.46 "FDA" means the United States Food and Drug Administration, and any successor agency(ies) thereto.

1.47 "FFDCA" means the United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.).

1.48 "First Regulatory Approval" means the first Regulatory Approval of the Product in any jurisdiction in the Territory.

1.49 "FTE" means the equivalent of the work of one (1) employee full time for one (1) Year consisting of a total of (a) [*] hours per Year for employees of a Party or its Affiliate [*] and (b) [*] hours per Year for employees of a Party or its Affiliate [*] (or, in each case ((a) and (b)), such other number as may be agreed to by the Parties by mutual Party Written Consent, or by the JSC) directly related to the Commercialization of the Product, or any other activities contemplated under this Agreement. Any such employee who devotes less than [*] hours or [*] hours, as applicable, per Year (or such other number as may be agreed by the Parties by Party Written Consent or by the JSC) shall be treated as an FTE on a pro-rata basis upon the actual number of hours worked divided by [*] or [*] (or such other number as may be agreed by the Parties by mutual Party Written Consent, or by the JSC).

1.50 "FTE Costs" means, with respect to FTEs for Development, Manufacturing, Commercialization and other activities conducted under this Agreement for the Product, the cost of an FTE based on a blended global rate of [*] for all activities conducted under this Agreement for the Product. Commencing January 1, 2021 and upon January 1 of each Year thereafter, such rate will be adjusted in accordance with the [*].

1.51 "Genmab Major Market" means [*].

1.52 "Global Plan" means the Global Development Plan (including the Global Regulatory Plan incorporated therein) and the Global Manufacturing Plan, individually or collectively, as the context requires.

1.53 "Good Clinical Practice" or "GCP" shall mean any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the ethical conduct of clinical trials, including the U.S. Code of Federal Regulations ("CFR") Title 21, ICH GCP Guidelines E6(R1), current step 4 version, dated 10 June 1996, national legislation implementing European Community Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, European Community Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards to investigational medicinal products for human use, in each case as amended from time to time.

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1.54 "Good Laboratory Practice" or "GLP" shall mean any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding quality control for laboratories to ensure the consistency and reliability of results, including the CFR Title 21, national legislation implementing European Community Directive 2004/9/EC of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) and European Community Directive 2004/10/EC of 11 February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, in each case as amended from time to time.

1.55 "Good Manufacturing Practice" or "GMP" shall mean any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the quality control and manufacturing of pharmaceutical products, including the CFR Title 21, ICH GMP Guidelines Q7, current step 4 version, dated 10 November 2000, national legislation implementing European Community Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use as amended by European Community Directives 2003/94/EC, the Rules Governing Medicinal Products in the European Community, Volume 4, including annexes, in each case as amended from time to time.

1.56 "Governmental Authority" means any supranational, national, federal, state, provincial, country, city or local government or any agency, department, authority, court, or other instrumentality thereof, including any Regulatory Authority.

1.57 "GxP" means GCP, GLP or GMP or any combination thereof, as applicable.

1.58 "Healthcare Professional" or "HCP" mean any member of the medical, pharmacy or nursing professions who in the course of his or her professional activities may prescribe, administer or dispense to an end-user a medicinal product.

1.59 "Hospital and Organized Customer Activities" means, with respect to field-based efforts regarding the Product: (a) meetings with or presentations to (in-person or otherwise) physicians, administrators, or other professionals identified in an applicable Commercialization Plan, that are conducted in a hospital setting, or within Integrated Delivery Networks (IDNs), group practices, Accountable Care Organizations (ACOs) or other healthcare systems; and (b) activities conducted with respect to formularies with hospitals, health systems, or integrated health care networks; but excluding, in each case, activities involving (i) Payors, pathways, clinical value, outcomes, or other related terms, (ii) the negotiation or, unless otherwise engaged in by SGI's Sales Representatives or MSLs (at SGI's sole discretion) with respect to the Product in the United States, the implementation, in each case, of agreements with hospitals, health systems, or integrated health care networks, or (iii) distribution partners (including wholesalers, specialty distributors and pharmacies).

1.60 "ICH" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use of the World Health Organization, or any successor conference, council or organization.

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1.61 "IND" means (a) an Investigational New Drug Application, or successor application, filed with the FDA or its equivalent in any country outside the United States where a regulatory filing is required or obtained to conduct a clinical trial or (b) with respect to any country where a regulatory filing is not required or obtained to conduct a clinical trial, the first enrollment of a patient in the first trial involving the first use of the Product in humans.

1.62 "Indirect Taxes" means value added taxes, sales taxes, consumption taxes and other similar taxes.

1.63 "Information" means all technical, scientific, regulatory and other information, results, knowledge, techniques and data, in whatever form and whether or not confidential, proprietary, patented or patentable, invention disclosures, plans, processes, practices, methods, knowledge, know-how, skill, experience, ideas, concepts, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, formulae, specifications, marketing, pricing, distribution, cost, sales, and manufacturing data or descriptions. For clarity, Information does not include issued Patents or the inventions claimed thereby.

1.64 "Joint Committee Consent" means the mutual consent or agreement of both Parties' representatives on a specified Committee, Team, or Working Group (or, if no other Committee is specified, the JSC) documented in the meeting minutes of such Committee, Team, or Working Group explicitly (i.e., identified as a Joint Committee Consent) and confirmed as accurate by representatives of each Party on the applicable Committee, Team, or Working Group in accordance with Section 2.10.2 or a writing signed by at least one representative of Genmab and one representative of SGI on such Committee, Team, or Working Group; provided, that if a matter may be approved or agreed by Joint Committee Consent of a specified Committee, Team or Working Group, such approval or agreement may be given by Joint Committee Consent of any other Committee, Team, or Working Group to which such Committee, Team, or Working Group directly or indirectly reports, including, in each case, the JSC.

1.65 "Joint Steering Committee" or "JSC" means the joint steering committee established pursuant to the terms of the Collaboration Agreement to provide oversight and endorsement of the development, manufacturing and commercialization plans, and associated budgets, for Collaboration Products, and which JSC's role is expanded and modified hereunder with respect to the Development, Manufacturing, Commercialization and other activities to be conducted hereunder for the Product (provided that, for clarity, the JSC shall continue to have the roles and responsibilities as set forth under the Collaboration Agreement with respect to Licensed Products (as defined thereunder) that are not the Product).

1.66 "Launch" means, with respect to the Product and an applicable country or territory, the first commercial sale of the Product to a Third Party in such country or territory after receipt of Regulatory Approval with respect thereto (and, if the context requires, for a particular Disease for which the Product has obtained Regulatory Approval). For the avoidance of doubt, sales of the Product prior to receipt of Regulatory Approval in a country or territory, such as so-called "treatment IND sales," "named patient sales," "compassionate use sales," and the like, shall not be construed as a Launch.

1.67 "[*] Agreement" means the [*], as amended by [*], dated [*].

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1.68 "MAA" means a Marketing Authorization Application filed with the EMA pursuant to the Centralized Procedure or, under Applicable Law for Product, with the applicable Regulatory Authority of a country in the European Economic Area with respect to the decentralized procedure, mutual recognition or any national approval procedure.

1.69 "Major Markets" means the Genmab Major Market and the SGI Major Markets, individually or collectively, as the context requires. Unless otherwise indicated, references to "Major Markets" mean (a) with respect to SGI, the SGI Major Markets and (b) with respect to Genmab, (i) the Genmab Major Market and (ii) the [*].

1.70 "Manufacture" means all activities related to the manufacture and supply of the Product, including manufacturing supplies for Development or Commercialization, packaging, labeling, in-process and finished Product testing, release of Product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of Product (except for CMC Development), ongoing stability tests, storage, distribution and shipment, import and export, and regulatory activities directly related to any of the foregoing, but not including any Sales and Distribution activities. For clarity, "Manufacturing" has a correlative meaning.

1.71 "Manufacturing Costs" means, with respect to the Product and incurred on or after the Effective Date:

1.71.1 To the extent that Product is Manufactured by a Third Party CMO, the [*] incurred by the Parties that are directly attributable or reasonably allocable to such Manufacture; or

1.71.2 To the extent that Product is Manufactured by either Party or its Affiliates, the [*], as calculated in a manner consistent with a costing methodology as agreed by the JFT, including (if applicable) [*] consistent with such costing methodology agreed by the JFT, but excluding [*] not reasonably allocated to the Manufacture of Product in accordance with the cost methodology agreed by the JFT;

provided, in each case, that "Manufacturing Costs" shall not include [*], or the costs of [*].

1.72 "Manufacturing Losses" means any and all Losses incurred by one or both Parties, or their Affiliates, resulting from any claim, suit, action, or demand to the extent that such Losses are incurred, relate to, or arise out of the Manufacturing of the Product (including any such claim, suit, action, or demand related to or arising out of Product Liability, breach of Product warranty, the inaccuracy of any representation or warranty, failure to comply with Applicable Law or other breach of any provision of this Agreement, the Collaboration Agreement, or any Related Manufacturing Agreement, in each case, with respect to the Manufacturing of Product), including Losses incurred, related to, or arising under a Related Manufacturing Agreement and Losses resulting, directly or indirectly, from the acts or omissions of any Third Party CMO Manufacturing the Product on the Manufacturing Party's behalf, except in all cases to the extent such Losses (a) are incurred, relate to, or arise out of the gross negligence, recklessness or willful misconduct of the Manufacturing Party (or its Affiliate) or (b) are caused by or result directly from a material uncured breach by the Manufacturing Party (or its Affiliate) of any relevant Manufacturing

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agreement entered into by the Manufacturing Party (or its Affiliate) with any Third Party CMO that Manufactures the Product on the Manufacturing Party's behalf if such material breach is acknowledged by the Manufacturing Party in writing, results from a failure by the Manufacturing Party to make any undisputed payment when due (after giving effect to any available cure period) or is finally determined by a court or arbitrator of competent jurisdiction; provided, that the foregoing clause (b) shall not apply to any such material breach that is caused by or results directly from an act or omission of a Third Party including any other Third Party CMO that Manufactures the Product on the Manufacturing Party's behalf.

1.73 "Medical Affairs Activities" means the following activities of medical affairs personnel (including, in certain cases, Medical Science Liaisons; provided, for clarity, that not all of the following activities are performed by MSLs) related to the Product: (a) providing input and assistance with consultancy meetings, recommending investigators for Clinical Trials and providing input in the design of trials, and delivering non-promotional scientific exchanges and conducting non-promotional activities such as presenting new Clinical Trial and other scientific Information; (b) providing grants to support continuing medical education or symposia for educational needs related to the Product, including with respect to its therapeutic use; (c) development, publication, presentation and dissemination of publications relating to the Product; (d) responding to medical inquiries and providing medical information services in response to inquiries communicated via Sales Representatives or received by letter, phone call or email, in each case, from HCPs; (e) conducting so-called "named patient," "compassionate use," or similar patient assistance or access programs; (f) providing appropriate support for investigator-initiated trials and investigator-sponsored research; and (g) CVO Activities.

1.74 "Medical Affairs Costs" means those [*] and [*] that are incurred by such Party or any of its Affiliates on or after the Effective Date that are directly attributable or reasonable allocable to Medical Affairs Activities conducted by or on behalf of such Party or its Affiliates for the Product in the Major Markets in accordance with the Medical Affairs Plans. For clarity, Medical Affairs Costs shall exclude [*]. Medical Affairs costs shall exclude the [*] and [*] incurred in connection with the planning and conduct of Clinical Trials, which shall be considered [*].

1.75 "Medical Affairs Plan" means the Combined Major Market Medical Affairs Plan, the SGI Major Market Medical Affairs Plan, or the Genmab Major Market Medical Affairs Plan, or any one or more of them, as the context requires.

1.76 "Medical Science Liaisons" or "MSLs" mean those health care professionals employed or engaged by a Party or any of their Affiliates with sufficient health care experience (including at least a four-year degree and either (a) clinical, residency or fellowship experience or (b) other highly specialized training relevant to a specific therapeutic area) to engage in in-depth dialogues with physicians or other HCPs regarding medical issues associated with the Product and who are not Sales Representatives or otherwise engaged in direct selling, Promotion, or Hospital and Organized Customer Activities for the Product.

1.77 "Net Profit/Net Loss" means, with respect to the Product during any period, [*] of the Product in [*] plus [*] actually received during such period, less the sum of [*] and [*] incurred during such period. For clarity, Net Profit/Net Loss shall be determined prior to application of any

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income or other direct taxes, and if such terms are used individually, "Net Profit" shall mean a positive Net Profit/Net Loss, and "Net Loss" shall mean a negative Net Profit/Net Loss.

1.78 "Net Sales" means the gross amount invoiced in arm's-length transactions by Related Parties or, solely in the Royalty Territory, Sublicensees, from or on account of the sale of the Product by such Related Party, or only as to the Royalty Territory, a Sublicensee, to a non-Related Party (including sales to any Third Party distributor, wholesaler, or the like), less the sum of the following:

1.78.1 credits or allowances, [*], on account of price adjustments, recalls, claims, damaged goods, and rejections or returns of items previously sold (including Product returned in connection with recalls or withdrawals);

1.78.2 import taxes, export taxes, excise taxes, sales taxes, value-added taxes, consumption taxes, duties or other taxes levied on, absorbed, determined or imposed with respect to such sales (excluding income or net profit taxes or franchise taxes of any kind), in each case, to the extent (a) [*] and (b) [*];

1.78.3 insurance, customs charges, freight, shipping and other transportation costs incurred in shipping Product to such non-Related Parties, in each case, to the extent [*];

1.78.4 amounts written off by reason of uncollectible debt, to the extent consistent with the relevant Party's business practices for its other pharmaceutical products, as determined on a country-by-country basis and in accordance with the Collaboration Accounting Standards (provided, that any such amounts subsequently collected will be included in Net Sales for the period in which collected);

1.78.5 discounts (including trade, quantity and cash discounts) [*], cash and non-cash coupons, retroactive price reductions, and charge-back payments and rebates granted to any non-Related Party (including to [*]); and

1.78.6 rebates (or their equivalent), administrative fees, chargebacks and retroactive price adjustments and any other similar allowances [*] to non-Related Parties (including to [*]) which effectively reduce the selling price or gross sales of the Product.

All of the foregoing deductions from the gross amount invoiced for such sales of the Product shall be determined in accordance with Collaboration Accounting Standards. Product transferred to non-Related Parties in connection with clinical and non-clinical research and trials, Samples, "named patient sales," "compassionate use sales," or any similar program or bona fide arrangement in which a Related Party agrees to forego a normal profit margin shall give rise to Net Sales only to the extent that any Related Party invoices or receives amounts therefor in excess of the cost of goods thereof.

Product shall be considered "sold" in accordance with Collaboration Accounting Standards. Net Sales shall be determined from the books and records of the Related Party.

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It is understood that any accruals for individual items reflected in Net Sales are periodically trued up and adjusted by each Related Party consistent with its customary practices and in accordance with Collaboration Accounting Standards.

Sale or transfer of Product between any of the Related Parties, or solely in the Royalty Territory, between a Related Party and a Sublicensee, shall not result in any Net Sales, and Net Sales shall be calculated based on any subsequent sales or dispositions to a non-Related Party who is not a Sublicensee. To the extent that any Related Party, or solely in the Royalty Territory, a Sublicensee receives consideration other than or in addition to cash in consideration for the sale of the Product to a non-Related Party and such consideration does not constitute Sublicensing Revenue hereunder in the Major Markets, Net Sales shall include the fair market value of such non-cash consideration for such sale of Product. For clarity, sales by a Related Party (or solely in the Royalty Territory, by a Sublicensee) to a Third Party wholesaler or similar distributor, group purchasing organization, pharmacy benefit manager, or retail chain customer shall be considered sales to a non-Related Party and Net Sales hereunder.

Solely with respect to Net Sales occurring in the Royalty Territory, Net Sales of any Combination Product for the purpose of calculating royalties due under this Agreement shall be determined on a country-by-country basis for a given accounting period as follows: first, the Related Party (or Sublicensee, solely with respect to the Royalty Territory) that owns or otherwise controls the Combination Product shall determine the actual Net Sales of such Combination Product (using the above provisions), and then: such Net Sales amount for the Combination Product shall be multiplied by the fraction A/(A+B), where "A" is the net selling price in such country of the Product, if sold separately for the same dosage as contained in the Combination Product, and "B" is the net selling price in such country of the Other Components in the combination if sold separately for the same dosage as contained in the Combination Product. All net selling prices of the elements of such end-user product or service shall be calculated as the average net selling price of said elements during the applicable accounting period for which the Net Sales are being calculated. In the event that, in any country, no separate sale of either the Product or Other Components included in such Combination Product are made during the accounting period in which the sale was made or if the net selling price for an active ingredient cannot be determined for an accounting period, Net Sales allocable to the Product in each such country shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account, on a country-by-country basis, all relevant factors (including variations in potency, the relative contribution and value to the end user of the Product and the Other Components in the combination).

In the case where a drug delivery device is sold with or for use with the Product and included in the gross sales amount, any appropriate adjustment to Net Sales shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account all relevant factors.

1.79 "Out of Pocket Costs" means amounts paid by a Party to Third Parties for goods and services required for such Party to perform its obligations under this Agreement in accordance with any applicable Approved Plan.

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1.80 "Packaging and Labeling" means secondary packaging, labeling, and serializing (as required by Applicable Law) for the Product.

1.81 "Party Combination Study" means any Clinical Trial regarding the combination (including co-administration or other coordinated use) of (a) the Product, on the one hand, and (b) one or more other products developed and/or commercialized by or on behalf of a Party or its Affiliates (including products co-developed by a Party or its Affiliate and a Third Party). A Party Combination Study involving a product developed and/or commercialized by or on behalf of (i) SGI (including products co-developed by SGI or its Affiliate and a Third Party) is referred to herein as an "SGI Party Combination Study" and (ii) Genmab (including products co-developed by Genmab or its Affiliate and a Third Party) is referred to herein as a "Genmab Party Combination Study."

1.82 "Party Major Market Commercialization Plan" means the Genmab Major Market Commercialization Plan and the SGI Major Market Commercialization Plan, individually or collectively, as the context requires.

1.83 "Party Major Market(s)" means (a) with respect to Genmab, the Genmab Major Market, and (b) with respect to SGI, the SGI Major Markets, individually or collectively, as the context requires.

1.84 "Party Major Market Plans" means the Party Major Market Commercialization Plans and the Party Major Market Medical Affairs Plans, individually or collectively, as the context requires.

1.85 "Party Major Market Medical Affairs Plan" means the Genmab Major Market Medical Affairs Plan and the SGI Major Market Medical Affairs Plan, individually or collectively, as the context requires.

1.86 "Party Tactical Matters" means, with respect to a Party, such Party's operational or tactical-level actions and decisions with respect to matters and functions allocated or delegated to such Party pursuant to (i) a Combined Major Market Plan, (ii) a Party Major Market Plan, (iii) the US Coordination Plan, or (iv) otherwise pursuant to this Agreement with respect to the Product (including, generally, Commercialization activities, Manufacturing activities, and Medical Affairs Activities with respect to the Product) to the extent that such actions or decisions are consistent with the terms of this Agreement, the scope of such allocation or delegation, Applicable Law, and the Combined Major Market Plans, Party Major Market Plans, and US Coordination Plan, including the tactical and strategic matters described in such plans, in each case, in or for such Party's Party Major Market(s) or, subject to ARTICLE 3 and the US Coordination Plan, the United States with respect to Genmab. For clarity, (1) Party Tactical Matters exclude any responsibilities or determinations that (a) are expressly delegated to a Committee hereunder, or (b) expressly require the consent of the other Party or any Committee (including via Joint Committee Consent or Party Written Consent), and (2) "Party Tactical Matters" of Genmab in or for the United States must be consistent with the US Coordination Plan and ARTICLE 3.

1.87 "Party Written Consent" means (a) with respect to a matter to be agreed by the Parties, the mutual written agreement or consent of the Parties, in each case, executed on behalf of

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each Party by an appropriate officer or employee of such Party; and (b) with respect to a matter to be consented to or approved by a Party, the written consent or agreement of such Party executed by an appropriate officer or employee of such Party. For the avoidance of doubt, a writing evidencing Party Written Consent may be executed by (i) delivery of electronically scanned copies of original signatures delivered by electronic mail or other means of electronic transmission, or (ii) electronic signature (e.g., DocuSign®), but electronic mail without execution will not evidence Party Written Consent.

1.88 "Patent Costs" means the [*] incurred by a Party or any of its Affiliates on or after the Effective Date in connection with the Patent prosecution, maintenance, and enforcement activities conducted pursuant to Sections 14.2 and 14.3 of the Collaboration Agreement or Section 11.6 of this Agreement with respect to the Product.

1.89 "Patents" means: (a) patent applications filed in the Territory; (b) all patents, including supplemental protection certificates, that have issued or in the future issue from any of the foregoing, including utility models, design patents and certificates of invention; and (c) all divisionals, continuations, continuations-in-part, reissues, re-examination certificates, renewals, extensions or additions to any such patents and patent applications (as applicable).

1.90 "Payments to Third Parties" means any amounts paid to a Third Party (whether in the form of a royalty, up-front payment, milestone payment or otherwise) by or on behalf of a Party following the Effective Date in consideration for the grant of a license or other rights under a Patent or other intellectual property rights controlled by such Third Party that are [*] to Develop, Manufacture, or Commercialize the Product under (i) a Third Party License Agreement for one or more Major Markets entered into by a Party in accordance with this Agreement, (ii) the [*] Agreement dated [*] between [*] and [*], as amended (the "[*] Agreement"), or (iii) the [*] Agreement.

1.91 "Payors" means, pharmacy benefit managers, managed health care organizations, group purchasing organizations, large employers, government agencies and government health care programs (e.g., the U.S. Department of Veterans Affairs and Medicare in any form), and similar programs or organizations.

1.92 "Person" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, Governmental Authority, association, or other entity.

1.93 "Post-Market Surveillance" means a program in place after the receipt of Regulatory Approval to be further defined in a pharmacovigilance agreement entered into pursuant to Section 8.2 that provides for (a) monitoring the safety of a product in the market, including reporting of certain Adverse Events to Regulatory Authorities; (b) monitoring, investigating, reporting, and responding to complaints from the market, whether medical, technical, or otherwise; and (c) evaluating whether additional actions, such as a label amendment, dear doctor letter, or recall, may be necessary.

1.94 "Primary Position Detail" means, with respect to the Product, a Detail (a) in which key attributes of the Product are orally presented consistent with the terms of this Agreement and

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(b) where the Product is given primary emphasis (i.e., an emphasis that is more important than the emphasis given to any other product presented, as a first position detail).

1.95 "Product" means Tisotumab Vedotin, as referenced in the Opt-In Notice dated [*] provided by SGI to Genmab pursuant to the Collaboration Agreement, in [*].

1.96 "Product Liability" means any liability in respect of any personal injury or death (or risk of personal injury or death) arising from, relating to or otherwise in respect of the use or ingestion of, or exposure to, the Product, whether based on negligence, strict product liability or any other product liability theory, including liability predicated on any alleged or actual manufacturing, design or formulation defect or failure to warn or any breach of any express or implied warranties.

1.97 "Product Liability Losses" means any and all Losses that relate to Claims in respect of Product Liability or alleged Product Liability, in each case, anywhere in the Territory.

1.98 "Promote" means, with respect to the Product, promotional activities to be conducted by Sales Representatives of a Party in the Major Markets that are set forth in an applicable Commercialization Plan or otherwise approved by the JCC, including the following (as approved by the JCC or set forth in an applicable Commercialization Plan): (a) Detailing; (b) utilizing Promotional Materials during Details; (c) conducting display booths, displaying Promotional Materials and conducting meetings with Target Prescribers in exhibits at conferences and trade shows; (d) sponsoring advertising in journals and publications directed to Target Prescribers; (e) conducting company-directed peer-to-peer programs regarding the Product (including speakers bureau and speaker training) directed at Target Prescribers; and (f) distributing Promotional Materials to Target Prescribers using direct mail, electronic media, digital channels or other appropriate dissemination methods. For clarity, "Promotion" shall not include: (i) discussing or responding to questions regarding the Product outside of the approved Product labeling; (ii) independently maintaining a website, call center or medical information hotline for the Product; (iii) taking Product orders or otherwise selling or offering the Product for sale; (iv) Hospital and Organized Customer Activities; or (v) other marketing activities not allocated to the applicable Party under this Agreement or in an approved Commercialization Plan. "Promotion" and "Promotional" shall have the correlative meanings.

1.99 "Promotional Materials" means any advertising, marketing, or Promotional materials, any communication, educational or training tools or materials related thereto, and any similar tools or materials (but not including materials for Medical Affairs Activities), in each case, relating to the Product and in any medium.

1.100 "QA" means quality assurance activities conducted to ensure that all products are of the quality required for their intended use and that quality systems are maintained in accordance with Applicable Law.

1.101 "QC" means quality control activities conducted to check or test that specifications are met in accordance with Applicable Law.

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1.102 "Quarter" means each of the three (3) month periods ending on March 31, June 30, September 30 and December 31; provided, that the first Quarter under this Agreement shall commence on the Effective Date and the final Quarter under this Agreement shall end on the last day of the Term. "Quarterly" shall have the correlative meaning.

1.103 "Regulatory Approval" means final regulatory approval (including, where applicable, pricing approval in the event that actual commercial sales are not permitted under Applicable Law absent such approval) required to Commercialize the Product for a disease or condition in accordance with the Applicable Law of a given country or regulatory jurisdiction. In the United States, Regulatory Approval means approval of a New Drug Application, BLA or an equivalent application by the FDA. In the EU, Regulatory Approval means approval of an MAA granted by the European Commission or the Regulatory Authority of a country in the European Economic Area.

1.104 "Regulatory Authority" means the FDA, the EMA, the European Commission, the Pharmaceuticals and Medical Devices Agency of Japan, or any comparable national or territorial regulatory entity within the Territory having substantially the same functions.

1.105 "Related Manufacturing Agreement" means any supply or quality agreement entered into between the Parties or their respective Affiliates with respect to the Product.

1.106 "Related Party" means a Party and its Affiliates. For clarity, Related Party shall not include any distributors, wholesalers or the like unless such entity is an Affiliate of the applicable Party.

1.107 "Royalty Territory" means all countries and territories within the Territory except for the Major Markets.

1.108 "Sales and Distribution" means all sales and distribution activities for the Product in connection with Commercialization thereof, including customer service, handling of returns, order processing, inventory, warehousing, shipping, serialization compliance, invoicing, booking of sales, distribution and collection of receivables.

1.109 "Sales Representative" of a Party means (a) an employee of such Party or an Affiliate of such Party engaged by such Party or Affiliate to Promote the Product on behalf of such Party or such Affiliate, or (b) an Approved Subcontractor, including a CSO, engaged by such Party or Affiliate (to the extent permitted in this Agreement) to Promote the Product on behalf of such Party or such Affiliate, excluding, in each case ((a) and (b)), (i) those employees or independent contractors of either Party or such an Affiliate that are solely engaged in telemarketing, professional education or other indirect activities in support of direct selling, and (ii) Medical Science Liaisons of a Party or such Affiliate. For clarity, "Sales Representatives" do not include employees or Approved Subcontractors engaged in Hospital and Organized Customer Activities.

1.110 "Samples" means Product units which are not intended to be sold or traded, which are intended to be distributed to authorized health care professionals, and which are intended to promote the sale of such prescription drug in accordance with 21 U.S.C. §§353(c) and (d), and the applicable regulations of Title 21 of the U.S. Food and Drug Administration governing

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prescription drug samples, including 21 C.F.R. Part 203, or any successor provisions to such laws and regulations and in accordance with Applicable Law in any non-U.S. jurisdiction where Product units are to be distributed, including with respect to the EU, Article 96 of Directive 2001/83.

1.111 "Secondary Position Detail" means, with respect to the Product, a Detail in which key attributes of the Product are orally presented consistent with the terms of this Agreement, where the Product is given significant but not primary emphasis (i.e., an emphasis that is at least or more important than the emphasis given to any other product presented other than the product that is presented as a Primary Position Detail), as a second position detail.

1.112 "Selling Party" means (a) SGI or its Affiliates in the SGI Major Markets and in the Royalty Territory, and (b) Genmab or its Affiliates in the Genmab Major Market.

1.113 "SGI Major Markets" means [*].

1.114 "Sublicensing Revenue" means (a) all consideration actually received by a Party or its Affiliates from a Sublicensee for the grant of a (sub)license to such Sublicensee of rights to Develop and/or Commercialize the Product in one or more countries in a Major Market (a "Major Market Sublicense"), net of any tax or similar withholding obligations imposed by any tax or other Governmental Authority, which consideration may include upfront, milestone, royalty or other payments; provided, that (i) if a Major Market Sublicense also includes rights granted both within the Major Markets and outside of the Major Markets, only the portion of the consideration reasonably allocable to the Major Markets will be included in the calculation of Sublicensing Revenue, (ii) if a Major Market Sublicense also includes rights to any intellectual property not necessary or useful for the Development, Manufacture or Commercialization of the Product, only the portion of the consideration reasonably allocable to the Product will be included in the calculation of Sublicensing Revenue, and (iii) Sublicensing Revenue shall not include any consideration paid by such Sublicensee for bona fide goods or services provided by such Party or its Affiliates to such Sublicensee up to [*], including a commercially reasonable supply or transfer price for any Product supplied to such Sublicensee, and (b) the amount of [*]; provided, that if such distributor has been granted rights both within and outside the Major Markets, only the consideration reasonably allocable to the Major Markets will be included in the calculation of Sublicensing Revenue. For clarity, neither (a) nor (b) will include (1) [*] (provided such consideration does not [*]), or (2) [*].

1.115 "Supply Chain Management" means the planning, management and execution of internal activities and activities of Third Party suppliers that (a) provide raw materials used in the manufacture of the Product; (b) manufacture, fill and finish, package and label the Product or any component thereof; or (c) test, assist in the release of, hold or distribute the Product or any component thereof. Supply Chain Management also includes management of forecasting activities.

1.116 "Territory" means the entire world.

1.117 "Third Party" means any Person other than Genmab, SGI or an Affiliate of either of them.

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1.118 "Third Party License Agreement" means an agreement between a Party and a Third Party pursuant to which a Party in-licenses rights to Patents or other intellectual property rights controlled by such Third Party that are [*] for the Development, Manufacture or Commercialization of the Product and executed after the Effective Date in accordance with this Agreement, including Section 5.8.

1.119 "Trademark Costs" means, subject to Section 11.3, (a) the [*] (including [*]) incurred by a Party or any of its Affiliates on or after the Effective Date in connection with (i) the clearance of the Product Trademarks and the establishment of the Product Trademarks in the Major Markets and (ii) the maintenance of rights of the Product Trademarks in the Major Markets and (b) the [*] and [*] incurred by a Party or any of its Affiliates on or after the Effective Date in connection with bringing, maintaining and prosecuting any action described in Section 11.3.1, in each case, with respect to the Product and determined in accordance with the Collaboration Accounting Standards.

1.120 "United States" or "U.S." means the United States of America, including its territories and possessions as recognized by the United Nations from time to time, but in all cases including, for clarity, Puerto Rico.

1.121 "Year" means a calendar year beginning on January 1 and ending on December 31; provided, that the first Year under this Agreement shall commence on the Effective Date and the final Year under this Agreement shall end on the last day of the Term. For clarity, references in this Agreement to "year" without capitalization mean a period of twelve (12) consecutive months (365 or 366 days, as applicable).

1.122 Other Definitions; Terms Defined in Collaboration Agreement. Capitalized terms defined elsewhere in this Agreement shall have the meanings ascribed to such terms for all provisions in this Agreement. See the Index of Defined Terms for the location of such other definitions in this Agreement. Except where the context otherwise requires, capitalized terms used in this Agreement without definitions have the meanings ascribed to such terms in the Collaboration Agreement.

1.123 Relationship to Collaboration Agreement. In the event a term is defined in this Agreement and in the Collaboration Agreement, the definition in this Agreement shall govern and control with respect to the Product and all matters under this Agreement (but, for clarity, not with respect to other "Licensed Products" as such term is defined in the Collaboration Agreement, subject to ARTICLE 12, which expressly amends and restates the sections of the Collaboration Agreement referenced therein).

ARTICLE 2
GOVERNANCE

2.1 Governance Generally.

2.1.1 General. Each Party shall assign responsibilities for the various operational aspects of the Collaboration allocated to such Party pursuant to this Agreement to those

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portions of its organization that have the appropriate resources, expertise and responsibility for such functions.

2.1.2 Collaboration Committees, Teams and Working Groups. The Parties have established a JSC, a JDT and a joint commercialization team pursuant to the Collaboration Agreement. The Parties desire to establish additional committees or teams or clarify and modify the roles and responsibilities of existing committees or teams formed under the Collaboration Agreement as Committees or Teams hereunder, as provided below, to further oversee the Collaboration, to provide additional decision-making structures, and to provide a forum for discussion of matters relating to the Collaboration, in each case, with respect to the Product. Each Committee established hereunder shall have the responsibilities and authority allocated to it in this ARTICLE 2 and elsewhere in this Agreement.

2.1.3 Limitations on the Authority of Committees.

(a) General. No rights, powers, or discretion shall be delegated to or vested in a Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree by mutual Party Written Consent. The Parties hereby agree that: (a) no Committee shall have any authority with respect to the amendment, modification or waiver of compliance with any provision of this Agreement, which matters may be approved only by mutual Party Written Consent (and in the case of a waiver of compliance, by Party Written Consent of the Party entitled to waive such compliance); (b) any matter that otherwise would be within the jurisdiction of any Committee may be agreed or resolved by mutual Party Written Consent; (c) any matter that is expressly reserved to the consent or other decision-making authority of one (1) Party in this Agreement may be decided only by such Party; (d) any matter that is expressly reserved to the consent or agreement of both of the Parties may be decided only by mutual Party Written Consent; (e) all determinations made by any Committee shall be subject to and shall comply with the terms of this Agreement; (f) a Committee may not make any decision that is inconsistent with the Combined Major Market Plans unless an amendment to the applicable Combined Major Market Plan addressing such inconsistency is approved by the JSC; and (g) the Committees shall have no authority over Royalty Territory matters except as set forth in Section 2.1.3(b). Additionally, and for the avoidance of doubt, neither the JSC nor the JCC shall have any authority with respect to [*] in or for the Party Major Market(s) of either Party, or any country therein; provided, that [*] approved by the JSC. Each Party shall have the exclusive right to [*] in its Party Major Market(s) [*], in compliance with Applicable Laws (including antitrust and competition laws).

(b) Additional Royalty Territory Limitations on Committees. Notwithstanding any other provision in this Agreement or the Collaboration Agreement to the contrary, no Committee shall have any decision-making authority with respect to the Development, Manufacturing, or Commercialization of the Product solely in the Royalty Territory or outside the Royalty Territory solely to support Development or Commercialization of the Product in the Royalty Territory ("Royalty Territory Decisions"), and such Royalty Territory Decisions shall be made by SGI at its discretion; provided, that such decisions shall be consistent with [*] (including with respect to [*]) and applicable terms of this Agreement.

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2.2 Joint Steering Committee. The JSC formed under the Collaboration Agreement shall have the following responsibilities with respect to the activities to be conducted for the Product pursuant to this Agreement (provided that, for clarity, the JSC shall continue to have the roles and responsibilities as set forth under the Collaboration Agreement with respect to Licensed Products (as defined thereunder) that are not the Product):

2.2.1 overseeing the Development, Manufacturing and Commercialization of the Product, generally;

2.2.2 approving each Combined Major Market Plan (and budgets therefor, as applicable), including the global Launch plan and Launch sequence set forth in the Combined Major Market Commercialization Plan;

2.2.3 subject to Section 8.1.6(a), approving the Core Data Sheet prepared in accordance with this Agreement, which shall be submitted to it by the JDC, and amendments thereto;

2.2.4 approving final target pricing bands for the Product both globally and regionally (with relevant regions recommended by the JCC) in the Territory, in compliance with Applicable Laws (including antitrust and competition laws);

2.2.5 approving any Third Party License Agreement for one or more Major Markets in accordance with Section 5.8, approving any amendment or modification to any such Third Party License Agreement, and approving any amendment or modification to any other agreement giving rise to Payments to Third Parties treated as Allowable Expenses or Development Costs hereunder;

2.2.6 deciding whether to pursue a Commercial Sublicense for one or more countries in the Major Markets and approving any Commercial Sublicense for a Party Major Market, in each case, in accordance with and to the extent provided in Section 4.7.2;

2.2.7 approving any determination to pursue an additional or alternative source of Manufacturing for the Product or any component thereof in accordance with Section 6.3 or Section 6.4 (as applicable); provided, that the specific arrangement(s) for any such Manufacturing, including any Manufacturing by a Party, itself or through an Affiliate, are subject to the review and approval of the JCMCT as provided in Section 6.3 or Section 6.4 (as applicable);

2.2.8 approving any global allocation of Product supply proposed by the JCMCT pursuant to Section 6.7;

2.2.9 approving any recommendation from the JDC regarding whether and when to submit a DAA, including a BLA, for the Product anywhere in the Territory;

2.2.10 conducting any other activities as expressly provided for in this Agreement; and

2.2.11 resolving disputes referred to it by other Committees pursuant to this Agreement.

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2.3 Joint Development Committee.

2.3.1 Formation and Purpose. Genmab and SGI have established a "Joint Development Team" or "JDT" pursuant to the Collaboration Agreement and wish to clarify and modify its role by way of forming a "Joint Development Committee" or "JDC" hereunder for the purposes of activities related to the Product to be conducted under this Agreement as set forth herein and to assume the role of the JDT under the Collaboration Agreement solely with respect to the Product (and for clarity the JDT shall continue to have the roles and responsibilities as set forth under the Collaboration Agreement with respect to Licensed Products (defined thereunder) that are not the Product). The JDC shall consist of [*] representatives from each Party (or such other equal number of representatives from each Party as may be agreed by mutual Party Written Consent). Subject to the oversight of the JSC and subject to Sections 2.1 and 2.10, the JDC shall be principally responsible for overseeing the Development (other than CMC Development, which shall be subject to the oversight of the JCMCT) of the Product globally under the Collaboration Agreement and this Agreement, including coordination and implementation of activities between the Parties. The JDC shall operate by the procedures set forth in Section 2.10. For clarity, (a) the JDT formed under the Collaboration Agreement shall have no authority or other role with respect to the Product following the Effective Date, and (b) following the Effective Date, references in the Collaboration Agreement to the "Joint Development Team" or "JDT" solely as they relate to the Product shall refer to the JDC under this Agreement.

2.3.2 Global Development Plan. Prior to the Effective Date, the JDT adopted a Joint Development Plan and Joint Budget (each, as defined in the Collaboration Agreement) that govern the global Development, Manufacturing, and regulatory activities of the Parties with respect to the Product under the Collaboration Agreement. As promptly as practicable following the Effective Date, the JDC shall (a) update such Joint Development Plan and Joint Budget to the extent necessary to (i) align the contents thereof with this Agreement and the Approved Plans hereunder, including by incorporating the Global Regulatory Plan prepared pursuant to Section 8.1.1 and by revising the Joint Development Plan and Joint Budget to exclude Manufacturing and instead addressing Manufacturing activities in the separate Global Manufacturing Plan to be drafted and approved hereunder, and (ii) otherwise reflect the global Development activities of the Parties with respect to the Product throughout the Territory, and the corresponding budget therefor, and (b) submit such updated plan and budget to the JSC for approval (as approved by the JSC, such plan and budget, collectively, the "Global Development Plan"). Following its approval by the JSC, the Global Development Plan under this Agreement shall replace the Joint Development Plan and Joint Budget under the Collaboration Agreement for all purposes with respect to the Product under this Agreement and the Collaboration Agreement. On an annual basis, or more often as the Parties deem appropriate, the JDC shall prepare amendments to the then-current Global Development Plan for approval by the JSC. The JSC will endeavor to approve the Global Development Plan or such amendments before the end of the then-applicable Year. In the event of any inconsistency between the Global Development Plan and this Agreement, the terms of this Agreement shall prevail. For clarity, and without limiting the treatment of CMC Development Costs as Development Costs, the portions of the existing Joint Development Plan and Joint Budget relating to Manufacturing or CMC Development will not become part of the Global Development Plan pursuant to this Section 2.3.2, and will instead become part of the Global Manufacturing Plan as addressed in Section 6.2.

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2.3.3 Specific Responsibilities. Subject to the oversight of the JSC, the JDC shall be responsible for overseeing Development strategy for the Product globally under this Agreement. The JDC's responsibilities shall include the following:

(a) overseeing the preparation of annual updates and other amendments to the Global Development Plan (including the budget therefor) for approval by the JSC;

(b) subject to Section 8.1.6(a), reviewing and approving a form of Core Data Sheet and submitting a draft thereof to the JSC for its approval pursuant to Section 2.2.3;

(c) monitoring compliance with the then-current budget included in the Global Development Plan;

(d) reviewing, coordinating and monitoring the activities and progress of the Parties in implementing the Development activities contemplated by the Global Development Plan;

(e) monitoring the activities of its Working Groups, including the JMAT, JRT and CDS Working Group in accordance the terms of this Agreement (provided, for clarity, that despite the JDC's global role with respect to Development, its role with respect to the JMAT and Medical Affairs Activities will be limited to the JMAT's responsibilities under this Agreement with respect to the Major Markets);

(f) in consultation with the JRT, recommending to the JSC whether and when to submit a DAA, including a BLA, for the Product anywhere in the Territory;

(g) facilitating the flow of information with respect to the Development of the Product and coordinating such information flow with other Committees, as appropriate;

(h) overseeing the strategic planning and conduct of Clinical Trials consistent with the allocation of sponsorship and responsibility for Clinical Trials set forth in Section 4.6.2; provided, that the JDC shall coordinate with the JMAT with respect to the JDC's strategic planning and conduct of Phase III-B Studies and Phase IV Studies;

(i) making forecasts of Clinical Supply requirements for Development of the Product and reviewing the supply of Product;

(j) making recommendations for further Development of the Product, including Development for new indications that are not in the then current Global Development Plan;

(k) providing Quarterly updates on the JDC's activities to the JSC;

(l) establishing and implementing a responsibility assignment matrix consistent with this Agreement to define the roles and responsibilities between the Parties with respect to Development activities; and

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(m) performing such other functions as the JSC may request from time to time or are expressly assigned to the JDC in this Agreement.

2.4 Joint Commercialization Committee.

2.4.1 Formation and Purpose. Genmab and SGI have established a joint commercialization team pursuant to the Collaboration Agreement and wish to supersede such joint commercialization team by way of forming a "Joint Commercialization Committee" or "JCC" hereunder for the purposes of activities related to the Product to be conducted under this Agreement as set forth herein. The JCC shall consist of [*] representatives from each Party (or such other equal number of representatives from each Party as may be agreed by mutual Party Written Consent). Subject to the oversight of the JSC and subject to Sections 2.1 and 2.10, the JCC shall be principally responsible for strategic oversight for the Commercialization of the Product in the Major Markets in accordance with the Combined Major Market Commercialization Plan. The JCC shall operate by the procedures set forth in Section 2.10 and as of the Effective Date the joint commercialization team formed under the Collaboration Agreement shall disband and have no further role, rights, or responsibilities with respect to the Product.

2.4.2 Specific Responsibilities. Subject to the oversight of the JSC, the JCC shall be responsible for general oversight of Commercialization of the Product in the Major Markets, and to coordinate consistent messaging and branding across the Major Markets and, subject to Section 2.1.3, the Royalty Territory, including the following:

(a) overseeing the development of a Major Market Commercial strategy for the Product, including goals and strategy for Product positioning and messaging, and preparation of an overall brand strategy for the Product (the "Global Brand Strategy"), and at a minimum annual updates thereto, which shall be consistent with the Combined Major Market Commercialization Plan, for review and approval by the JSC;

(b) developing the core content for Promotional Materials for the Product for use in the Major Markets;

(c) overseeing the development of goals and strategy for Product pricing and reimbursement for review and approval by the JSC, including recommending to the JSC target pricing bands for the Product both globally and regionally (with relevant regions recommended by the JCC) in the Territory, in compliance with Applicable Laws (including antitrust and competition laws), and monitoring Product pricing and reimbursement in the Territory;

(d) overseeing the preparation of the Combined Major Market Commercialization Plan (including the budget therefor and the global Launch plan and Launch sequence contained therein) and annual updates and other amendments thereto, in each case, for review and approval by the JSC;

(e) monitoring compliance with the then-current budget included in the Combined Major Market Commercialization Plan;

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(f) monitoring progress under and overseeing the implementation of the Combined Major Market Commercialization Plan;

(g) reviewing the Party Major Market Commercialization Plans and annual updates thereto for consistency, and confirming whether they are consistent, with the Combined Major Market Commercialization Plan (subject to Section 2.10.5(c));

(h) reviewing and approving the US Coordination Plan relating to the Commercialization activities of the Parties in the United States incorporated into the SGI Major Market Commercialization Plan (and any updates or amendments thereto), subject to Section 3.5, including reviewing such plan and activities for consistency, and confirming that they are consistent, with the Combined Major Market Commercialization Plan, subject to Section 2.10.5(c), and monitoring compliance with the core job description and time periods for hiring Sales Representatives in the United States set forth in the US Coordination Plan;

(i) reviewing the recommendations of the independent Third Party consultant engaged pursuant to Section 3.4 with respect to the total target headcount or number of FTEs for Sales Representatives in the United States and making a determination with respect to such allocation and deployment pursuant to Section 3.4 which shall be reflected in the US Coordination Plan;

(j) reviewing and monitoring the forecasting of unit volume demand in the Territory for purposes of the Global Manufacturing Plan;

(k) reviewing and monitoring Allowable Expenses and each Party's sales and financial reports pertaining thereto in coordination with the JFT;

(l) facilitating the flow of information with respect to the Commercialization of the Product and coordinating such information flow with other Committees, as appropriate;

(m) providing Quarterly updates on Commercialization activities in the Major Markets and the JCC's activities to the JSC; and

(n) performing such other functions as the JSC may request from time to time or are expressly assigned to the JCC in this Agreement.

2.5 Joint Finance Team.

2.5.1 Formation and Purpose. Genmab and SGI hereby establish a joint finance team (the "Joint Finance Team" or "JFT"), which shall consist of [*] representatives from each Party (or such other equal number of representatives as may be agreed by mutual Party Written Consent). Subject to the oversight of the JSC and Sections 2.1 and 2.10, the JFT shall provide support to all other Committees with respect to accounting and financial matters relating to the Collaboration and the Product. The JFT shall report directly to the JSC. The JFT shall operate by the procedures set forth in Section 2.10. Additionally, as of the Effective Date, the Financial Representatives (as defined in the Collaboration Agreement) shall be superseded and

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replaced by the JFT and shall have no further role, rights, or responsibilities with respect to the Product.

2.5.2 Specific Responsibilities of the JFT. Subject to the oversight of the JSC, the JFT shall:

(a) work with the other Committees and the Parties to assist in financial, budgeting and planning matters as required, including (i) assisting in the preparation of such reports on financial matters as are requested by the JSC for the implementation of the financial aspects of the Collaboration, and (ii) assisting with the preparation of budgets for the relevant Approved Plans;

(b) agree on procedures, formats and timelines consistent with this Agreement for reporting financial data;

(c) assist in resolving differences that relate to the financial terms of this Agreement; provided, that no Party shall be required to make any material change to its internal accounting and reporting systems and standards (as opposed to generating ad hoc or additional reports which the Parties shall generate upon reasonable request);

(d) review each Party's reporting of financial data, including Net Sales and Allowable Expenses, under this Agreement;

(e) facilitate the flow of financial information with respect to the Development, Commercialization and Manufacture of the Product in the Major Markets and coordinate such information flow with other Committees, as appropriate;

(f) to the extent that the JSC and the JCMCT have approved Manufacturing by a Party, itself or through an Affiliate, in each case, pursuant to Section 6.3 or Section 6.4 (as appropriate), review and approve the amount of capital expenditures, including for plant and equipment, directly attributable or reasonably allocable to the Manufacture of Product for Commercialization by such Party or its Affiliate in the Major Markets and not accounted for in Manufacturing Costs or Commercial Packaging and Labeling Costs, as such amount is proposed by the JCMCT to be budgeted as an Allowable Expense in the Global Manufacturing Plan;

(g) review and propose any changes to the FTE rates used to calculate FTE Costs for activities conducted under this Agreement with respect to the Product for review and approval by Party Written Consent; and

(h) perform such other functions as the JSC may request from time to time or are expressly assigned to the JFT in this Agreement.

2.6 Joint Chemistry, Manufacturing & Controls Team.

2.6.1 Formation and Purpose. Genmab and SGI have established a joint chemistry, manufacturing & controls committee pursuant to the Collaboration Agreement and wish to clarify and modify its role by way of forming a "Joint Chemistry, Manufacturing & Controls Team" or "JCMCT" hereunder solely for the purposes of activities related to the Product

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to be conducted under this Agreement as set forth herein. The JCMCT shall consist of [*] representatives from each Party (or such other equal number of representatives from each Party as may be agreed by mutual Party Written Consent). Subject to the oversight of the JSC and Sections 2.1 and 2.10, the JCMCT shall oversee the Manufacture and supply of the Product globally, as well as all CMC Development activities and the global supply chain. The JCMCT shall operate by the procedures set forth in Section 2.10. For the avoidance of doubt, the specific allocation of responsibilities for Manufacturing activities between Genmab and SGI shall be made in accordance with ARTICLE 6 and as of the Effective Date the joint chemistry, manufacturing & controls committee formed under the Collaboration Agreement shall be superseded and replaced by the JCMCT and shall disband and have no further role, rights, or responsibilities with respect to the Product.

2.6.2 Specific Responsibilities of the Joint Chemistry, Manufacturing & Controls Team. Subject to the oversight of the JSC, Sections 2.1 and 2.10, and ARTICLE 6, the JCMCT shall, in particular and in addition to its other responsibilities set forth in this Agreement:

(a) oversee CMC Development activities and clinical and commercial Manufacturing of the Product;

(b) with input from the JDC, JCC, and JFT, as necessary, oversee the preparation of an annual Global Manufacturing Plan (and budget therefor) for the Product, including, to the extent that the JSC and the JCMCT have approved Manufacturing by a Party, itself or through an Affiliate in accordance with Section 6.3 or Section 6.4 (as applicable), and proposing the amount of capital expenditures, including for plant and equipment, directly attributable or reasonably allocable to the Manufacture of Product for Commercialization in the Major Markets by such Party or its Affiliate and not accounted for in Manufacturing Costs or Commercial Packaging and Labeling Costs to be budgeted as an Allowable Expense, for review and approval by the JFT pursuant to Section 2.5.2(f);

(c) monitor compliance with the budget under the Global Manufacturing Plan for Manufacturing Commercial Supply, Manufacturing Clinical Supply and for CMC Development;

(d) review and monitor Manufacturing Costs, CMC Development Costs, Commercial Packaging and Labeling Costs, and any other Manufacturing-related costs proposed for inclusion in Allowable Expenses or Development Costs;

(e) oversee the preparation of submissions to Regulatory Authorities related to chemistry, manufacturing and controls ("CMC") matters;

(f) oversee the preparation for and reviewing responses to regulatory inspections related to CMC aspects related to the Product, including the development of policies and procedures therefor;

(g) oversee and monitor QA- and QC-related matters concerning the Product, including QA- and QC-related matters with respect to Post-Market Surveillance;

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(h) review and monitor Manufacturing processes and specifications for the Product, and to the extent agreed by the JCMCT, develop and implement continuous improvement or similar programs to promote Manufacturing quality and efficiency;

(i) oversee Supply Chain Management, develop a global supply and risk mitigation strategy for the Product, and consider whether additional or alternative sourcing is necessary;

(j) facilitate the flow of information with respect to the Manufacture of the Product and coordinate such information flow with other Committees, as appropriate;

(k) provide Quarterly updates on the JCMCT's activities to the JSC; and

(l) perform such other functions as the JSC may request from time to time or are expressly assigned to the JCMCT in this Agreement.

2.7 Joint Medical Affairs Team.

2.7.1 Formation and Purpose. Genmab and SGI hereby agree to establish a joint medical affairs team solely for the purposes of activities related to the Product to be conducted under this Agreement as set forth herein (the "Joint Medical Affairs Team" or "JMAT") within [*] days after the Effective Date. The JMAT shall constitute a Working Group of the JDC and shall consist of [*] representatives from each Party (or such other equal number of representatives from each Party as may be agreed by mutual Party Written Consent). The JMAT shall report to the JDC; provided, however, that notwithstanding anything contained herein to the contrary, the Combined Major Market Medical Affairs Plan prepared by the JMAT and its corresponding budget, and any amendments thereto which shall be proposed by the JMAT, shall be submitted directly to the JSC for its review and approval pursuant to Section 2.2.2. Subject to the oversight of the JDC, Sections 2.1 and 2.10, and ARTICLE 7, the JMAT shall be responsible for strategic oversight of the Medical Affairs Activities in the Major Markets with respect to the Product under this Agreement, including coordination of such activities between the Parties. The JMAT shall operate by the procedures set forth in Section 2.10. For the avoidance of doubt, the specific allocation of responsibilities for Medical Affairs Activities between Genmab and SGI shall be made in accordance with ARTICLE 7.

2.7.2 Specific Responsibilities of the Joint Medical Affairs Team. Subject to Sections 2.1 and 2.10, and ARTICLE 7, the JMAT shall, in particular and in addition to its other responsibilities set forth in this Agreement:

(a) oversee the preparation of the Combined Major Market Medical Affairs Plan (including the budget therefor) and annual updates and other amendments thereto;

(b) monitor compliance with the then-current budget included in the Combined Major Market Medical Affairs Plan;

(c) monitor progress under, and oversee the implementation of, the Combined Major Market Medical Affairs Plan, including with respect to named

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patient/compassionate use programs, grants, investigator-initiated and investigator-sponsored research for the Product, in each case, included in such plan;

(d) review the Party Major Market Medical Affairs Plans and annual updates thereto for consistency with the Combined Major Market Medical Affairs Plan (subject to Section 2.10.5(c));

(e) review and approve the US Coordination Plan relating to the Medical Affairs Activities of the Parties in the United States incorporated into the SGI Major Market Medical Affairs Plan (and any updates or amendments thereto), subject to Section 3.5, and reviewing such plan and activities for consistency, and confirming that they are consistent, with the Combined Major Market Medical Affairs Plan, subject to Section 2.10.5(c), and monitoring compliance with the core job description and time periods for hiring MSLs in the United States set forth in the US Coordination Plan;

(f) review the recommendations of the independent Third Party consultant engaged pursuant to Section 3.4 with respect to the total target headcount or number of FTEs for MSLs for the Product, allocation and deployment thereof in the United States and making a determination with respect to such allocation and deployment pursuant to Section 3.4 which shall be reflected in the US Coordination Plan;

(g) review, discuss and coordinate the Parties' global scientific presentation and publication strategy relating to the Product in accordance with this Agreement and the Publication Charter;

(h) in coordination with the JDC prior to obtaining Regulatory Approval in a given jurisdiction and other Committees, as appropriate, develop a strategy for investigator-initiated trials and investigator-sponsored research in the Major Markets;

(i) coordinate with the JDC with respect to the JDC's planning and conduct of Phase III-B Studies and Phase IV Studies;

(j) facilitate the flow of information with respect to the Medical Affairs Activities for the Product in the Major Markets and coordinate the flow of such information with other Committees, as appropriate;

(k) monitor Allowable Expenses for Medical Affairs Activities in coordination with the JFT;

(l) provide Quarterly updates on Medical Affairs Activities in the Major Markets and the JMAT's activities to the JDC; and

(m) perform such other functions as the JDC or JSC may request from time to time or are expressly assigned to the JMAT in this Agreement.

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2.8 Joint Regulatory Team.

2.8.1 Formation and Purpose. Genmab and SGI have established a joint regulatory team pursuant to the Collaboration Agreement and wish to clarify and modify its role by way of forming a "Joint Regulatory Team" or "JRT" hereunder solely for the purposes of activities related to the Product to be conducted under this Agreement as set forth herein. The Joint Regulatory Team shall constitute a Working Group of the JDC and consist of [*] representatives from each Party (or such other equal number of representatives from each Party as may be agreed by mutual Party Written Consent). The JRT shall report to the JDC. Subject to the oversight of the JDC, Sections 2.1 and 2.10, and ARTICLE 8, the JRT shall be principally responsible for strategic oversight and coordination of global regulatory activities with respect to the Product, except that the JCMCT will oversee CMC-related regulatory activities in coordination with the JRT, as applicable. For clarity, while the JDC will retain overall oversight of global regulatory activities with respect to the Product, the JRT will have the responsibilities for global regulatory activities with respect to the Product described in this Section 2.8. The JRT shall operate by the procedures set forth in Section 2.10 and as of the Effective Date the joint regulatory team formed under the Collaboration Agreement shall be superseded and replaced by the JRT and shall disband and have no further role, rights, or responsibilities with respect to the Product.

2.8.2 Specific Responsibilities of the Joint Regulatory Team. Subject to the oversight of the JDC, Sections 2.1 and 2.10, and ARTICLE 8, the JRT shall, in particular and in addition to its other responsibilities set forth in this Agreement:

(a) discuss, prepare and submit to the JDC on an annual basis a Global Regulatory Plan or the regulatory portions of the Global Development Plan as contemplated by Section 8.1.1 (which shall include a high-level summary prepared by SGI with respect to the Royalty Territory) describing the Parties' global regulatory strategy for the Product in the Territory which shall be incorporated into the Global Development Plan by the JDC and submitted to the JSC for approval;

(b) monitor progress under, and oversee the implementation of, the Global Regulatory Plan;

(c) review the Party Regulatory Plans and annual updates thereto for consistency with the Global Regulatory Plan as provided in Section 8.1.1;

(d) consult with the JDC to develop the JDC's recommendations to the JSC regarding whether and when to submit a DAA, including a BLA, for the Product anywhere in the Territory;

(e) subject to Section 8.1.6(a), in conjunction with the CDS Working Group, review the draft Core Data Sheet prepared by SGI and any amendments to the Core Data Sheet proposed by SGI, and agree on a proposed form of Core Data Sheet for submission to the JDC and ultimately review and approval by the JSC;

(f) provide Quarterly updates on the JRT's activities to the JDC; and

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(g) perform such other functions as the JDC may request from time to time or are expressly assigned to the JRT in this Agreement.

2.9 CDS Working Group. Genmab and SGI hereby agree to establish a Core Data Sheet working group (the "CDS Working Group") within [*] days after the Effective Date. The CDS Working Group shall constitute a Working Group of the JDC and consist of [*] representatives from each Party (or such other equal number of representatives from each Party as may be agreed by mutual Party Written Consent). The CDS Working Group shall report to the JDC. Subject to Section 8.1.6(a), the CDS Working Group shall, in conjunction with the JRT, review the draft Core Data Sheet prepared by SGI and any amendments to the Core Data Sheet proposed by SGI, and agree on a proposed form of Core Data Sheet for submission to the JDC for review and approval, and ultimately submission by the JDC to the JSC for review and approval.

2.10 General Committee, Team, and Working Group Membership and Procedures.

2.10.1 Teams and Working Groups. From time to time, the JSC and the Committees may establish and delegate duties to working groups, teams, sub-teams, sub-committees or similar bodies formed under such Committee (each, a "Team" or a "Working Group") on an "as-needed" basis to oversee particular projects or activities, which delegations shall be reflected in the minutes of the meetings of the applicable Committee. Such Teams or Working Groups may be established on an ad hoc basis for purposes of a specific project, for the life of the Product or on such other basis as the establishing Committee may determine, and shall be constituted and shall operate as the establishing Committee may determine; provided, that (a) decision-making shall be [*], with each Party's representatives on the applicable Team or Working Group collectively having [*] on all matters brought before the Team or Working Group and (b) a Team or Working Group may not make any decision that is inconsistent with the Global Plans or Combined Major Market Plans unless an amendment to the applicable Global Plan or Combined Major Market Plan addressing such inconsistency is approved in accordance with this Agreement. Each Team and Working Group and their respective activities shall be subject to the oversight, review and approval of, and, shall report to, the Committee that established such Team or Working Group. In no event shall the authority of the Team or Working Group exceed that specified for the relevant Committee in this ARTICLE 2. Teams or Working Groups shall meet as needed to accomplish the objectives for which they were formed, and shall keep minutes of such meetings in accordance with Section 2.10.2. A Committee that forms a Team or Working Group shall have the ability to dissolve such Team or Working Group; provided, that (a) the JFT, JMAT and JCMCT are all to be deemed Teams established under the JSC for that purpose, and (b) the JRT is to be deemed a Team established under the JDC for that purpose.

2.10.2 Committee Membership. Each of Genmab and SGI shall designate representatives with appropriate expertise to serve as members of each Committee, Team, or Working Group and each representative may serve on more than one Committee, Team or Working Group as appropriate in view of the individual's expertise. Each Party may replace its Committee, Team, or Working Group representatives at any time upon written notice to the other Party. Each member of each Committee, Team, or Working Group shall be made aware of the Parties' obligation of compliance with all Applicable Laws, including antitrust and competition laws, as set forth in Section 9.1.5. Each Committee, Team, or Working Group shall have a

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chairperson; provided, that the chairperson for each Committee shall be staggered such that the chairperson for each Committee, Team, or Working Group shall alternate from one Party to the other Party annually. The initial chairperson of each of the Committees or Teams formed under this Agreement shall be a representative of a Party designated by the JSC. Each Party may change its designated chairpersons from time to time upon written notice to the other Party. The chairperson of each Committee, Team, or Working Group (or their respective designees), with assistance and guidance from the Alliance Managers, shall be responsible for calling meetings and preparing and circulating an agenda in advance of each meeting of such Committee, Team, or Working Group; provided, that the Committee, Team, or Working Group chairpersons shall call a meeting of the applicable Committee promptly upon the written request of either Party to convene such a meeting. The then-current chairperson of each Committee, Team, or Working Group shall appoint its Alliance Manager to attend the meeting and record the minutes of the meeting in writing; provided, that such minutes shall be based on contemporaneous notes reflecting the substance of such meeting shared and mutually agreed between such Alliance Manager and the Alliance Manager or other representative of the other Party immediately following or as soon as practicable following such meeting. Notwithstanding the foregoing, such minutes shall be circulated to the other Party's Alliance Manager no later than [*] following the meeting for review, comment and approval of the other Party. If no comments are received within [*] of the receipt of the minutes by a Party, unless otherwise agreed, they shall be deemed to be approved by such Party. Furthermore, if the Parties are unable to reach agreement on the minutes within [*] of the applicable meeting, the sections of the minutes which have been agreed between the Parties by that date shall be deemed approved and, in addition, each Party shall record in the same document its own version of those sections of the minutes on which the Parties were not able to agree.

2.10.3 Meetings. Each Committee, Team, or Working Group shall hold meetings at such times as it elects to do so, but in no event shall such meetings of each Committee be held less frequently than [*] unless otherwise agreed by the JSC (provided, that a Committee, Team, or Working Group shall meet upon the reasonable request of a Party or any member thereof to discuss a matter within its purview). Each Committee shall meet alternately at a location designated by Genmab and a location designated by SGI, or at such other locations, including by audio or video teleconference as permitted below, as the Parties may agree. Except under exigent circumstances requiring Committee input, each Party will notify the other Party of proposed agenda items and provide appropriate information at least [*] in advance of each meeting of the JSC and at least [*] in advance of each meeting of any other Committee. The Alliance Managers (or their respective designees) shall attend meetings of each Committee as non-voting observers. Additional employees, consultants, and representatives of a Party may attend meetings of each Committee as non-voting observers; provided, that (a) any such employees, consultants or representatives are (i) under obligations to comply with all Applicable Laws (including antitrust and competition laws as set forth in Section 9.1.5), (ii) under obligations of confidentiality and non-use applicable to the Confidential Information of each Party that are at least as stringent as those set forth in this Agreement and (iii) obligated to assign to the Parties any inventions made by any of them arising out of their participation in such meetings, and (b) with respect to non-employees of a Party, such attendance is subject to consent of the other Party. Each Party shall be responsible for all of its own expenses of participating on the Committees. Meetings of any Committee may be held by audio or video teleconference with the consent of each Party; provided, that (A) each Committee formed or initially organized under this Agreement as of the Effective Date will endeavor to meet by videoconference in lieu of audio-only teleconference to the extent

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reasonably practicable, and (B) the Parties will discuss in good faith holding at least [*] meeting per year of each such Committee in person at a location alternately designated by Genmab and SGI (subject to travel restrictions, public health guidance and Applicable Law). No Committee shall take any action or make any decision except at a meeting properly called, and no action taken at any meeting of a Committee shall be effective unless a representative of each Party is present or participating. Subject to each Party's regulatory compliance policies and Applicable Law, the JMAT and the JCC may meet as a single body to discuss and exchange information if mutually agreed by such Committees or reasonably requested by either Party.

2.10.4 Charter. Each Committee shall adopt a charter setting forth such additional rules and procedures as may be necessary for the performance of its responsibilities; provided, that such rules and procedures must be consistent with the terms of this Agreement. In the event of any conflict or inconsistency between any such Committee charter and the terms and conditions of this Agreement, the terms and conditions of this Agreement shall govern and control.

2.10.5 Decision-Making.

(a) Decisions. Decisions of each Committee, Team and Working Group shall be made by Joint Committee Consent, with each Party's representatives on a Committee, Team or Working Group collectively having [*] on all matters brought before it; provided, that (i) Party Tactical Matters are subject to Section 2.10.6, (ii) any dispute between the Parties regarding the US Coordination Plan, including any decision or failure to reach consensus by a Committee, Team or Working Group regarding the US Coordination Plan shall be resolved in accordance with Section 3.5.2 (provided that any dispute regarding whether the US Coordination Plan is consistent with the Combined Major Market Plans shall be resolved pursuant to Section 2.10.5(c)), and (iii) each Committee's authority is limited as set forth in Section 2.1.3.

(b) Committee Dispute Resolution in General. Working Groups, Teams and Committees should make every effort to resolve disputes promptly without escalation. Any disagreement between the representatives of Genmab and SGI on any Working Group, Committee or Team as to matters within such Working Group, Team or Committee's purview (including, for clarity, whether a matter constitutes a Party Tactical Matter) shall, at the election of either Party, be referred for resolution as follows: (i) disputes between the representatives of Genmab and SGI on any Working Group or Team shall be referred for resolution to the applicable Committee to which it reports, and (ii) disputes between the representatives of Genmab and SGI on any Committee (including a dispute referred from a Working Group or Team to the applicable Committee that is not resolved within [*] Business Days after such referral) shall be referred to the JSC for resolution. The Alliance Managers shall assist the relevant Committee in attempts to amicably resolve any such dispute in connection with the decision-making and dispute-resolution processes outlined in this Section 2.10.5 generally.

(c) Combined Major Market Plan Disputes. Notwithstanding Section 2.10.5(b) above, the following principles shall apply to a Committee responsible under this Agreement for reviewing a Party Major Market Plan (including, if applicable, the US Coordination Plan incorporated therein pursuant to Section 2.4.2(h), Section 2.7.2(e) or Section 3.5.1) for consistency with an applicable Combined Major Market Plan. Such reviewing Committee may consult with the relevant market-level and/or functional leads of each Party in

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connection with its review. If there is a dispute on such Committee regarding whether or not such Party Major Market Plan is consistent with the applicable Combined Major Market Plan and such dispute is not resolved within [*] Business Days, the question of such Party Major Market Plan's consistency with the applicable Combined Major Market Plan shall be referred to the JSC for resolution. If the JSC determines that such Party Major Market Plan is consistent with the applicable Combined Major Market Plan (either as such Party Major Market Plan was presented to the JSC, or with any amendments requested by the JSC in order to make such Party Major Market Plan consistent with the applicable Combined Major Market Plan), the JSC's determination shall be binding on the Parties without further review by the Committee originally charged with reviewing such Party Major Market Plan; provided, that any subsequent amendment or update to such Party Major Market Plan shall be reviewed by such Committee for consistency, and confirmed by the Committee to be consistent, with the applicable Combined Major Market Plan (subject again to this Section 2.10.5(c)). If the JSC cannot agree on whether a Party Major Market Plan is consistent with the applicable Combined Major Market Plan or determines that a Party Major Market Plan is not consistent with the applicable Combined Major Market Plan (and the JSC cannot agree on amendments to such Party Major Market Plan that would make it consistent with the applicable Combined Major Market Plan), in each case, within [*] Business Days of its referral to the JSC, such matter shall be referred to [*] for resolution. If [*] are unable to resolve the matter within [*] Business Days after the matter is first referred to them, then [*]. Any portion of the proposed Party Major Market Plan and corresponding budget that is not in dispute (i.e., not specifically subject to such dispute resolution process) will go into effect immediately notwithstanding such ongoing dispute resolution proceedings, and the portions of the most recently approved Party Major Market Plan and budget that correspond to the matters in dispute will be deemed to carry forward and apply to subsequent budget periods to the extent practicable, mutatis mutandis, until the resolution of such dispute, so as to minimize any disruption to the ongoing Development, Manufacturing, or Commercialization of the Product.

(d) Disputes at the JSC. Except for matters subject to Section 2.10.5(c), any dispute or disagreement arising on the JSC as to matters within the JSC's purview or that are submitted to the JSC by another Committee in accordance with this Agreement for attempted resolution that are unable to be resolved within [*] Business Days after the matter is first submitted to the JSC (or such other time period as may be agreed by the JSC) shall be referred to [*] for resolution. If the [*] are unable to resolve a matter within [*] days after the matter is first referred to them, then [*].

2.10.6 Party Tactical Matters. Notwithstanding Section 2.10.5 or anything to the contrary contained in this Agreement or the Collaboration Agreement, but subject to this Section 2.10.6, Party Tactical Matters (a) with respect to the SGI Major Markets other than the United States shall be Party Tactical Matters of SGI and as such within the sole decision-making authority of SGI, (b) with respect to the Genmab Major Market shall be Party Tactical Matters of Genmab and as such within the sole decision-making authority of Genmab, (c) with respect to activities allocated to Genmab under the US Coordination Plan shall be Party Tactical Matters of Genmab and as such, subject to ARTICLE 3, within the sole decision-making authority of Genmab, and (d) except as provided in clause (c) above, with respect to all other activities in or for the United States shall be Party Tactical Matters of SGI and as such within the sole decision-making authority of SGI; provided, that (and so long as) all such decisions shall be consistent with the terms of this Agreement, the scope of such allocation or delegation of responsibility for the

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Major Markets, Applicable Law, the Global Plans, the Combined Major Market Plans, and the relevant Party Major Market Plans (including the US Coordination Plan). Subject to Section 2.1.3 and this Section 2.10.6, Party Tactical Matters may be discussed by applicable Committee(s); provided, that a Party's decision with respect to its Party Tactical Matters (in the case of Genmab's activities in the United States, subject to the US Coordination Plan and ARTICLE 3) shall be final, and not subject to Committee decision-making or the dispute resolution procedures contained in this Section 2.10, ARTICLE 16, or elsewhere in this Agreement or the Collaboration Agreement.

2.10.7 Exception for Urgent or Serious Safety Matters. Notwithstanding anything to the contrary in this Section 2.10, in the event of any dispute or disagreement arising on any Committee or otherwise between the Parties regarding an urgent or serious safety matter (including patient risk management and risk minimization events and safety issues that impact Product labeling) that a Party believes in good faith requires a determination on an expedited basis, then either Party may require that the dispute be referred to their respective safety officers (or similar functions) for the purpose of seeking to resolve the dispute on an expedited basis (including within, to the extent applicable, any timeframes required by Applicable Law). Such safety officers may designate an appropriate advisory group of each Party, as well as obtain any Third Party advice on their decision (with any such Third Parties to be bound by obligations of confidentiality at least as restrictive as those contained in this Agreement). If such safety officers are not able to resolve the dispute on any action referred to them [*], within [*] Business Days of such referral and at least [*] Business Days in advance of any timeframes required by Applicable Law, [*] with respect to such matter to the extent consistent with Applicable Law (including for clarity requirements of a Regulatory Authority).

2.11 Alliance Managers.

2.11.1 Each of the Parties shall appoint one (1) representative who possesses a general understanding of biopharmaceutical Development, regulatory matters, Medical Affairs Activities, and Commercialization to act as its Alliance Manager in connection with the Collaboration (each, an "Alliance Manager"). The role of the Alliance Managers is to act as a single point of contact between the Parties to enable a successful Collaboration. The Alliance Managers (or their respective designees) may attend all meetings of any Committee, Team or Working Group and support the chairpersons of each Committee in the discharge of their responsibilities. An Alliance Manager (or designee) may bring any matter to the attention of any Committee, Team or Working Group if such Alliance Manager (or designee) reasonably believes that such matter warrants such attention. In addition, Alliance Managers (or their respective designees) may attend any joint meetings of the Parties regarding the Collaboration that are held independent of the Committees, Teams, or Working Groups.

2.11.2 Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. Each Party and its Alliance Manager may designate a substitute to temporarily perform the functions of Alliance Manager upon written notice to the other Party's Alliance Manager.

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2.12 Budgetary Matters.

2.12.1 Prior to each regular meeting of the JSC and not less than Quarterly, the JFT shall prepare an analysis of actual Allowable Expenses and Development Costs incurred and Net Profit/Net Loss recorded by the Parties through the most recent date practicable in relation to the amounts budgeted therefor in the applicable Approved Plans. The JFT shall determine the frequency and timing of projections for each category described in the previous sentence, with the goal of accommodating each Party's corporate financial processes. Each Party shall provide to the JFT in a timely manner such information as the JFT may reasonably request for use in the preparation of such analysis; provided, that such information is in the possession of such Party. Each Party shall promptly notify the JFT in the event it anticipates any cost overrun with respect to Development Costs and/or Allowable Expenses in a given functional area (e.g., Medical Affairs Activities or Commercialization activities) incurred or to be incurred by it with respect to any Year or any material variation in Net Sales amounts from the amounts projected in the Approved Plans. The JFT shall promptly review any actual or projected cost overrun that is reported to it and thereafter shall, in conjunction with the JSC, consider and recommend to the JSC for approval either (a) an appropriate variance to the applicable Approved Plans, which variance, if approved by the JSC, shall be considered a part of the Approved Plans or (b) such other amendments to the Approved Plans as may be necessary or appropriate to bring the operation of the Collaboration within the budgetary guidelines set forth in the Approved Plans; provided, that the JSC shall approve such variance unless such cost overrun exceeds the lower of [*] of the budgeted amount for a given functional area (e.g., Medical Affairs Activities or Commercialization activities) in a given Year, in which case the JSC may elect not to approve the variance or amend the applicable Approved Plan. If the JSC does not approve such variance or does not amend the applicable Approved Plan, [*], and such expense shall [*].

2.12.2 In order to facilitate planning and budgetary control by the relevant Committees and the Parties, each Party shall provide to the JFT and to the other Party not later than [*] after the end of each Quarter a projection (representing a good faith estimate) of the Allowable Expenses it expects to incur and the Net Sales it expects to record in its Major Markets and the Development Costs it expects to incur, in each case, in such Quarter.

ARTICLE 3
GENMAB CO-PROMOTION

3.1 Genmab Right to Co-Promote and Provide Medical Affairs Efforts.

3.1.1 Genmab U.S. Co-Promotion Rights. Notwithstanding anything to the contrary contained in this Agreement, but without prejudice to the status of the United States as an SGI Major Market, the Parties agree that Genmab will be SGI's co-promotion and medical affairs partner with respect to the Product in the United States on the terms and subject to the conditions contained in this ARTICLE 3. In particular, Genmab will provide with respect to the Product in the United States:

(a) the Sales Representatives as described in Section 1 of Schedule 3.1 to Promote the Product in the United States;

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(b) the MSLs described in Section 2 of Schedule 3.1 to engage in in-depth dialogues with physicians or other HCPs regarding medical issues associated with the Product; and

(c) FTEs for [*] management of such Sales Representatives and MSLs as described in Section 3 of Schedule 3.1 (collectively, "Genmab Managers");

in each case ((a) through (c)), as more fully described in this ARTICLE 3.

The Sales Representatives contemplated by Section 3.1.1 are referred to herein as "Genmab Sales Representatives," the MSLs contemplated by Section 3.1.1 are referred to herein as "Genmab MSLs," and the Genmab Sales Representatives, Genmab MSLs and Genmab Managers are referred to herein, collectively, as "Genmab US Personnel."

3.1.2 Genmab US Activities. All activities undertaken by the Genmab US Personnel with respect to the Product in or for the United States (collectively, the "Genmab US Activities") will be subject to and taken in accordance with the SGI Major Market Commercialization Plan, the SGI Major Market Medical Affairs Plan, the US Coordination Plan, and this ARTICLE 3.

3.1.3 SGI Rights. The rights and responsibilities of SGI with respect to Commercialization and Medical Affairs Activities for the Product in the United States will remain the same as elsewhere in the SGI Major Markets except as explicitly stated in this ARTICLE 3. In particular, subject only to the consistency of SGI's Party Major Market Plans with the applicable Combined Major Market Plans, the US Coordination Plan, and the terms and conditions of this Agreement, SGI will have authority and responsibility for:

(a) subject to [*], [*] for the Product in the United States [*] in accordance with this Agreement;

(b) subject to consistency with [*] the terms of this Agreement [*] with respect to the Product in the United States; and

(c) subject to [*] and consistency with [*] the terms of this Agreement, [*] with respect to the Product in the United States.

3.1.4 Limitations on Genmab Activities. Except to the extent expressly provided in the US Coordination Plan or otherwise with the prior written authorization of SGI, Genmab shall have no independent right or authority to, and shall not, through the Genmab US Personnel or otherwise, with respect to the Product in or for the United States:

(a) conduct any form of [*] or [*]; or

(b) conduct any [*] or other activities [*].

3.1.5 Genmab Activities. To the extent expressly provided in the US Coordination Plan or otherwise with the prior written authorization of SGI, Genmab may, through the Genmab US Personnel, with respect to the Product in or for the United States:

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(a) participate in and provide input on [*], or similar activity, whether [*] or [*], and Genmab may [*] in accordance with this Agreement and [*];

(b) participate in and provide input as to [*], including [*] with respect to the Product for the United States;

(c) participate in and provide input on and support for [*], or similar activity, [*] with respect to the Product for the United States;

(d) provide [*] or [*] regarding the Product;

(e) authorize, support or facilitate [*], or otherwise [*];

(f) participate in and provide input on and support for [*] with respect to the Product;

(g) retain, engage, or otherwise contract with [*]; or

(h) [*] or [*], in each case, to the extent that [*] have been approved by SGI.

The Parties agree that each Party's role in the co-Promotion of and Medical Affairs Activities for the Product in the United States will be conducted only as set forth in [*]. Notwithstanding the foregoing, [*] (provided that such decisions are consistent with the US Coordination Plan and this ARTICLE 3), but, for the avoidance of doubt, [*] in the United States shall not include decisions [*] as set forth in the [*] or this ARTICLE 3.

3.1.6 Genmab Collaboration. Following the Effective Date and so long as the Product has obtained Regulatory Approval for only one Disease in the United States, the Parties will each designate a [*] to interact for non-field coordination. Each Party will [*] for its [*]. In connection with obtaining Regulatory Approval in the United States for a second or subsequent Diseases, the Parties will discuss and consider in good faith whether to add further personnel to serve as, and/or to [*] for, [*]. For clarity, the [*] shall not be assigned to or perform services at any facility of [*] or its [*] and each Party acknowledges and agrees that the [*] and [*] are not, are not intended to be, and will not be treated as, employees of [*] for any purpose.

3.2 Co-Promotion in the United States. The Parties agree that the activities of their Sales Representatives and MSLs for the Product in the United States for each Disease for which Regulatory Approval is obtained will be conducted consistent with the following:

3.2.1 activities to be conducted by each Party's Sales Representatives and MSLs will be allocated in a manner consistent with Section 3.4;

3.2.2 at a minimum, [*] related to the Launch of the Product for a Disease in the United States will be jointly attended by the Parties' personnel performing such co-Promotion activities and Medical Affairs Activities;

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3.2.3 the Parties will share information related to the activities of their Sales Representatives and MSLs for the Product in the United States, including to the extent applicable in relation to [*], on a timely and recurring basis and in any event, upon the reasonable request of the JCC or JMAT, as applicable, or the other Party; and

3.2.4 as of the Effective Date and so long as the Product has obtained Regulatory Approval for only one Disease in the United States, each Party will provide an equal number of Sales Representatives in the United States who will be dedicated solely to the Product and such Disease, and consistent with Section 1.34, "Details" for purposes of this Agreement will include only Primary Position Details; provided, that in connection with the Launch of the Product for a second or subsequent Disease in the United States, the Parties may agree to amend the Agreement to include Secondary Position Details as "Details" hereunder, in which case the Parties shall also review and determine the terms and conditions applicable to Primary Position Details and Secondary Position Details under this Agreement and, if applicable, Sales Representative FTEs, including for example methods to assess performance against key performance indicators.

3.3 Performance of US Activities. Each Party will hire and maintain Sales Representatives and MSLs of sufficient number and expertise to permit such Party to fully perform the activities allocated to it for the United States under this ARTICLE 3, in each case, in accordance with the core job descriptions and time periods set forth in the US Coordination Plan. Compliance with such criteria will be monitored by the JCC with respect to Sales Representatives pursuant to Section 2.4.2(h) and by the JMAT with respect to MSLs pursuant to Section 2.7.2(e). If either Party fails at any time to meet the applicable hiring goals or maintain the agreed level of Sales Representatives and MSLs as set forth in the US Coordination Plan (including a failure to satisfy the criteria set forth in the applicable core job description), it shall, at its own cost and expense, provide a plan to the JCC and/or JMAT, respectively, designed to remedy such failure expeditiously, and then take such actions as are reasonably necessary to cure any such failure as promptly as practicable, such as by offering hiring bonuses or other incentives, [*], as applicable. If any such failure to meet its applicable hiring goals or maintain the agreed level of Sales Representatives and MSLs as set forth in the US Coordination Plan, as applicable, continues without cure for (a) more than [*] days or (b) more than [*] days during the [*] prior to the anticipated first Launch of the Product in the United States, the other Party may, in its sole discretion, elect to assume responsibility for and provide Sales Representatives or MSLs to perform activities allocated to the first Party under the US Coordination Plan, to the extent of such failure. If the first Party disputes whether it failed to satisfy the hiring goals or cure any such failure, it may submit such failure to the JSC for resolution; provided, that the other Party shall be permitted to provide such Sales Representatives and MSLs and perform such activities pending the resolution of any such dispute. If the first Party cures any failure to satisfy such hiring goals or to maintain the agreed level of Sales Representatives and MSLs after the time periods described in clauses (a) or (b) and such cure is confirmed by the JCC or JMAT, as applicable, [*], and the Parties shall [*]. Without limiting the foregoing, the Parties acting through the JCC or JMAT, as applicable, shall mutually consider the [*] set forth in the Combined Major Market Commercialization Plan and Combined Major Market Medical Affairs Plan, as applicable, and agree on [*].

3.4 Size and Deployment of Sales Representatives and MSLs in the United States. Except as otherwise mutually agreed by the Parties through the JSC, the Parties shall engage a

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mutually agreed independent Third Party consultant with requisite expertise regarding the commercialization of pharmaceutical products and therapies (such as [*]) to: (a) recommend options for [*] for Sales Representatives and MSLs for the Product in the United States and (b) propose options for Sales Representative and MSL FTEs [*] within the United States for the Product in the United States with the goal of equitably sharing responsibilities between the Sales Representatives and MSLs of both Parties consistent with each Party's respective fifty percent (50%) share of the total Sales Representative and MSL FTEs for the Product in the United States as set forth on Schedule 3.1, in each case of (a) and (b), for the Parties to [*]. The Parties shall engage in such process both initially in anticipation of first Regulatory Approval of the Product in the United States, and additionally in anticipation of each subsequent Regulatory Approval of the Product in the United States for additional Disease(s). The recommendations of such independent Third Party consultant with respect to the [*] of Sales Representative and MSL FTEs in the United States shall be taken [*], which shall make determinations with respect to such [*] Sales Representatives and MSLs pursuant to Section 2.4.2(i) and Section 2.7.2(f), respectively. The recommendations of such independent Third Party consultant with respect to [*] of Sales Representative and MSL FTEs in the United States shall be taken [*] by [*], which shall make a determination with respect to such Sales Representative and MSL FTEs in the United States in its [*] in advance of the anticipated Regulatory Approval of the Product in the United States for a given Disease; provided, that such [*] of Sales Representative and MSL FTEs selected by [*] shall fall within the [*] for Sales Representative and MSL FTEs agreed by [*] or by [*], as applicable.

3.5 US Coordination Plan.

3.5.1 In General. SGI, in collaboration with Genmab as provided in this Section 3.5.1, will prepare a plan describing (a) the sales and marketing plans for the Product in the United States, (b) the activities to be performed by the Parties' Sales Representatives and MSLs with respect to the Product in or for the United States, (c) a mechanism to ensure that the Parties hire and maintain Sales Representatives and MSLs of sufficient number and expertise to permit the Parties to fully perform the activities allocated to them under this ARTICLE 3, including core job descriptions (e.g., responsibilities, core competencies, experience and other qualifications), a methodology for demonstrating proficiency, time points at which progress against hiring goals will be measured, (d) procedures for monitoring Sales Representatives and MSLs in the United States, and (e) training programs for such Sales Representatives and MSLs (the "US Coordination Plan"). SGI will provide an initial draft of the US Coordination Plan to Genmab for its review and comment for a period of not less than [*] Business Days. Genmab's representatives on the JCC and JMAT, respectively, will work with SGI's representatives on such Committees to develop the US Coordination Plan relating to the Commercialization activities (for the JCC) and Medical Affairs Activities (for the JMAT) of the Parties under this ARTICLE 3 with respect to the Product in or for the United States, respectively, and the US Coordination Plan will be subject to JCC and JMAT approval pursuant to Sections 2.4.2(h) and 2.7.2(e), respectively. SGI shall update the initial US Coordination Plan on an annual basis (or more frequently as directed by the JCC). For each such update, Genmab shall have not less than [*] Business Days to review and comment thereon. Such updated US Coordination Plan will be subject to JCC and JMAT approval pursuant to Sections 2.4.2(h) and 2.7.2(e), respectively. The US Coordination Plan will be incorporated into the SGI Major Market Commercialization Plan and the SGI Major Market Medical Affairs Plan, as applicable. Accordingly, the US Coordination Plan will be consistent with the Combined Major Market

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Commercialization Plan and the Combined Major Market Medical Affairs Plan, as applicable, and the strategic matters described therein, and will be reviewed for consistency, and confirmed to be consistent, with the Combined Major Market Plans by the JCC and JMAT, respectively. For clarity, the US Coordination Plan will include a stand-alone budget, and the activities contemplated by the US Coordination Plan will be included in the applicable budgets under the SGI Major Market Commercialization Plan and SGI Major Market Medical Affairs Plan, as applicable.

3.5.2 US Coordination Plan Disputes. Notwithstanding SGI's role as the Selling Party in the United States and that the United States is a SGI Major Market country, it is agreed and acknowledged that the US Coordination Plan (and any material updates or amendments thereto) shall be subject to review and approval of the JCC and JMAT pursuant to Sections 2.4.2(h) and 2.7.2(e), respectively. However, in the event of any dispute between the Parties regarding the US Coordination Plan that is not a Party Tactical Matter (which is to be resolved pursuant to Section 2.10.6) or a dispute regarding whether the US Coordination Plan is consistent with an applicable Combined Major Market Plan (which is to be resolved pursuant to Section 2.10.5(c)), including any failure despite good faith efforts by the Parties' representatives on the JCC or JMAT to approve or otherwise reach consensus on any aspect of the US Coordination Plan after the US Coordination Plan is first presented to such Committee, the Parties (through their representatives on the relevant Committee) will endeavor in good faith to amicably resolve the dispute as promptly as practicable, but if such dispute is not resolved within [*] Business Days of the US Coordination Plan first being referred to the JCC or JMAT, as applicable, then such matter (which shall be limited to only that portion of the US Coordination Plan in dispute) will be submitted for resolution to the JSC. Upon request by either Party made during such [*] Business Day period, the Parties' respective Chief Executive Officers (or their delegates mandated with equivalent decision-making authority) shall during such [*] Business Day period discuss any such matter that is material to either Party or the Collaboration. If the JSC does not resolve such matter within [*] Business Days after the matter is first referred to it, then SGI shall have final decision-making authority over the matter(s) in dispute and the contents of the US Coordination Plan, subject only to consistency of the US Coordination Plan with the Combined Major Market Commercialization Plan and/or the Combined Major Market Medical Affairs Plan, as applicable, as required under Section 3.5.1. For clarity, SGI's final decision-making authority under this Section 3.5.2 shall be final and is not be subject to dispute resolution under Section 2.10.5 or ARTICLE 16, except to the extent Section 2.10.5(c) applies with respect to consistency of the US Commercialization Plan with the Combined Major Market Commercialization Plan and/or the Combined Major Market Medical Affairs Plan, as applicable. During the pendency of any dispute regarding the US Coordination Plan, all of the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder in good faith and, to the extent practicable, maintain the status quo and operate under the last approved US Coordination Plan (if applicable) until resolution of the relevant dispute or approval of the US Coordination Plan.

3.6 Compliance and Training.

3.6.1 In General. All Genmab US Activities as well as Promotional activities and Medical Affairs Activities conducted by SGI in the United States shall be undertaken in

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accordance with (a) all Applicable Laws and (b) notwithstanding anything contained herein or the Collaboration Agreement to the contrary, the compliance practices, policies and procedures of SGI (as to Genmab, to the extent such practices, policies and procedures are communicated to Genmab or the Genmab US Personnel); provided, however, that neither Party or its personnel will be required to undertake any obligation in connection with such activities to the extent that such Party reasonably believes in good faith that such activities violate or are reasonably likely to violate Applicable Law or such Party's written policies regarding the promotion of pharmaceutical products (and any such deviations made by a Party shall not be considered a material breach of this Agreement). For the avoidance of doubt, the preceding sentence shall not entitle [*]. Genmab agrees to use Commercially Reasonable Efforts to make available to SGI, upon SGI's reasonable request, such information regarding the [*] in or for the United States as may be provided in the US Coordination Plan or otherwise reasonably required in order for SGI to Commercialize the Product in the United States and monitor compliance with this Agreement and Applicable Law.

3.6.2 Training. All Genmab US Personnel and SGI personnel performing Promotion and Medical Affairs Activities for the Product in the United States must complete, prior to performing such activities and on an ongoing basis, the applicable mandatory training program(s) developed by SGI and described in the US Coordination Plan. Each Party may conduct such other non-mandatory training for its personnel performing such activities as it determines at its sole cost and expense (i.e., the expenses thereof shall not be included in Allowable Expenses); provided, that Genmab shall permit a representative of SGI to attend such other non-mandatory Product-related training (such attendance of such SGI representative to be at SGI's sole cost and expense, and not included in Allowable Expenses) and SGI shall permit a representative of Genmab to attend such other non-mandatory Product-related training (such attendance of such Genmab representative to be at Genmab's sole cost and expense, and not included in Allowable Expenses).

3.6.3 Promotional Materials. In connection with the Genmab US Activities, unless otherwise agreed by the Parties by mutual Party Written Consent, Genmab [*]; provided, that such Promotional Materials shall in all cases be consistent with (a) the core content for Promotional Materials prepared by the JCC and approved by the JSC pursuant to Section 2.4.2(b), (b) the Approved Plans, and (c) the Product labeling approved by the FDA. Without limiting the foregoing, Genmab will have a reasonable opportunity (not less than [*] Business Days) through the Committees or otherwise to [*] (and [*] shall in good faith consider any comments provided by [*]) before such Promotional Materials are finally approved by [*].

3.7 Miscellaneous.

3.7.1 Genmab Diligence. Genmab shall use Commercially Reasonable Efforts to conduct the Genmab US Activities allocated to Genmab US Personnel in the US Coordination Plan, SGI Major Market Commercialization Plan, SGI Major Market Medical Affairs Plan, or otherwise under this Agreement.

3.7.2 Invoicing and Booking of Sales. [*] may not accept [*], and if [*] receives any [*] in or for the United States, it shall refer such [*] for acceptance or rejection.

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3.7.3 No Sublicensing or Subcontracting. [*] may not [*] any Genmab US Activities, in whole or in part, to any [*] without [*] prior written consent.

3.7.4 No Other Co-Promotion or Participation Rights. Except as expressly contemplated with respect to the Genmab US Activities under this ARTICLE 3, neither Party will have the right to Promote, co-Promote, or otherwise conduct or participate in Commercialization activities, Medical Affairs Activities, or similar activities with respect to the Product in the other Party's Party Major Market(s).

3.7.5 Responsibility for Acts and Omission of Personnel. Each Party shall be solely responsible for: (a) the acts and omissions of its Sales Representatives, MSLs, and other personnel while performing any of the activities to be performed by such Party under this Agreement; and (b) all disciplinary, probationary and termination actions taken by it, as well as for the formulation, content, and for the dissemination (including content) of all human resources policies and rules (including written disciplinary, probationary and termination policies) applicable to any members of its personnel. Each Party shall comply with all Applicable Laws in the hiring, employment, and discharge of all members of its personnel.

3.7.6 Employment of Personnel. Each Party acknowledges and agrees that all matters of compensation, benefits and other terms of employment for all personnel of such Party are solely between such Party or its Affiliate and such individual. Each Party shall be solely responsible and liable for the payment of all compensation and benefits to its employees and any other members of its field force, and each Party acknowledges and agrees that neither Party will maintain or procure any worker's compensation, healthcare, or other insurance for or on behalf of the other Party or its personnel, all of which shall be the sole responsibility of the Party to which such person is employed or engaged. Without limiting the foregoing, a Party shall not be responsible to the other Party, or to any member of the other Party's field force (or any other personnel), for any compensation, expense reimbursements, benefits, or payroll-related taxes or withholdings that may be imposed upon or be related to the performance by individuals employed or engaged by such other Party, all of which shall be the sole responsibility of the Party to which such person is employed or engaged, even if it is subsequently determined by any court or Governmental Authority that any such individual may be an employee or a common law employee of the other Party or any of its Affiliates, or is otherwise entitled to such payments and benefits.

3.7.7 Non-Compliance by Field Force. In the event that a Party has a reasonable basis for believing (i.e., based on evidence or other reasonable substantiation) that any personnel of the other Party or any of its Affiliates may have violated any Applicable Law or failed to comply with this Agreement or the US Coordination Plan, or is otherwise damaging relationships with any health care professional or health care organization, or the Product brand, in each case, in connection with activities performed by such personnel in the United States pursuant to this Agreement, then such Party shall promptly notify the other Party in writing of such belief and the basis therefor. Following such notification and a reasonable opportunity to investigate the relevant facts, the Parties shall meet to discuss such belief and basis. The notified Party shall take such actions as are reasonable under the circumstances in response to the notifying Party's justified concerns, including, if necessary, excluding such individual from Product-related activities. For clarity, the foregoing shall not limit any rights or remedies of a Party hereunder.

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3.7.8 Termination of U.S. Rights.

(a) Genmab may terminate its rights and activities with respect to the Product in the United States under this ARTICLE 3 by providing SGI at least [*] prior written notice. Any such termination shall be with respect to Genmab's rights under this ARTICLE 3 in their entirety.

(b) In the event that Genmab exercises its right to terminate its activities with respect to the Product in the United States under Section 3.7.8(a), Genmab shall promptly (and in any event within [*] of such termination) wind down, discontinue and terminate all activities undertaken or to be undertaken, directly or indirectly, by Genmab, its Affiliates, or Genmab US Personnel with respect to the Product in the United States, in each case, in an orderly manner consistent with Applicable Law. Without limiting the foregoing, the Parties will discuss in good faith and endeavor to agree on a transition plan for such wind down and termination through the JCC and JSC, such agreement not to be unreasonably withheld, conditioned, or delayed. Without limiting any rights of SGI contemplated by this ARTICLE 3, following any termination of Genmab's rights under this Section 3.7.8(b), SGI shall have no further obligations under this ARTICLE 3, including any obligation to prepare a US Coordination Plan. For clarity, after any such termination of Genmab's rights under this Section 3.7.8(b), the Parties' rights and obligations with respect to the Product in the United States will be consistent with their rights and obligations with respect to the Product in any other SGI Major Market.

ARTICLE 4
COMMERCIALIZATION; FURTHER DEVELOPMENT

4.1 Commercialization in Major Markets Generally. Subject to the terms and conditions of this Agreement, including Genmab's rights with respect to the United States under ARTICLE 3, (a) SGI shall have the sole and exclusive right to Commercialize the Product in the SGI Major Markets or any portion thereof consistent with an annual Commercialization plan and budget for the SGI Major Markets prepared by SGI in accordance with Section 4.3.1 (such plan and budget, collectively, the "SGI Major Market Commercialization Plan"), and (b) Genmab shall have the sole and exclusive right to Commercialize the Product in the Genmab Major Market or any portion thereof consistent with an annual Commercialization plan and budget for the Genmab Major Market prepared by Genmab in accordance with Section 4.3.1 (such plan and budget, collectively, the "Genmab Major Market Commercialization Plan"); provided, in each case ((a) and (b)), that such Party Major Market Commercialization Plans shall be consistent with the annual Combined Major Market Commercialization Plan, including the corresponding budget therein, prepared by the Parties and approved by the JSC in accordance with Section 4.2 (such plan and budget, collectively, the "Combined Major Market Commercialization Plan"). In the event of (i) any inconsistency between the Combined Major Market Commercialization Plan and this Agreement, the terms of this Agreement shall prevail, and (ii) any inconsistency between a Party Major Market Commercialization Plan and the Combined Major Market Commercialization Plan, the terms of the Combined Major Market Commercialization Plan shall prevail.

[*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

4.2 Combined Major Market Commercialization Plan.

4.2.1 Generally. The Combined Major Market Commercialization Plan will set forth the Parties' mutually agreed: (a) Commercialization strategy and resourcing plans with respect to the Product (including with respect to strategic imperatives, branding, positioning, campaign and messaging platforms) in the Major Markets; (b) anticipated performance obligations and funding requirements for the Commercialization of the Product in the Major Markets; (c) target pricing bands for the Product both globally and regionally (with relevant regions recommended by the JCC) in the Territory; (d) reimbursement strategy for the Product in the Major Markets; (e) global Launch plan and Launch sequence for the Product in the Territory; (f) budget for activities contemplated by the Combined Major Market Commercialization Plan, including anticipated Sales Representatives and other personnel conducting Commercialization activities for the Product; (g) an agreed range for the aggregate number of Sales Representatives expected to be deployed in the Major Markets either by country or region as reasonably determined by the JCC; (h) key performance indicators either by country or region, as reasonably determined by the JCC, that the Parties shall implement, and that shall apply to the activities of the Sales Representatives of each Party in the Major Markets to monitor and assess Product performance, such as sales, attitudes, trial and usage market research, vial volume, and, to the extent such information is reasonably available, total prescriptions, new patient starts, sales, first claim fill rates, and prescription duration, and (i) [*] forecasts and projections for an additional [*] for such topics included in the Combined Major Market Commercialization Plan; in each case of (a)-(i), for the Major Markets except as otherwise indicated. The topics included in the Combined Major Market Commercialization Plan will be presented both on a global basis across all Major Markets and on a regional or Major Market-by-Major Market basis as reasonably determined by the JCC. For the avoidance of doubt, the Combined Major Market Commercialization Plan will contain detailed strategic plans and, where applicable, budgets for the elements set forth in clauses (a)-(i) above for each region or Major Market as determined by the JCC, and each Party's Party Major Market Commercialization Plan will be consistent with the overall plan and budget for each of the relevant region(s) or Major Market(s) contained in the Combined Major Market Commercialization Plan. The Combined Major Market Commercialization Plan and each amendment or annual update thereto shall reflect each Party's good faith estimate of its anticipated Commercialization commitments for each of the relevant region(s) or Major Market(s).

4.2.2 Initial Combined Major Market Commercialization Plan and Annual Updates. The Parties shall jointly prepare an initial draft of the Combined Major Market Commercialization Plan which shall be submitted to the JCC for review and approval at least [*] prior to the first anticipated Launch of the Product in a Major Market (as such date is determined by the JDC) and cover such period (including forecasts and projections) as determined by the JCC. Once agreed by the JCC, the JCC shall recommend the Combined Major Market Commercialization Plan to the JSC for approval. The Combined Major Market Commercialization Plan shall be updated at least [*], and all updates and amendments shall be reviewed and approved by the JCC and then submitted to the JSC for approval. The Parties shall agree on a timeline for conducting all such reviews and approvals that accommodates the Parties' respective planning and budgeting purposes and allows for necessary or reasonably useful coordination between the Committees.

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4.3 Commercialization by each Party in its Party Major Market(s).

4.3.1 Generally. Subject to the terms and conditions of this Agreement, including Genmab's rights in the United States under ARTICLE 3, each Party (itself or through its Affiliates or (sub)licensees as otherwise permitted herein) shall have the right to Commercialize the Product in its Party Major Market(s) or any portion thereof, including by performing activities for such Party Major Market(s) as follows: (a) preparing Promotional Materials for use in its Party Major Market(s) (provided, that such materials are consistent with the core content approved by the JSC), (b) preparing training materials and training programs for personnel engaged in such Commercialization activities, and implementing such training, and (c) making decisions with respect to its Party Tactical Matters in connection with such Commercialization activities; provided, that, in each case ((a) through (c)), such activities shall be consistent with the Party Major Market Commercialization Plan, Combined Major Market Commercialization Plan, and US Coordination Plan, including the tactical and strategic matters described in such plans, and otherwise conducted in accordance with this Agreement (including ARTICLE 3 with respect to the United States).

4.3.2 Party Major Market Commercialization Plans. Each Party will prepare a Party Major Market Commercialization Plan for its respective Party Major Market(s) that is consistent with the Combined Major Market Commercialization Plan, which Party Major Market Commercialization Plan covers the same time period addressed by such Combined Major Market Commercialization Plan. The Genmab Major Market Commercialization Plan and the SGI Major Market Commercialization Plan will each describe the plan for Commercialization of the Product in the applicable Party Major Market(s), specify in reasonable detail the Commercialization activities to be performed by or on behalf of the applicable Party for the Product in the applicable Party Major Market(s), and include a budget for such Party's Commercialization activities to be conducted in its Party Major Market(s). In addition, the SGI Major Market Commercialization Plan will incorporate the Commercialization activities set forth in the US Coordination Plan. Each Party shall prepare its own Party Major Market Commercialization Plan and provide it to the JCC, which shall review such plans for consistency with the Combined Major Market Commercialization Plan (subject to Section 2.10.5(c)). The initial draft of each Party Major Market Commercialization Plan shall be submitted to the JCC within [*] after submission to the JSC of the initial draft of the Combined Major Market Commercialization Plan by the JCC in accordance with Section 4.2.2. The Party Major Market Commercialization Plans shall be updated at least annually, and all updates and amendments shall be reviewed and approved by the JCC for consistency with the Combined Major Market Commercialization Plan (subject to Section 2.10.5(c)). The Parties shall agree on a timeline for conducting all such reviews and approvals that accommodates the Parties' respective planning and budgeting purposes and allows for necessary or reasonably useful coordination between the Committees. Each Party Major Market Commercialization Plan shall include with respect to the Product and the relevant Party's Party Major Market(s), as applicable and as consistent with the Combined Major Market Commercialization Plan:

(a) an executive summary;

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(b) an overview of tactical planning, consistent with the Global Brand Strategy and the Combined Major Market Commercialization Plan, for the Promoting, Detailing and Commercialization of the Product for each relevant indication;

(c) an overview of plans for the number, structure and deployment of Sales Representatives and other personnel conducting Commercialization activities for the Product by geography, target audience, activities, or other relevant criteria;

(d) an overview of (i) market research plans and market assessments and (ii) general plans for the marketing, Promotion and sale of the Product, with appropriate input as to financial matters from the JFT;

(e) a market, unit sales, and Net Sales forecast (provided, for clarity, that the Parties are not required to mutually agree on a Net Sales forecast or a Net Profit/Net Loss forecast, but, if relevant, they will cooperate with respect to preparing such forecasts in accordance with Section 5.1.2(d));

(f) an overview of pricing and discounting strategies for the applicable Party Major Market(s) consistent with Section 2.4.2(c); and

(g) key performance indicators to monitor and assess Product performance consistent with the key performance indicators set forth in the Combined Major Market Commercialization Plan.

4.3.3 Commercialization Diligence in the Major Markets. Following the receipt of relevant Regulatory Approvals in relevant country(ies), each Party shall use Commercially Reasonable Efforts to Commercialize the Product in its Party Major Market(s) in accordance with and to the extent provided in the Combined Major Market Commercialization Plan, the applicable Party Major Market Commercialization Plan, and otherwise in accordance with this Agreement.

4.3.4 Sales Efforts Reporting for the Party Major Market(s). Within [*] after the end of each Year beginning in the Year in which the first Regulatory Approval of the Product in a Party's Party Major Market(s) is obtained, each Party shall provide a high-level report to the JCC summarizing its selling efforts for the Product where the Product receives a primary or secondary ranking in its Party Major Market(s).

4.3.5 Packaging and Labeling; Booking of Sales; Distribution in the Major Markets. In its Party Major Market(s), the Selling Party (a) will hold title to the Product inventories until such inventory is sold to customers, (b) shall effect all sales of Product and shall be responsible for invoicing all sales of Product and shall book all sales of Product for its own account, and (c) shall be responsible for all Packaging and Labeling and Sales and Distribution activities for the Product. Notwithstanding the foregoing, to the extent not prohibited by Applicable Law and subject to approval by the applicable Regulatory Authorities, unless the Parties otherwise agree by mutual Party Written Consent, all product labels for the Product worldwide shall include, in equal prominence, the [*].

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4.4 Commercialization in the Royalty Territory. Following the receipt of relevant Regulatory Approvals in relevant country(ies), SGI shall use Commercially Reasonable Efforts to Commercialize the Product in [*], as determined by SGI in its reasonable discretion consistent with its obligation to use Commercially Reasonable Efforts to Commercialize the Product in the Royalty Territory, in accordance with the terms and conditions of this Agreement, and except as otherwise provided in this Agreement shall be solely responsible for all costs and expenses incurred by or on behalf of SGI or any of its Affiliates for Commercializing the Product in the Royalty Territory or any portion thereof. For the avoidance of doubt, SGI may satisfy its obligations under this Section 4.4 by using Commercially Reasonable Efforts to enter into (or entering into) one or more Commercial Sublicenses with respect to one or more countries in the Royalty Territory.

4.5 Recalls and Withdrawals. The initiation and implementation of a Product distribution hold, recall, clinical hold, market withdrawal, or similar action in the Territory will be determined in accordance with the relevant clinical or commercial quality agreement agreed to by the Parties in accordance with Section 6.3 (including the process for consultation and, if possible, reaching consensus set forth therein); provided, that the Lead Regulatory Party shall have final decision-making authority, after consultation with the other Party with respect to the initiation and conduct of any such hold, recall, withdrawal, or similar action in a particular country if there is a dispute between the Parties with respect thereto (unless there is a mandatory hold, recall, withdrawal, or similar action by the Regulatory Authorities, which shall supersede any decision of the Lead Regulatory Party to the contrary). The costs of implementing any such hold, recall, withdrawal, or action in accordance with this Section 4.5 in the Major Markets shall constitute Commercialization Costs except to the extent that such hold, recall, withdrawal, or action is (a) attributable to (i) a breach by a Party or its Affiliates of this Agreement or (ii) the gross negligence, recklessness or willful misconduct of a Party or its Affiliates, or (b) caused by or results directly from a material uncured breach by a Party or its Affiliates of any agreement with a Third Party CMO engaged by such Party or its Affiliate for the Manufacture of Product if such material breach is acknowledged by such Party in writing, results from a failure by the Manufacturing Party to make any undisputed payment when due (after giving effect to any available cure period) or is finally determined by a court or arbitrator of competent jurisdiction; provided, that the foregoing clause (b) shall not apply to any such material breach that is caused by or results directly from an act or omission of a Third Party including any other Third Party CMO that Manufactures the Product on the Party's behalf. Any such costs not included in Commercialization Costs pursuant to the preceding sentence shall be borne solely by the applicable Party.

4.6 Development Activities.

4.6.1 In General. Except as otherwise expressly provided in this Agreement, including Sections 2.3, 4.6.2 and 8.1.2, Development of the Product in the Territory following the Effective Date will continue to be conducted in accordance with the terms and conditions of the Collaboration Agreement.

4.6.2 Clinical Trials. Notwithstanding anything to the contrary contained in the Collaboration Agreement or the Joint Development Plan as of the Effective Date, following the Effective Date: (a) Genmab shall be the sponsor of and solely conduct and be responsible for

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the performance of (i) the Clinical Trials known as [*], (ii) to the extent such studies are included in the Global Development Plan, any Phase III-B Studies or Phase IV Studies conducted in the Genmab Major Market, (iii) any Genmab Party Combination Studies to be conducted by or on behalf of Genmab, to the extent such studies are included in the Global Development Plan (such Global Development Plan to also set forth the details regarding Clinical Supply and data sharing with respect to such Genmab Party Combination Studies), and (iv) any Genmab [*] Approval Trial initiated by Genmab in accordance with Section 0; and (b) SGI shall be the sponsor of and solely conduct and be responsible for the performance of any other Clinical Trials of the Product which are not specified in clause (a) above, including (1) the Clinical Trials known as [*], (2) any other Clinical Trials for the Product to be conducted for [*], (3) any Phase III-B or Phase IV Studies, (4) any SGI Party Combination Studies to be conducted by or on behalf of SGI, to the extent such studies are included in the Global Development Plan (such Global Development Plan to also set forth the details regarding Clinical Supply and data sharing with respect to such SGI Party Combination Studies), and (5) any Clinical Trial regarding the Product and any other product owned or otherwise controlled by a Third Party, to the extent such studies are included in the Global Development Plan. For clarity, the foregoing is intended to establish which Party will have operational control over relevant Clinical Trials following the Effective Date, but it is not intended to prevent the other Party from performing Medical Affairs Activities, including through outreach and contacts with Clinical Trial sites, in its Party Major Market(s) to the extent otherwise permitted under this Agreement.

Development in [*]. It is the expectation of the Parties that Clinical Trials for the Product conducted by SGI as sponsor in accordance with Section 4.6.2 will include an adequate patient population from [*] to support Regulatory Approval of the Product in [*] for the Disease(s) for which such Clinical Trials are intended to treat. However, to the extent that it is not reasonably practicable for such Clinical Trials to include an adequate patient population from [*] to support such Regulatory Approval of the Product in [*], the Parties, acting through the JDC, will promptly amend the Global Development Plan to add such Clinical Trial(s) to be conducted in [*] with an adequate patient population from [*] to support such Regulatory Approval in [*] (any such Clinical Trial, a "Genmab [*] Approval Trial"), and Genmab shall be the sponsor of and solely conduct and be responsible for the performance of any such Genmab [*] Approval Trial. For the avoidance of doubt, the FTE Costs of Genmab's personnel and Out of Pocket Costs incurred by Genmab in connection with the planning and conduct of any Genmab [*] Approval Trial, including Manufacturing Costs for Clinical Supply and any comparator or placebo therefor, shall be considered Development Costs hereunder.

4.6.3 Development in the Royalty Territory. SGI shall use Commercially Reasonable Efforts to Develop the Product in the Royalty Territory, as determined by SGI in its reasonable discretion consistent with its obligation to use Commercially Reasonable Efforts to Develop the Product in the Royalty Territory, in accordance with and to the extent provided from time to time in the mutually agreed Global Development Plan (including any amendments or modifications to the Global Development Plan with respect to the Royalty Territory proposed by SGI consistent with its obligation to use Commercially Reasonable Efforts). For clarity, if Genmab or its representatives on any Committee refuse to approve any such amendment or modification to the Global Development Plan with respect to the Royalty Territory, SGI shall not be deemed to have failed to use [*].

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4.6.4 Development Costs. Development Costs incurred by the Parties in connection with Development activities conducted for the Product under this Agreement (including [*]) in accordance with the Global Development Plan shall be shared as Net Profit/Net Loss in accordance with Section 5.1 and the other applicable terms and conditions of this Agreement. For clarity, any Development activities conducted by or on behalf of SGI or its Affiliates or their Sublicensees for countries in the Royalty Territory that are not included in the Global Development Plan shall be at SGI's sole cost and expense, and shall not be shared as Net Profit/Net Loss hereunder.

4.7 Subcontracting and Sublicensing.

4.7.1 Subcontracting. Each Party may perform some or all of its obligations (a) under the Global Development Plan (including the Global Regulatory Plan), Global Manufacturing Plan and Party Major Market Commercialization Plan or (b) otherwise under this Agreement for the Product in its Party Major Market(s) (or with respect to Genmab and the Genmab US Activities, in the United States subject to ARTICLE 3), in each case ((a) and (b)), solely through one or more Approved Subcontractors or as otherwise approved by the JSC; provided, that (i) none of the rights of the other Party shall be diminished or otherwise adversely affected as a result of such subcontracting, (ii) nothing in this Section 4.7.1 shall limit a requirement to obtain Party Written Consent or Joint Committee Consent for Third Party Manufacturing under ARTICLE 6, (iii) each subcontractor shall undertake in writing obligations of confidentiality and non-use regarding each Party's Confidential Information which are substantially the same as those undertaken by the Parties hereunder, and (iv) the subcontracting Party shall be responsible for the performance by such subcontractor of such Party's obligations hereunder. For clarity, the Parties and their Affiliates may enter into arrangements with (X) nationally recognized shipping or transportation companies such as United Parcel Service or FedEx or (Y) with contract research organizations with respect to non-clinical Development, in each case of (X) and (Y), with respect to the Product or their obligations under this Agreement without the prior Committee approval and, solely with respect to (X), such arrangements shall be excluded from the requirements of clause (ii) above. Notwithstanding the foregoing or anything to the contrary contained in this Agreement or the Collaboration Agreement, SGI may engage subcontractors to perform Development, Manufacturing, or Commercialization activities with respect to the Product in the Royalty Territory or outside the Royalty Territory solely to support Development or Commercialization of the Product in the Royalty Territory without the prior written consent of Genmab or any Committee, provided that subsections (i)-(iii) above shall continue to apply.

4.7.2 Sublicensing. This Section 4.7.2 supersedes Section 5.11 of the Collaboration Agreement with respect to the grant by either Party of a Commercial Sublicense for the Product to a Third Party. In addition, to the extent any sublicense permitted under this Agreement would require the grant of a sublicense under the Collaboration Agreement with respect to the Product, the Parties agree to grant that sublicense with respect to the Product notwithstanding anything to the contrary in the Collaboration Agreement.

(a) In General. Except as expressly provided in this Section 4.7.2, neither Party shall grant any [*] with respect to their [*] to any Third Party without the consent of the JSC, such consent not to be unreasonably withheld, delayed, or conditioned.

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(b) Service Providers. Subject to Section 4.7.2(a), each Party may sublicense its rights and obligations under this Agreement and the Collaboration Agreement to a subcontractor permitted under Section 4.7.1 to the extent necessary to enable such subcontractor to perform its obligations to the subcontracting Party.

(c) Third Party Sublicensing. With respect to the grant by a Party or its Affiliate to a Third Party sublicensee that includes the right to Commercialize the Product, but not including any wholesaler, distributor, or the like (such sublicensee, a "Sublicensee," and such sublicense, a "Commercial Sublicense"):

(i) In the [*] Markets. If a Party desires to grant a Commercial Sublicense in countries or territories that include one or more of its Party [*] Market(s), such Party shall notify the other Party in writing thereof. Thereafter, the Parties, through the JSC, shall discuss the strategy, timing, and other considerations relating to finding an appropriate Sublicensee for such [*] Market Sublicense. If the JSC agrees to pursue a Sublicensee to Commercialize Product in such [*] Market, then (i) each Party shall take the [*] Market Sublicense that includes solely the Party [*] Market(s) of such Party, and (ii) if such [*] Market Sublicense would involve the grant of rights in or for the Party [*] Market(s) of both Parties, the JSC shall determine which Party [*]. The [*] Party shall provide the other Party [*] without the approval of the JSC, such approval not to be unreasonably withheld, delayed, or conditioned.

(ii) In the Royalty Territory. SGI may grant a Commercial Sublicense in or for countries or territories solely within the Royalty Territory in its sole discretion; provided, that, without limiting the foregoing, SGI will first notify Genmab and upon a written request by Genmab within [*] of SGI's notice, SGI shall reasonably consider [*]. For the avoidance of doubt, (A) Product sales by any such Sublicensee in the Royalty Territory shall be considered Net Sales to the extent provided in the definition of "Net Sales" hereunder, (B) Product sales to any Third Party distributor, wholesaler, or the like in or for the Royalty Territory shall be considered Net Sales to the extent provided in the definition of "Net Sales" hereunder, and (C) any other consideration paid to SGI or any of its Affiliates by or on behalf of any such Sublicensee or distributer, wholesaler, or the like shall be retained by SGI and shall not be considered "Sublicensing Revenue" hereunder.

(d) [*] Sublicensing. Without limiting subsection (c)(i) above, the Parties acknowledge that prior to the Effective Date, [*] initiated a business development process with respect to the potential out-license of rights to Commercialize the Product in [*] (the "Process"). Subject to subsection (c)(i) above, [*] shall transition the Process to [*] following the Effective Date, and [*] may continue the Process or otherwise pursue a Commercial Sublicense with respect to [*] in accordance with subsection (c)(i) above.

ARTICLE 5
FINANCIAL TERMS

The Parties shall make or cause to be made the payments provided for in this ARTICLE 5. For clarity, this ARTICLE 5 supersedes Sections 11.4, 11.5, 11.6, and Article 12 of the Collaboration Agreement with respect to activities conducted after the Effective Date with respect to the Product.

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5.1 Profit Sharing in the Major Markets. Following the Effective Date, the terms and conditions of this Section 5.1 shall govern the rights and obligations of Genmab and SGI with respect to Net Profit/Net Loss relating to the Product.

5.1.1 Share of Net Profits/Net Losses. Subject to the terms of this Agreement and Section 5.10 of the Collaboration Agreement, for so long as Product is being sold in the Major Markets or Sublicensing Revenue is being generated, Genmab and SGI shall share all Net Profit/Net Loss (as applicable) for the Product on the basis of fifty percent (50%) to SGI and fifty percent (50%) to Genmab.

5.1.2 Calculation and Payment.

(a) Within [*] days after the end of each Quarter beginning with the first Quarter in which either Development Costs or Allowable Expenses are incurred, each Party shall report to the JFT its Net Sales and Sublicensing Revenue in the Major Markets, as well as its Allowable Expenses and Development Costs. Each such report shall, as applicable, specify in reasonable detail all deductions allowed in the calculation of such Net Sales, documentation supporting its receipts of such Sublicensing Revenue, and all expenses or costs included in Allowable Expenses or Development Costs, and, if requested by Genmab or SGI, any invoices or other supporting documentation for any payments to a Third Party that constitute Allowable Expenses or Development Costs and that individually exceed [*] or with respect to which documentation is otherwise reasonably requested shall be promptly provided. In addition, each such report shall specify the amount of gross sales of Product for the Quarter and the amount offset from gross sales to Net Sales by category for the Quarter. Within [*] Business Days after receipt of such reports, the JFT shall confer and agree in writing on a consolidated financial statement setting forth the Net Profit/Net Loss for such Quarter for the Product and calculating each Party's share of such Net Profit/Net Loss.

(b) Within [*] Business Days after the Parties (through the JFT) have reconciled the reports delivered under Section 5.1.2(a) for each Quarter, the Party who will receive payment shall issue to the other Party an invoice for the agreed amount and the other Party shall, within [*] Business Days of such invoice, make a payment to SGI or Genmab, as applicable, so that each of Genmab and SGI has been compensated for its respective share or has borne its respective share of such Net Profit/Net Loss, as applicable, after giving effect to the (i) Net Sales invoiced and Sublicensing Revenue received for the Major Markets as well as Allowable Expenses and Development Costs incurred by SGI, and (ii) Net Sales invoiced and Sublicensing Revenue received for the Major Markets, as well as Allowable Expenses and Development Costs incurred by Genmab, to effect the intent of Section 5.1.1; provided, however, that in the event of any disagreement with respect to the calculation of such payment, any undisputed portion of such payment shall be paid in accordance with the foregoing timetable and the remaining, disputed portion shall be paid within [*] Business Days after the date on which Genmab and SGI, using good faith efforts, resolve the dispute or such dispute is resolved pursuant to a dispute resolution mechanism under this Agreement.

(c) In addition, for planning purposes, each Party shall report to the other Party and the JFT within [*] Business Days after the end of each calendar month following the first Launch of the Product in its Party Major Market(s) its estimated Net Sales (including the

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estimated amount of gross sales of Product by stock keeping units of Product) in its Party Major Market(s) in such month and its estimated Allowable Expenses in such month. Further, each Party shall consider in good faith other reasonable procedures proposed by the other Party for sharing financial information in order to permit each Party to close its books periodically in a timely manner.

(d) If either Party intends to include a Net Sales forecast or a Net Profit/Net Loss forecast in any public filings or public statements in connection with its required financial reporting to any Securities Exchange, the Parties agree to cooperate in good faith to prepare Net Sales or Net Profit/Net Loss forecasts reasonably in advance of such filing or public statement; provided, that if the Parties are unable to agree to such forecasts in advance of such filing or public statement, the filing Party shall be permitted to use its good faith Net Sales or Net Profit/Net Loss forecasts in such filing or public statement.

(e) For the avoidance of doubt, no cost or expense shall be counted more than once in calculating Allowable Expenses or Development Costs, even if such cost or expense falls into more than one of the cost categories that comprise Allowable Expenses or Development Costs. For purposes of determining Allowable Expenses, Development Costs and Net Profit/Net Loss, each Party shall be required to record for relevant employees aggregate FTE hours worked or FTE hours worked on activities related to the Product (subject to Section 1.49) and all such allowed FTE Costs shall be charged based on the percentage of time allocated to the Product and activities under this Agreement (or as otherwise set forth in Section 1.49). Out of Pocket Costs will be charged based on actual expenses incurred or accrued.

5.1.3 Consistency with Accounting Treatment. All calculations of Net Profit/Net Loss hereunder shall be made in accordance with Collaboration Accounting Standards, including the provisions thereof regarding expense recognition, as applied by Genmab and SGI consistently with their application in their respective external financial reporting.

5.1.4 Integrity of Profit Sharing in the Major Markets.

(a) The Parties recognize that in certain regions, restrictions on cross-border sales of the Product are not permitted, and that in such regions (e.g., within the EU), sales of units of the Product intended to be sold in a Major Market and therefore subject to payment obligations under Section 5.1 may instead be sold in a country that is in the Royalty Territory instead, and initially included in amounts subject to royalty obligations under Section 5.2. In such case, the Parties have agreed to perform an annual assessment of whether their intended allocation of economic benefit as set forth in Sections 5.1 and 5.2 has been effected and, if not, to make reconciling payments between the Parties to effectuate their intent as set forth in Sections 5.1 and 5.2, pursuant to the mechanism set forth in this Section 5.1.4.

(b) Within [*] days after the end of the Quarter in which the first Launch of the Product in a Major Market occurs, and within [*] days after the end of each Quarter thereafter, the Parties, through the JCC and in coordination with the JFT, shall review for such Quarter that most recently ended ("Relevant Review Period") the following information: (A) the total amount of Net Sales allocated to the Major Markets for the purpose of calculating the Net Profit/Net Loss for the Major Markets in accordance with this Section 5.1, (B) the total amount

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of Net Sales allocated to the Royalty Territory for the purpose of calculating the total royalties due by SGI to Genmab in accordance with Section 5.1.4, (C) the estimated amount of total prescriptions issued for the Product in the Major Markets, in accordance with data obtained from IQVIA or another source mutually acceptable to the Parties, and (D) the estimated amount of total prescriptions issued for the Product in the Royalty Territory, in accordance with data obtained from IQVIA or another source mutually acceptable to the Parties, in each case of (A)-(D), during the Relevant Review Period. To the extent that the fraction A/B is less than or greater than the fraction C/D, then the JCC, in coordination with the JFT shall determine reconciling payments to be made between the Parties with respect to the Relevant Review Period as necessary to effectuate their intended allocation of the economic benefit as set forth in such Sections (a "Reconciling Payment Determination"). Any such reconciling payments shall be made within [*] days after the JFT has made a Reconciling Payment Determination.

5.2 Royalty Territory.

5.2.1 Royalty Payments. Subject to Sections 5.2.2 and 5.2.3, during each Quarter in which such Net Sales are received, SGI shall pay Genmab a running royalty on aggregate annual Net Sales of the Product in the Royalty Territory by SGI, its Affiliates and their Sublicensees at the following percentages as set forth in the table below:

Portion of aggregate annual Net Sales of the Product in the Royalty Territory by SGI, its Affiliates, and their Sublicensees	Percentage of such Net Sales to be paid as a running royalty:
[*]	[*]
[*]	[*]
[*]	[*]

5.2.2 Biosimilar Step-Down. If, on a country-by-country basis within the Royalty Territory, one or more Biosimilar Products in respect of the Product are sold in such country, and if sales of all Biosimilar Products in respect of the Product combined in such country during any [*] are greater than [*] (on a unit basis) of the combined sales of all such Biosimilar Products and the Product together (on a unit basis) in such country (the "Trigger Condition"), then the royalties payable with respect to Net Sales of the Product pursuant to Section 5.2.1 in such country starting with [*] giving rise to the Trigger Condition shall be reduced to [*] of the royalties otherwise payable pursuant to Section 5.2.1; provided, that if the Trigger Condition ceases to apply in a future Quarter, after royalties are subject to reduction pursuant to this Section 5.2.2, such reduction in royalties shall cease to apply effective as of the subsequent Quarter unless and until the Trigger Condition occurs again for the Product in such country.

5.2.3 Royalty Term. SGI's obligation to pay royalties under this Section 5.2 with respect to the Product in each country in the Royalty Territory will commence upon Launch of the Product in such country and will continue until the later of (i) expiration of the last-to-expire [*] of the [*] covering Program Inventions claiming or covering the Product in such country or (ii)

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[*] after such Launch of the Product in such country (such period, the "Royalty Term"); provided, however, that if the Product is royalty-bearing in a given country only pursuant to clause (ii) above, then the each royalty rate set forth in Section 5.2.1 shall be reduced by [*] for such country for the remainder of the Royalty Term and; provided, further, that in no event shall the royalty rates set forth in Section 5.2.1 be reduced pursuant to Section 5.2.2 and this Section 5.2.3 by more than [*], in the aggregate.

5.2.4 Royalty Payments and Reports. Within [*] days after the end of each March, June, September and December during which royalties under this Section 5.2 are due, SGI shall deliver to Genmab a report setting forth on a country-by-country basis the unit volume and amount of gross sales of Product sold by SGI its Affiliates and their Sublicensees in the Royalty Territory during the applicable Quarter, a calculation of such Net Sales in the Royalty Territory showing the aggregate deductions from gross sales provided for in the definition of Net Sales during such Quarter, and a calculation of the royalty payment due for such Quarter. All royalty amounts payable to Genmab pursuant to this Section 5.2.4 shall be paid to Genmab in Dollars in connection with the delivery of such report, but not later than [*] days after the end of each Quarter.

5.3 Taxes.

5.3.1 Taxes on Income. Except as otherwise provided in this Section 5.3 or Schedule 5.3.4, each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly under this Agreement.

5.3.2 Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding, Indirect Taxes, or similar obligations in respect of Net Profit, royalties and other payments made by one Party to the other under this Agreement. Without limiting the generality of the foregoing, to the extent that a Party (or its assignee) (the "Paying Party") is required by Applicable Law to deduct and withhold taxes on any payment due to the other Party (or its assignee) (the "Payee Party") under this Agreement, the Paying Party shall provide [*] Business Days' notice of such intention to withhold to the Payee Party, and the Payee Party shall provide the Paying Party any tax forms and other information that may be reasonably necessary in order not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. The Payee Party shall provide any such tax forms to the Paying Party at least [*] Business Days prior to the due date for any payment for which the Payee Party desires that the Paying Party apply a reduced withholding rate.

All payments payable under this Agreement are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any payments made under this Agreement, the Paying Party shall pay such Indirect Taxes at the applicable rate in respect of such payments following receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by the Payee Party in respect of those payments.

Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, Indirect Taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or Indirect Tax. For clarity, if such withholding taxes, Indirect

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Taxes, or similar obligations have been shared equally by the Parties as an Allowable Expense, the Parties shall share equally in the amount of such recovery.

5.3.3 Payment of Tax.

(a) To the extent that a Paying Party is required by Applicable Law to deduct and withhold taxes on any payment due to the Payee Party under this Agreement or allocation of Net Profits/Net Losses under this Agreement, such Paying Party shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to the Payee Party evidence of such withholding in the form customarily provided by the applicable Governmental Authority to enable the Payee Party to claim such payment of taxes. Any taxes that are so deducted and withheld shall be treated as paid to the Payee Party hereunder. If the Paying Party failed to deduct or withhold tax required by Applicable Law, the Payee Party shall [*]. In the event that a liability for withholding taxes is imposed or asserted by a Governmental Authority upon the Paying Party in respect of a failure to withhold such taxes from or in respect of any amount payable to a Payee Party under this Agreement (a "Withholding Tax Claim"), (1) the Paying Party shall notify the Payee Party promptly upon the receipt of any such Withholding Tax Claim from a Governmental Authority which might give rise to an indemnification under this Section 5.3.3 (although the Paying Party's delay in promptly notifying the Payee Party shall only reduce the Payee Party's liability to indemnify the Paying Party to the extent that the Payee Party is actually prejudiced by such delay); (2) the Payee Party shall be entitled to participate, at its own expense, and with counsel of its choosing, in the defense of any such Withholding Tax Claim which may give rise to liability under this Section 5.3.3(a); (3) the Paying Party may not settle the Withholding Tax Claim with a Governmental Authority, to the extent such settlement would create a liability for the Payee Party under this Section 5.3.3(a), without the prior written consent of the Payee Party, which consent shall not be unreasonably withheld, conditioned or delayed; and (4) the Payee Party shall indemnify the Paying Party for any reasonable out-of-pocket expenses incurred by the Paying Party in the defense of the Withholding Tax Claim; provided, further, that the foregoing indemnification obligation shall not apply to the extent that if the Paying Party had withheld such taxes, it would have been required to increase such amount payable under Section 5.3.3(b).

(b) Notwithstanding the foregoing, if (a) any Party redomiciles or assigns its rights or obligations under this Agreement, (b) as a result of such redomiciliation or assignment, such Party (or its assignee) is required by Applicable Law to withhold taxes, or such redomiciliation or assignment results in the imposition of Indirect Taxes that were not otherwise applicable, from or in respect of any amount payable from such Party to the other Party under this Agreement, and (c) such withholding taxes or Indirect Taxes exceed the amount of withholding taxes or Indirect Taxes that would have been applicable had such redomiciliation or assignment not occurred, then any such amount payable shall be increased to take into account such withholding taxes or Indirect Taxes as may be necessary so that, after making all required withholdings (including withholdings on the additional amounts payable) and/or paying such Indirect Taxes, as the case may be, the Payee Party (or its assignee) receives an amount equal to the sum it would have received had no such increased withholding been made and no such Indirect Taxes had been imposed. The obligation to pay additional amounts pursuant to the preceding sentence shall not apply, however, to the extent such increased withholding tax or Indirect Taxes (i) would not have been imposed but for the assignment by the Payee Party of its rights or

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obligations under this Agreement or the redomiciliation of such Payee Party outside of the United States, to the extent such assignment or redomiciliation occurs after the redomiciliation or assignment by the Paying Party described in the first sentence of this Section 5.3.3(b) or (ii) are attributable to the failure by the Payee Party to comply with the requirements of Section 5.3.3(c).

(c) Each Party has provided a properly completed and duly executed IRS Form W-9 or applicable Form W-8 to the other Parties. Each Party and any other recipient of payments under this Agreement shall provide to the other Party, at the time or times reasonably requested by such other Parties or as required or permitted by Applicable Law, such properly completed and duly executed documentation (for example, IRS Forms W-8 or W-9) as will permit payments made under this Agreement to be made without, or at a reduced rate of, withholding for taxes.

5.3.4 Partnership Tax Treatment. Each Party understands, acknowledges and agrees that to the extent the Parties are sharing Net Profits/Net Losses pursuant to Section 5.1.1 with respect to the Development and Commercialization of the Product then a partnership for United States income tax purposes is formed between the Parties (the "Tax Partnership"). The Parties further agree and acknowledge that, for U.S. federal income tax purposes, the Tax Partnership commenced upon the effective date of the Joint Commercialization Agreement (the "Tax Partnership Formation Date"). The Parties intend that for U.S. federal (and applicable state) income tax purposes, each of Genmab and SGI shall be treated as having contributed property of equal value to the Tax Partnership on the Tax Partnership Formation Date (such value to be determined by mutual agreement of the Parties) in a transaction intended to qualify for non-recognition treatment under Section 721(a) of the U.S. Internal Revenue Code of 1986, as amended (the "Tax Code"). The Parties further acknowledge and agree that the Royalty Payments provided for under Section 5.2 shall not be treated as contributions to or distributions from the Tax Partnership, but shall be treated by the Parties as payments made outside of the Tax Partnership (by SGI to Genmab not in their capacity as Partners in the Tax Partnership). The Tax Partnership shall be governed and operated in accordance with the rights and obligations set forth in Schedule 5.3.4. The Parties further acknowledge that the arrangements described in this Agreement (including Schedule 5.3.4) shall be treated by the Parties as a partnership solely for U.S. federal (and applicable state) income tax purposes and is not intended to constitute a partnership for any non-tax purpose or for tax purposes under the laws of any non-U.S. jurisdiction. The Parties agree to cooperate in good faith to take such reasonable actions and execute such documents as reasonably necessary to support the tax position set forth in this Section 5.3.4 and Schedule 5.3.4.

5.3.5 Effectively Connected Income. The Parties shall coordinate and cooperate reasonably and in good faith to review the anticipated tax consequences associated with the Development and Commercialization activities undertaken by the Parties (and their respective Affiliates) pursuant to this Agreement and structure such activities in a manner to minimize, to the extent permitted by Applicable Law, the income generated from activities that constitutes income effectively connected with a trade or business within the United States (within the meaning of Section 864 of the Tax Code) ("ECI") or profits attributable to a permanent establishment or other similar taxable presence of either Party in any jurisdiction outside of the United States. Each Party, upon request, shall provide information to the other Party about the location and structure of its Development and Commercialization activities reasonably in connection with the foregoing

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review. The determination of the structure of Development and Commercialization activities for the foregoing purposes shall be made by the JCC; provided, however, that neither Party shall be required to undertake actions that could reasonably be expected to result in adverse tax or business consequences to such Party (including any liability for taxes that are not indemnified by the other Party under Section 5.3.3) or that would cause such Party to incur material out-of-pocket costs (other than any out-of-pocket costs that the other Party agrees to reimburse).

5.4 Currency. All payments hereunder will be in Dollars in immediately available funds and will be made by wire transfer from a United States bank located in the United States to such bank account as payee may designate in writing from time to time.

5.5 Foreign Exchange. The amounts accruing in a currency other than Dollars will be converted to Dollars using an exchange rate equal to, unless otherwise agreed by the JFT, the arithmetic average of the U.S. daily closing rates published by Reuters during the applicable Quarter for which payments are being made or applicable costs are accrued. The conversion calculations will be provided in any statement reporting converted amounts.

5.6 Late Payments. Any undisputed payments or portions thereof due hereunder which are not paid on the date such payments are due under this Agreement will bear interest at a rate equal to the lesser of (a) the prime rate as published in The Wall Street Journal, Eastern Edition, under the heading "Money Rates," on the first date of each Quarter in which such payments are overdue, plus [*] or (b) the maximum rate permitted by Applicable Law, in each case ((a) and (b)), calculated on the number of days such payment is delinquent, compounded monthly using a three hundred sixty-five (365)-day year.

5.7 Financial Records; Audits. Each Party shall maintain, and require its Affiliates to maintain, complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of any calculations by the other Party or any payments due by the other Party under this Agreement, including (a) amounts to be included in the calculation of Allowable Expenses or other amounts to be reimbursed or shared pursuant to this Agreement, (b) Net Sales, (c) royalty payments for purposes of determining any under- or over-payment of royalties, (d) Manufacturing Costs, Commercial Packaging and Labeling Costs, Commercialization Costs, and Medical Affairs Costs, (e) amounts payable under any supply agreement with respect to the Product to which the Parties or their Affiliates are party, and (f) other compensation or reimbursement payable under this Agreement. Upon reasonable prior notice, such records for any Year(s) ending not more than [*] prior to the date of such request shall be open during regular business hours for examination at the auditing Party's expense, and not more often than once each [*] period, by an independent certified public accountant selected by the auditing Party and reasonably acceptable to the audited Party for the sole purpose of verifying for the auditing Party the accuracy of the financial statements or reports furnished by the audited Party pursuant to this Agreement or of any payments made, or required to be made, by or to the audited Party to the other Party pursuant to this Agreement or any supply agreement with respect to the Product to which the Parties or their Affiliates are party. Such accountant shall be provided access to the audited Party's data for the purpose of verifying, without limitation, the audited Party's determination of the number of FTEs (if applicable), and calculation of such other information included in the calculation for Manufacturing Costs, Commercial Packaging and Labeling Costs, Commercialization Costs, and Medical Affairs

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Costs actually incurred by the audited Party for the Product. Any such auditor shall not disclose the audited Party's information to the auditing Party, except to the extent that such disclosure is necessary to report on the accuracy of the financial reports furnished by the audited Party or the amount of payments due by the audited Party under this Agreement. Any amounts shown to be owed but unpaid, or overpaid, shall be paid or refunded (as the case may be) within [*] days after the accountant's report, unless such report is challenged in good faith by the audited Party, in which case any undisputed portion shall be paid within [*] days after the accountant's report and any remaining disputed portion shall be paid within [*] days after resolution of the dispute, and interest shall not accrue with respect to the disputed portion during the period of time the dispute is being resolved. The auditing Party shall bear the full cost of such audit unless such audit reveals an overpayment to, or an underpayment by, the audited Party that resulted from a discrepancy in a report that the audited Party provided to the other Party during the applicable audit period, which underpayment or overpayment was more than [*], in which case the audited Party shall bear the Out of Pocket Costs of such audit.

5.8 Third Party License Agreements.

5.8.1 Each Party shall promptly notify the other Party via discussion at the JSC or any Committee charged with oversight for intellectual property matters, or between the Alliance Managers, if either Party believes that Patent or other intellectual property rights controlled by a Third Party (but not already Controlled by a Party) may be necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Product in or for one or more Major Markets and such notifying Party proposes that a Party should enter into a Third Party License Agreement therefor for one or more Major Markets.

5.8.2 The Parties, through the JSC, shall discuss whether or not to negotiate the terms of such Third Party License Agreement for one or more Major Markets. The determination of whether to pursue the negotiation of any such Third Party License Agreement for one or more Major Markets must be made by the JSC.

5.8.3 If the JSC decides to pursue the negotiation of a Third Party License Agreement for one or more Major Markets, the JSC shall also decide which Party or whether the Parties jointly shall take the lead on negotiating the terms of such Third Party License Agreement (the "Lead Negotiating Party"); provided, that the presumption shall be that (a) SGI shall be the Lead Negotiating Party for a Third Party License Agreement for one or more SGI Major Markets, unless such Third Party License Agreement relates primarily to the Genmab Technology rather than the Product, in which case Genmab shall be the Lead Negotiating Party, and (b) Genmab shall be the Lead Negotiation Party for a Third Party License Agreement for the Genmab Major Market, unless such Third Party License Agreement relates primarily to the SGI Technology rather than the Product, in which case SGI shall be the Lead Negotiating Party. If the Lead Negotiating Party elects not to or to cease taking the lead on negotiating the terms of a Third Party License Agreement, it shall promptly notify the other Party and transition the negotiation thereof to the other Party. For the avoidance of doubt, the JSC may decide to discontinue any such negotiation or decide that neither Party shall enter into any Third Party License Agreement so negotiated.

5.8.4 In connection with any negotiation of a Third Party License Agreement for one or more Major Markets: (a) the terms of any such license shall permit the Party obtaining

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such Third Party License Agreement to grant to the other Party a sublicense thereunder to practice the licensed rights thereunder; (b) the Parties, in consultation through the JSC, shall cooperate in negotiating the terms of such Third Party License Agreement with such Third Party as reasonably necessary to enable such other Party to exercise its rights under this Agreement; and (c) the Lead Negotiating Party for such Third Party License Agreement shall consult with the other Party through the JSC prior to making any material proposal regarding, or otherwise agreeing to, the terms of any such license. Additionally, the Parties shall negotiate and structure such Third Party License Agreement in a fair and equitable manner, taking into consideration the manner in which such license rights are to be used, and, unless otherwise mutually agreed by the Parties, shall not structure any such arrangement with the purpose or effect of shifting to one Party or the other the amount of Payments to Third Parties for which either Party will be responsible (if any) pursuant to this Agreement.

5.8.5 The terms of a Third Party License Agreement for one or more Major Markets, and any amendment thereto, must be approved by the JSC prior to execution thereof.

5.8.6 SGI shall promptly notify Genmab via discussion at the JSC or any Committee charged with oversight for intellectual property matters, or between the Alliance Managers, if SGI believes that Patent or other intellectual property rights controlled by a Third Party (but not already Controlled by a Party) may be necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Product in or for one or more countries in the Royalty Territory. Prior to execution, SGI will discuss with Genmab any proposed Third Party License Agreement for one or more countries in the Royalty Territory and SGI will consider any Genmab input thereon in good faith, but, for the avoidance of doubt, SGI may enter into one or more Third Party License Agreements for one or more countries in the Royalty Territory in its sole discretion; provided, that neither Party is aware of equivalent Third Party intellectual property rights that exist outside of the Royalty Territory which may be necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Product in or for one or more Major Markets. In case such equivalent Third Party intellectual property rights exist outside of the Royalty Territory, any Third Party License Agreement with respect to the Royalty Territory and Major Market(s) shall be handled in accordance with Sections 5.8.1 to 5.8.5.

5.9 Payment to Third Parties.

5.9.1 All Payments to Third Parties (i) (A) if triggered by Development activities directed towards obtaining Regulatory Approval of the Product in the Major Markets, shall be included as Development Costs for the Product, and (B) if triggered by Development activities directed towards obtaining Regulatory Approval of a Product in the Royalty Territory, shall be borne solely by SGI and (ii) (A) if triggered by Commercialization of a Product in a country in the Major Markets, shall be treated as Allowable Expenses for the Product, and (B) if triggered by Commercialization of a Product in a country or territory in the Royalty Territory, shall be borne solely by SGI. If a given Payment to Third Parties is not triggered by territory-dependent activities (e.g., an upfront payment), then a reasonable portion of such Payment to Third Parties shall, (X) to the extent directly attributable or reasonably allocable to the Major Markets, be treated as an Allowable Expense for the Product and (Y) to the extent directly attributable or reasonably allocable to the Royalty Territory, be borne solely by SGI.

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5.9.2 Genmab represents and warrants to SGI, as of the Effective Date, that the copies of the [*] Agreement and the [*] Agreement provided to SGI prior to the Effective Date are true, complete (except for redactions relating to products other than the Product), and correct in all respects, and that neither Genmab nor its Affiliates are party to any other agreement or arrangement, whether written or oral, that either would or would be reasonably likely to result in Payments to Third Parties following the Effective Date. SGI warrants to Genmab, as of the Effective Date, that neither SGI nor its Affiliates are party to any agreement or arrangement, whether written or oral, that either would or would be reasonably likely to result in Payments to Third Parties following the Effective Date. For clarity, and without limiting the definition of "Payments to Third Parties," the foregoing is not intended to extend to payments to be made to subcontractors of either Party.

ARTICLE 6
MANUFACTURE AND SUPPLY

6.1 Overview. The provisions of this ARTICLE 6 shall apply to the Manufacture of the Product unless otherwise agreed by mutual Party Written Consent.

6.2 Global Manufacturing Plan. Prior to the Effective Date, the JDT adopted a Joint Development Plan and Joint Budget (each, as defined in the Collaboration Agreement) that govern the global Development, Manufacturing, and regulatory activities of the Parties with respect to the Product under the Collaboration Agreement. As promptly as practicable following the Effective Date, the JCMCT shall (a) update the portions of such Joint Development Plan and Joint Budget relating to Manufacturing and CMC Development to the extent necessary to (i) align the contents thereof with this Agreement and the Approved Plans hereunder, and (ii) otherwise reflect the global Manufacturing and CMC Development activities of the Parties with respect to the Product throughout the Territory, including the topics set forth in this Section 6.2, (provided that such plan and budget shall include a high-level summary prepared by SGI with respect to the Royalty Territory) and (b) submit such updated plan and budget to the JSC for approval (as approved by the JSC, such plan and budget, collectively, the "Global Manufacturing Plan"). Following its approval by the JSC, the Global Manufacturing Plan under this Agreement shall replace the portions of the Joint Development Plan and Joint Budget under the Collaboration Agreement for purposes of Manufacturing and CMC Development for the Product. On an annual basis, or more often as the Parties deem appropriate, the JCMCT shall prepare amendments to the then-current Global Manufacturing Plan, including any amendments proposed by SGI with respect to the Royalty Territory, for approval by the JSC. In the event of any inconsistency between the Global Manufacturing Plan and this Agreement, the terms of this Agreement shall prevail. The Global Manufacturing Plan shall include: (A) the Parties' global Manufacturing strategy for the Product to meet the forecasts set forth in the Approved Plans or otherwise agreed by the JCMCT, in each case, throughout the Territory, together with appropriate safety stock of key intermediates, drug substance and drug product; (B) a plan for CMC Development and other related activities, including activities related to process improvements that could materially impact cost, efficiency, or stability of supply, and line extensions; (C) a Supply Chain Management plan; and (D) a strategy for risk management and evaluating the need for second or additional source Manufacturing of the Product, including a plan for monitoring the performance of CMOs.

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6.3 Manufacturing Transition; Supply and Quality Agreements.

6.3.1 Notwithstanding any determinations of the JSC or the JCMCT made prior to the Effective Date, the Parties agree that SGI will be responsible for global Manufacturing for the Product following the Effective Date, subject to the oversight of the JCMCT and otherwise in accordance with the Global Manufacturing Plan and this Agreement; provided, that the Selling Party shall perform Packaging and Labeling and Sales and Distribution for the Product in such Party's Party Major Market(s) and, as to SGI, the Royalty Territory. Accordingly, [*] following the Effective Date, the JCMCT shall develop a plan to transition global Manufacturing for the Product (but not including Packaging and Labeling or any Sales and Distribution activities, in each case, for the Genmab Major Market) to SGI (the "Manufacturing Transition Plan"). The Manufacturing Transition Plan will provide for, where possible, the assignment or an appropriate delegation to SGI (including the grant of a sublicense to SGI, where appropriate), or other appropriate disposition or substitution consistent with this ARTICLE 6, of existing agreements between Genmab or its Affiliates and contract manufacturing organization ("CMOs") with respect to supply of the Product, which agreements are listed on Schedule 6.3 ("Existing Product CMO Agreements," and the relevant Third Party CMOs that are counterparties thereto, the "Existing Product CMOs"). Each Party shall use Commercially Reasonable Efforts to implement the Manufacturing Transition Plan and complete the transition of Manufacturing contemplated by this Section 6.3.1 as promptly as practicable, and in any event within the timelines contemplated therein. Unless otherwise agreed by the JSC, SGI shall continue to use the Existing Product CMOs for the Manufacturing of the Product in the Major Markets for the remaining terms of such Existing Product CMO Agreements. Without limiting the foregoing, with respect to Clinical Supply for the Major Markets, the JSC shall agree on whether to renew any then-existing agreements with CMOs (including the Existing Product CMOs) for the Clinical Supply of the Product or to transition the Clinical Supply of Product to an alternative CMO (or to a Party or its Affiliate, if so determined by the JCMCT in accordance with Section 6.4) at a reasonable time prior to the expiration of the remaining term of each then-existing agreement with a CMO for the Clinical Supply of the Product (including the Existing Product CMOs). With respect to the Commercial Supply of the Product for the Territory, the Parties acknowledge that Genmab is in the process of negotiating a commercial supply agreement with [*] for the Manufacture of the Product for the Territory, and that, subject to the consent of [*], Genmab and SGI will finalize the commercial supply agreement in close consultation with [*] after the Effective Date and, to the extent reasonably possible, the Parties shall make SGI the contracting party to such agreement instead of Genmab, or mutually agree on an alternative path to assign or transition such agreement to SGI.

6.3.2 Following the assignment, sublicensing, or other disposition of such Existing Product CMO Agreements to SGI in accordance with Section 6.3.1, the Parties shall (a) transition to a new clinical supply agreement and quality agreement that provide for SGI or its Affiliate to Manufacture and supply to Genmab Clinical Supply in accordance with Genmab's requirements for Clinical Supply and terminate the existing Clinical Supply Agreement and related quality agreement in connection with such transition, and (b) enter into a supply agreement (the "Commercial Supply Agreement") and quality agreement between SGI and Genmab, as contemplated by Section 6.2.1 of the Collaboration Agreement and consistent with this Agreement, setting forth the terms and conditions on which SGI or its Affiliate shall Manufacture and supply, or have Manufactured and supply, to Genmab Commercial Supply for the Genmab Major Market, and, in the case of the quality agreement, quality-related matters relating to such Manufacture.

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Such supply and quality agreements shall be prepared by or under the oversight of the JCMCT, but shall be mutually agreed and entered into by the Parties or their respective Affiliates. The terms and conditions of such supply agreement will set forth the details of a supply arrangement with financial terms that support the supply of Product and sharing of Manufacturing Costs consistent with this Agreement and otherwise reflect customary terms and conditions for the supply and quality of pharmaceutical products in the context of a collaboration with a profit sharing arrangement such as the Collaboration, including with respect to forecasting and ordering, payment terms, financial and compliance audits, the engagement of subcontractors, a fair and equitable allocation of Product between the Parties and their Affiliates in the event of any defects or Product shortfalls, and representations and warranties. Such quality agreement shall govern processes for product distribution holds, recalls, clinical holds, or market withdrawals (as set forth in Section 4.4) and any other quality control and quality assurance-related activities agreed between the Parties.

6.4 Existing CMOs; Second Source. The JCMCT will, from time to time, evaluate the need for a second or additional source for the Manufacturing (other than Packaging and Labeling), in whole or in part, of the Product or any component thereof (i.e., source(s) other than the then-current source(s) for such Manufacturing of the Product or its components) for specific countries globally, and make any recommendations agreed by the JCMCT with respect to the foregoing to the JSC for approval. Unless otherwise agreed by the JSC, the Parties shall continue to use the Existing Product CMOs for the Manufacturing of the Product in Major Markets as well as the Royalty Territory, and JSC approval shall be required before either Party engages in second or additional source Manufacturing for the Product.

6.5 Manufacturing Costs. In the event that the Parties develop a costing methodology for Manufacturing Costs under Section 1.71.2, such methodology shall be developed by the JCMCT and approved by the JFT before its application in a relevant Commercial Supply Agreement or other supply agreement entered into under this Agreement. SGI will be solely responsible for all Commercial Packaging and Labeling Costs and Manufacturing Costs for Product for the Royalty Territory, and after the expiration of the Royalty Term in a country, SGI will be solely responsible for those additional costs no longer included in [*] that are directly attributable or reasonably allocable to such country as set forth in Sections 1.3.4, 1.3.5 and 1.3.6.

6.6 Inventory. The Parties shall each track and record on a Quarterly basis their respective inventory of Product (including components thereof) and their respective costs of Packaging and Labeling to enable the calculation of Allowable Expenses and Development Costs for the Product. Each Party shall provide a report to the JFT and JCMCT of such inventory and costs on a Quarterly basis.

6.7 Product Shortfall; Allocation. In the event of any material Product shortfall or defect, the JCMCT will develop a methodology to fairly and equitably allocate Product supply between the Parties and their Affiliates on a global basis (with first priority given to the Major Markets relative to the Royalty Territory), and propose such global allocation and any changes thereto for review and approval by the JSC.

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ARTICLE 7
MEDICAL AFFAIRS ACTIVITIES

7.1 Overview. Subject to the Combined Major Market Medical Affairs Plan and oversight by the JMAT, JDC, JCC and the JSC, and the terms of this Agreement (including ARTICLE 3 with respect to Genmab's right to provide MSLs in the United States), each Party shall have the right and responsibility for Medical Affairs Activities in support of the Product in its Party Major Market(s) in accordance with this Agreement, including as provided in this ARTICLE 7, including by performing activities for such Party Major Market(s) as follows: (a) preparing materials for use in connection with Medical Affairs Activities in its Party Major Market(s), (b) preparing training materials and training programs for personnel engaged in such Medical Affairs Activities and implementing such training, and (c) making decisions with respect to its Party Tactical Matters in connection with such Medical Affairs Activities; provided, that, in each case ((a) through (c)), such activities shall be consistent with the Party Major Market Medical Affairs Plan, Combined Major Market Medical Affairs Plan, and US Coordination Plan, including the tactical and strategic matters described in such plans, and otherwise conducted in accordance with this Agreement (including ARTICLE 3 with respect to the United States). Notwithstanding the foregoing, each Party will be permitted to list the Product as part of its portfolio in any country in the Major Markets (including the other Party's Party Major Market(s)) in settings where the Party has a "corporate presence" (e.g., within a booth at a conference or congress), including by providing totems or videos with respect to the Product in any such setting; provided, that (i) any such totems or videos and any other signs or materials used by a Party in connection therewith comply with the Medical Affairs Plans, the Publication Charter and all other applicable terms and conditions of this Agreement, (ii) the activities of the Parties at conferences and congresses in the United States will be subject to the US Coordination Plan, and (iii) in any other country in the Major Markets, any request for information relating to the Product by an applicable HCP requesting information in the other Party's Party Major Market(s) will be referred to the other Party if practicable (i.e., the applicable HCP will be directed to the other Party's booth, if available).

7.2 Combined Major Market Medical Affairs Plan. The Medical Affairs Activities in support of the Product in the Major Markets shall be described in a plan and budget for Medical Affairs Activities and Medical Affairs Costs (a "Combined Major Market Medical Affairs Plan"). The JMAT shall prepare the first draft of the Combined Major Market Medical Affairs Plan for review and approval by the JSC at least [*] months prior to the first anticipated Launch of the Product in the Major Markets (as such date is reasonably projected by the JDC), and cover a period of [*] years ([*] year forecasted and [*] year projections). Once agreed by the JMAT, the JMAT shall recommend the Combined Major Market Medical Affairs Plan to the JSC for approval. The Combined Major Market Medical Affairs Plan shall be updated at least annually, and all updates and amendments shall be reviewed and approved by the JMAT and then submitted to the JSC for approval. The Parties shall agree on a timeline for conducting all such reviews and approvals that accommodates the Parties' respective planning and budgeting purposes and allows for necessary or reasonably useful coordination between the Committees. The Combined Major Market Medical Affairs Plan and subsequent revisions thereto will include, with respect to the Major Markets (a) the Parties' strategy for Medical Affairs Activities for the Product (including the relative responsibilities of the Parties with respect thereto), (b) an agreed range for the aggregate number of MSLs or MSL FTEs expected to be deployed in the

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Major Markets either by country or region as reasonably determined by the JMAT, (c) key performance indicators either by country or region, as reasonably determined by the JMAT, that the Parties shall implement, and that shall apply to the activities of the MSLs of each Party in the Major Markets, (d) such information as the JMAT believes necessary for the successful medical affairs support of the Product, such as overall medical strategy, the medical narrative, global advisory boards, publication plans, outcomes/real world evidence strategy, and strategy for investigator-initiated trials and investigator-sponsored research in the Major Markets, and (e) [*] year forecasts and projections for an additional [*] years for such topics included in the Combined Major Market Medical Affairs Plan. The topics included in the Combined Major Market Medical Affairs Plan will be presented both on a global basis across the Major Markets and on a regional basis. In the event of any inconsistency between (i) the Combined Major Market Medical Affairs Plan and this Agreement, the terms of this Agreement shall prevail and (ii) the Combined Major Market Medical Affairs Plan and a Party Major Market Medical Affairs Plan, the Combined Major Market Medical Affairs Plan shall prevail.

7.3 Party Major Market(s) Medical Affairs.

7.3.1 Party Major Market Medical Affairs Plans. The Medical Affairs Activities in support of the Product (a) in the SGI Major Markets shall be described in a high-level plan and corresponding budget (collectively, the "SGI Major Market Medical Affairs Plan") and (b) in the Genmab Major Market shall be described in a high-level plan and corresponding budget (collectively, the "Genmab Major Market Medical Affairs Plan"), in each case ((a) and (b)), that describe the strategy for Medical Affairs Activities for the Product in the corresponding Party Major Market(s). In addition, the SGI Major Market Medical Affairs Plan will incorporate the Medical Affairs Activities set forth in the US Coordination Plan. Each Party shall prepare their own Party Major Market Medical Affairs Plan and provide it to the JMAT, which shall review such plans for consistency with the Combined Major Market Medical Affairs Plan (subject to Section 2.10.5(c)). The initial draft of each Party Major Market Medical Affairs Plan shall be submitted to the JMAT within [*] of submission of the initial draft of the Combined Major Market Medical Affairs Plan to the JMAT in accordance with Section 7.2. The Party Major Market Medical Affairs Plans shall be updated at least annually, and all updates and amendments shall be reviewed and approved by the JMAT for consistency with the Combined Major Market Medical Affairs Plan. The Parties shall agree on a timeline for conducting all such reviews and approvals that accommodates the Parties' respective planning and budgeting purposes and allows for necessary or reasonably useful coordination between the Committees.

7.3.2 Medical Affairs Reports for the Major Markets. Within thirty (30) days after the end of each Quarter, each Party shall provide to the JMAT such information regarding the Medical Affairs Activities in support of the Product in its respective Party Major Market(s) as the JMAT or the other Party may reasonably request.

7.4 Medical Affairs Standards of Conduct.

7.4.1 Diligence; Compliance. Each Party shall carry out the tasks assigned to it under the Medical Affairs Plans in a timely and effective manner and in compliance with Applicable Laws and applicable industry compliance standards.

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7.4.2 Diligence Obligations. Each Party shall use Commercially Reasonable Efforts to perform Medical Affairs Activities in support of the Product in its Party Major Market(s) following obtaining Regulatory Approval therefor with respect to the applicable country or territory in accordance with and to the extent provided in the Combined Major Market Medical Affairs Plan, the applicable Party Major Market Medical Affairs Plan, and otherwise in accordance with this Agreement.

ARTICLE 8
REGULATORY MATTERS

8.1 Regulatory Matters.

8.1.1 Global Regulatory Plan. As part of the Global Development Plan, (a) the Parties, acting through the JRT and JDC, shall jointly prepare a global regulatory plan for the Product or the portions of the Global Development Plan describing the regulatory actions to be taken by each Party in the Territory (provided that such plan or portions of the Global Development Plan shall include a high-level summary prepared by SGI with respect to the Royalty Territory) (such plan or portions of the Global Development Plan are referred to herein as the "Global Regulatory Plan") and (b) each Party shall prepare a regulatory plan for the Product or the portions of the Global Regulatory Plan describing the regulatory actions to be taken by such Party in or for its Major Market(s) consistent with the Global Regulatory Plan and the strategic matters described therein (each, a "Party Regulatory Plan"), in each case ((a) and (b)), that describe how such activities shall be coordinated if necessary, including (i) the content of the Core Data Sheet for the Product (prepared in accordance with Section 8.1.6) that will be used to support global submissions to Regulatory Authorities, (ii) planned meetings with Regulatory Authorities regarding the Product, (iii) plans for INDs, Drug Regulatory Approval Applications, Regulatory Approvals and related filings for the Product, and (iv) the amount of annual or other fees projected to be assessed by Regulatory Authorities. Each Party Regulatory Plan shall be reviewed by the JRT for consistency with the Global Regulatory Plan (for clarity, if the JRT does not agree that a Party Regulatory Plan is consistent with the Global Regulatory Plan, such dispute will be escalated to the JDC and resolved in accordance with Section 2.10.5(b)). Without limiting the foregoing, the JRT (and JDC) shall coordinate with the JCMCT with respect to the regulatory aspects of CMC Development and the regulatory activities related to CMC Development that are addressed in the Global Development Plan and the Global Regulatory Plan. In the event of (x) any inconsistency between a Global Regulatory Plan and this Agreement, the terms of this Agreement shall prevail, and (y) any inconsistency between a Party Regulatory Plan and the Global Regulatory Plan, the terms of the Global Regulatory Plan shall prevail. For clarity, unless otherwise determined by the JRT, neither Party nor the JRT shall be obligated to prepare the Global Regulatory Plan or the Party Regulatory Plans as stand-alone planning documents, and as used in this Agreement, the terms "Global Regulatory Plan" and "Party Regulatory Plans" refer to the relevant content whether it is included in a stand-alone document, incorporated into an applicable Approved Plan, or otherwise.

8.1.2 Ownership. Notwithstanding Section 7.2 of the Collaboration Agreement, as between the Parties, legal title to and legal ownership of all INDs, Drug Regulatory Approval Applications, Regulatory Approvals and related filings for the Product (a) in the Genmab Major Market shall be held by Genmab or its Affiliates, and (b) in the SGI Major Markets and the

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Royalty Territory shall be held by SGI or its Affiliates (such Party holding legal title to and legal ownership of such materials in the applicable country or region being referred to as the "Lead Regulatory Party"); provided, that (i) Section 7.2 of the Collaboration Agreement shall not be superseded by this Agreement to the extent that this Agreement would otherwise reallocate responsibility with respect to regulatory materials relating to Drug Conjugation Technology (as defined in the Collaboration Agreement), and (ii) sponsorship of Clinical Trials and ownership of INDs during the conduct of Clinical Trials shall be in accordance with Section 4.6.2. Subject to the foregoing, to the extent any INDs, Drug Regulatory Approval Applications, Regulatory Approvals, and related filings for the Product existing as of the Effective Date (or at any time during the Term) are not owned by the Lead Regulatory Party under this Agreement, the other Party hereby assigns to the applicable Lead Regulatory Party all of its right, title, and interest in and to all such INDs, Drug Regulatory Approval Applications, Regulatory Approvals and related filings for the Product that it or any of its Affiliates owns. Such other Party shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary to effectuate such assignment.

8.1.3 Responsibilities. With respect to each country in the Territory, the Lead Regulatory Party shall, in accordance with the Global Regulatory Plan, Party Regulatory Plan (if applicable), and the terms and conditions of this Agreement: (a) be responsible for the day-to-day implementation of the regulatory activities required to obtain and maintain Regulatory Approval of the Product in the applicable country (provided that any decision to file a DAA for the Product anywhere in the Territory must be approved by the JSC); (b) subject to consistency with the Core Data Sheet, be responsible for labeling of the Product in the applicable country for which it is the Lead Regulatory Party; (c) take the lead with respect to communications with the Regulatory Authorities in such country; and (d) designate a representative to serve as the designated regulatory official for the Product in such country for purposes of receiving and delivering communications from the Regulatory Authorities in such country. The other Party will cooperate with the Lead Regulatory Party as reasonably necessary, and solely with respect to the Major Markets, the costs thereof will be Development Costs.

8.1.4 Regulatory Authority Submissions and Correspondence. In accordance with the Global Development Plan, Global Regulatory Plan, and Party Regulatory Plan (if applicable), the Lead Regulatory Party shall be responsible for the preparation of all documents and other correspondence to be submitted to Regulatory Authorities pertaining to the Product (other than the Core Data Sheet, which shall be subject to Section 8.1.6(a)). Solely with respect to the Major Markets, the Lead Regulatory Party shall provide to the other Party drafts of any material documents or correspondence to be submitted to a Regulatory Authority in a Major Market pertaining to the Product sufficiently in advance of submission so that the other Party may review and comment on such documents or correspondence prior to submission, and the Lead Regulatory Party shall take such comments under good faith consideration. Solely with respect to the Major Markets, the Lead Regulatory Party shall as promptly as practicable (and, in any event, within [*] Business Days of its receipt) provide the other Party with copies of any material documents or correspondence received from a Regulatory Authority in a Major Market pertaining to the Product. Neither Party shall be required to translate any documents received or submitted to a Regulatory Authority except to the extent required by such Regulatory Authority.

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8.1.5 Meetings with Regulatory Authorities. Subject to the Global Development Plan, the Global Regulatory Plan, and the Party Regulatory Plan (if applicable), the Lead Regulatory Party with respect to a country shall be responsible for conducting all meetings and telephone or video conferences related to the Product with Regulatory Authorities in such country, including all Product labeling discussions. To the extent permitted under Applicable Law and with the prior consent of the relevant Regulatory Authority, the other Party shall have the right to have [*] representative attend all such in-person meetings and material telephone conferences or videoconferences with Regulatory Authorities solely in the Major Markets, and to the extent practicable the Lead Regulatory Party shall schedule such meetings in consultation with the other Party to permit such attendance and participation by the other Party.

8.1.6 Approval of Core Data Sheet and CMC Information.

(a) Subject to the terms and conditions of this Section 8.1.6(a), SGI shall be responsible for preparing a draft Core Data Sheet for the Product and may propose amendments thereto from time to time during the Term. The JRT, together with the CDS Working Group, will (i) review a draft Core Data Sheet prepared by SGI and any amendments thereto proposed by SGI, and (ii) agree on a proposed version of the Core Data Sheet to submit to the JDC. The JDC will then review such version and approve a draft of the Core Data Sheet for submission to the JSC for the JSC's approval. The Core Data Sheet and any amendments thereto must be approved by the JSC. Notwithstanding the foregoing, each Party shall (A) be responsible for creating and updating the local product information for the Product in its Party Major Market(s) (and SGI shall have such responsibility for the Royalty Territory) and (B) solely with respect to such Party's Major Market(s) shall submit such information to the JRT and CDS Working Group. All such local product information (including with respect to the Royalty Territory) shall be subject to approval by the JSC if any substantive deviations are made from the then-current Core Data Sheet as last approved by the JSC. The JRT and CDS Working Group shall decide if any such local product information requires approval of the JSC. Notwithstanding anything herein to the contrary, (1) the Lead Regulatory Party shall be responsible for maintaining the Core Data Sheet, including local product information, for each country in the Territory for which it is Lead Regulatory Party, and (2) any changes to the local product information required by Applicable Law or a Governmental Authority in any Major Market may be made by the applicable Lead Regulatory Party irrespective of any Committee review or approval contemplated by this Section 8.1.6(a); provided, that any such changes shall be communicated by the applicable Party to the JRT and the CDS Working Group in a timely manner. For the avoidance of doubt, SGI shall be responsible for (x) maintaining the Core Data Sheet for each country in the Royalty Territory, (y) making any amendments thereto subject to JSC approval, and (z) creating, updating and maintaining any local product information for the Product for each country in the Royalty Territory without an obligation to obtain JSC approval unless such local product information would constitute a substantive deviation from the then-current Core Data Sheet as last approved by the JSC, in which case such local product information must be approved by the JSC. For clarity, the Core Data Sheet and any amendment thereto or local product information related thereto, in each case, that is approved by the JSC shall be deemed approved for all purposes under this Agreement irrespective of whether the JRT, CDS Working Group, or JDC formally approved a particular document or the information contained therein.

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(b) The JDC in collaboration with the JCMCT shall review and approve the CMC components of any Drug Regulatory Approval Application in the Major Markets; provided, that if the CMC components of any Drug Regulatory Approval Application for the Product in the Major Markets have previously been approved as set forth above, the Lead Regulatory Party may request permission from the JCMCT to submit such components (or subset thereof) to the applicable Regulatory Authorities without such prior review and approval (such permission to be granted only by the JCMCT).

8.1.7 Advertising and Promotion. The Lead Regulatory Party in the applicable country shall be the point of contact and the responsible Party for Regulatory Authorities with respect to any Promotional Materials relating to the Product consistent with the Combined Major Market Plans. Section 8.1.4 shall apply with respect to the other Party's rights to review and comment on any such correspondence with or submissions to Regulatory Authorities in connection therewith.

8.1.8 Drug Naming Regulatory Approvals. Subject to Section 11.2.1, the Lead Regulatory Party in the applicable country will take the lead in drug naming procedures with the Governmental Authorities and Regulatory Authorities relating to the Product consistent with Section 11.2. To the extent applicable, Section 8.1.4 shall apply with respect to the other Party's rights to review and comment on any such correspondence with or submissions to Regulatory Authorities in connection therewith, provided that such activities in the Major Markets are in accordance with the Combined Major Market Plans and performed in consultation with the other Party through the JRT or JDC.

8.1.9 Rights of Reference. The Lead Regulatory Party shall have the right to cross reference, file or incorporate by reference any regulatory submission or drug master file (and any data contained therein) for the Product, or any component thereof, made or maintained in any country in the Territory (including all Regulatory Approvals) by the other Party in order to support regulatory submissions that the Lead Regulatory Party is permitted or required to make under this Agreement for the Product and to enable either Party to fulfill its obligations, or exercise its rights, under this Agreement.

8.1.10 Notice of Inspection, Investigation or Inquiry. If any Governmental Authority, including any Regulatory Authority (a) contacts a Party with respect to the alleged improper Development, Manufacture, or Commercialization of the Product in the Territory, (b) conducts, or gives notice of its intent to conduct, a non-routine inspection at such Party's facilities (or the facilities of any clinical trial site or vendor) to the extent related to the Product, or (c) takes, or gives notice of its intent to take, any other regulatory or enforcement action with respect to any activity of such Party that could reasonably be expected to adversely affect any Development, Manufacture, or Commercialization activities with respect to the Product in the Territory, then such Party shall immediately notify the other Party of such contact, inspection or notice ("Product Inquiry Notice") within [*] Business Day of receipt thereof and shall to the extent reasonably practicable and permitted under any relevant subcontracting agreement permit the other Party to be present at the site of any such inspection, investigation or inquiry to be conducted by such Governmental Authority in connection with such Product Inquiry Notice. The contacted, inspected or notified Party ("Affected Party") shall provide such other Party with copies of all pertinent information and documentation issued by any such Regulatory Authority as promptly as

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practicable (and, in any event, within [*]) after receipt, and the other Party, through the JDC in collaboration with the JRT and/or JCMCT, as applicable, shall have the right to oversee and comment on the preparation of any responses that pertain to the Product; provided, that (i) where the time limit for a response to the competent Regulatory Authorities would prevent the Parties from consulting the JDC and JRT and/or JCMCT in advance of such response, the Affected Party shall immediately notify the other Party's representatives on JDC and JRT and/or JCMCT and send a copy of any response not later than [*] after the response to the competent Regulatory Authorities is submitted, and (ii) final decision-making authority with respect to such submissions shall belong to the Lead Regulatory Party unless otherwise set forth in the quality agreement contemplated by Section 6.3; provided, further, that any such responses that relate to critical issues or significant non-compliance may, to the extent practicable, be escalated by either Party to the JSC for review and approval of such responses on an expedited timeline to comply with time periods to respond as required by Applicable Law. For the avoidance of doubt, nothing in this Section 8.1.10 shall prevent the Lead Regulatory Party from taking any action reasonably necessary to comply with Applicable Law or address an urgent or serious health or safety matter.

8.2 Pharmacovigilance; Adverse Event Reporting. The Parties entered into a Pharmacovigilance Agreement, effective [*], covering the management of safety information, adverse event reporting and the maintenance of a global safety database with respect to the Product. Prior to the First Regulatory Approval of the Product, the Parties shall amend the existing pharmacovigilance agreement or enter into a new pharmacovigilance agreement to address the Commercialization and other activities with respect to the Product contemplated by this Agreement. The amended or new pharmacovigilance agreement, as applicable, shall provide that (a) SGI will maintain the global safety database for the Product and be responsible for drafting and submitting periodic reports to Regulatory Authorities in any country or jurisdiction for which it is the Lead Regulatory Party, and SGI will provide to Genmab copies of such reports throughout the Territory, (b) Genmab and SGI will exchange all safety data as provided in the pharmacovigilance agreement(s) for the purpose of Genmab maintaining a mirror copy of the SGI global safety database for the Product, and (c) Genmab will be responsible for drafting periodic reports to Regulatory Authorities in any country or jurisdiction for which it is the Lead Regulatory Party, and Genmab will provide to SGI copies of such reports. To the extent the terms and conditions of this Agreement conflict or are otherwise inconsistent with the terms of such pharmacovigilance agreement(s), the terms and conditions of the pharmacovigilance agreement(s) shall prevail with respect to drug safety matters (including adverse event reporting or the maintenance of a global safety database) and the terms and conditions of this Agreement shall prevail with respect to all other matters.

ARTICLE 9
COMPLIANCE

9.1 Compliance. In connection with all activities undertaken pursuant to this Agreement or otherwise relating to the Product, each Party hereby covenants and agrees to comply, and cause its Affiliates to comply, with the then-current Pharmaceutical Research and Manufacturers of America (PhRMA) Code or such similar industry code as may exist in each country or jurisdiction in the Territory in which such Party undertakes activities under this Agreement, including the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (EFPIA HCP Code), the EFPIA HCP/HCO

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Code on Disclosure of Transfers of Value From Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (EFPIA Disclosure Code) and the codes of conduct approved by the national industry associations of the individual EFPIA member countries (the "Industry Codes"), and (c) all Applicable Laws. In particular:

9.1.1 Each Party shall (a) instruct its personnel not to, and shall ensure that its personnel do not, take any action that could jeopardize the goodwill or reputation of the Product or the other Party (or any of this Affiliates), (b) maintain a corporate compliance program that includes a mechanism for its employees to report, anonymously if they choose (and where legally permissible), any concerns about potential illegal or out-of-policy activity, and that will require such Party to investigate any such reports, and (c) immediately notify the other Party of the substance of any such report in the event that (i) such report concerns illegal activity that potentially impacts the Product, and (ii) such Party has a reasonable basis for believing such report has merit; provided, that, in each case ((i) and (ii)), a Party shall not be required to disclose any information regarding individual employees alleged to have violated any Applicable Laws, or to have failed to comply with this Agreement, except to the extent necessary to report the resolution of alleged violation of Applicable Laws or failure to comply with this Agreement.

9.1.2 In performing the activities contemplated by this Agreement, neither Party shall make any payment, either directly or indirectly, of money or other assets (hereinafter collectively referred as a "Payment") to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively referred as "Officials") where such Payment would constitute violation of any Applicable Law or the applicable Industry Codes. In addition, no Party shall make any Payment, either directly or indirectly, to Officials if such Payment is for the purpose of unlawfully influencing decisions or actions with respect to the subject matter of this Agreement. No employee of a Party or its Affiliates shall have authority to give any direction, either written or oral, relating to the making of any commitment by such Party or its agents to any Third Party in violation of terms of this Section 9.1.2 or any other provision of this Agreement.

9.1.3 With respect to the Product, each Party must track and report (a) all payments made by that Party or any of its Affiliates to health care providers and health care organizations, and (b) such other information as may be required to comply with its obligations under Applicable Law or the applicable Industry Codes.

9.1.4 Genmab and SGI agree to abide by all Data Protection Laws with respect to their processing of personal data in the course of their performance under this Agreement. Upon the reasonable request by either Party, the Parties shall negotiate and enter into such mutually agreeable data protection agreement(s), or amend that certain [*] Data Processing Agreement, dated as of [*], by and between the Parties, to further clarify their respective roles in complying with the Data Protection Laws.

9.1.5 Genmab and SGI agree to abide by all Applicable Law of all applicable Governmental Authorities, including antitrust and competition laws with respect to not restricting passive sales among EU member states.

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9.1.6 Each Party agrees to provide any information or documentation related to this Agreement or the activities hereunder required by the other Party in order to enable such other Party to comply with Applicable Law or any Third Party agreements relating to the Collaboration.

9.2 Export. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries which may be imposed upon or related to SGI or Genmab from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental Regulatory Approval, without first obtaining the written consent to do so from the appropriate Governmental Authorities.

ARTICLE 10
REPRESENTATIONS AND WARRANTIES; COVENANTS

10.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party, as of the Effective Date, that:

10.1.1 Corporate Power. It is duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.

10.1.2 Due Authorization. It is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person(s) executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action.

10.1.3 Binding Agreement. This Agreement is legally binding upon it and enforceable against it in accordance with its terms. The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may otherwise be bound, nor violate any material law or regulation of any Governmental Authority having jurisdiction over it.

10.1.4 No Conflicts. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder do not and will not (a) conflict with or violate in any material respect any requirement of Applicable Law or any judgment, decree, order, regulation, or rule of any Governmental Authority by which such Party is bound or subject; (b) conflict with or violate the organizational documents of such Party; or (c) result in a breach (or any event which, with notice or lapse of time or both, would constitute a breach) of any material term or provision of, or constitute a material default under any contractual obligations of, such Party or any of its Affiliates.

10.2 No Debarment. In the course of the Development of the Product pursuant to the Collaboration Agreement, each Party has not used and, during the Term, will not use, any employee or consultant that is debarred, disqualified, or restricted by any Governmental Authority or Regulatory Authority or, to the best of such Party's knowledge, is the subject of

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debarment, disqualification, or restriction proceedings by any Governmental Authority or Regulatory Authority. If either Party learns that it or any employee or consultant performing services on its behalf under this Agreement has been debarred, disqualified, or restricted by any Governmental Authority or Regulatory Authority, or has become the subject of debarment, disqualification, or restriction proceedings by any Governmental Authority or Regulatory Authority, such Party shall promptly notify the other Party and, in the case of an employee or consultant, shall prohibit such employee or consultant from performing on its behalf under this Agreement.

10.3 DISCLAIMER. NEITHER PARTY MAKES ANY EXPRESS OR IMPLIED REPRESENTATION OR WARRANTY EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 10 OR ELSEWHERE IN THIS AGREEMENT, INCLUDING ANY REPRESENTATION OR WARRANTY REGARDING THE VALIDITY OR SCOPE OF ITS PATENT RIGHTS OR THAT THE MANUFACTURE, USE OR SALE OF THE PRODUCT WILL NOT INFRINGE THE PATENT RIGHTS OF THIRD PARTIES, OR ANY REPRESENTATION OR WARRANTY AS TO THE VALUE, ADEQUACY, FREEDOM FROM FAULT OF, OR QUALITY, EFFICIENCY, CHARACTERISTICS OR USEFULNESS OF, OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF, THE PRODUCT, THE LIKELIHOOD OF RECEIVING REGULATORY APPROVAL FOR THE PRODUCT IN ANY JURISDICTION, OR THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF THE PRODUCT UNDER THIS AGREEMENT WILL BE SUCCESSFUL.

ARTICLE 11
INTELLECTUAL PROPERTY

11.1 Copyrights. All copyrights for Promotional Materials or other Product-specific packaging, educational or training materials, in each case, jointly prepared or authored by or for the Parties or their respective Affiliates in furtherance of the Collaboration shall be jointly owned by the Parties; provided, that (a) such materials may not be used outside the Collaboration without the Party Written Consent of the other Party and (b) the foregoing shall not affect or constitute a waiver of any copyright rights that a Party may have in its individually owned materials that were incorporated into a jointly owned copyrighted material.

11.2 Product Trademarks.

11.2.1 Both Parties shall use the same brand name and associated trademarks for the Product in all countries in which the global trademark can reasonably be secured. The Product shall be sold under the same trademark and a generic or international non-proprietary name, and marketed using same logos, slogans, trade dress, domain names, and other similar intellectual property rights throughout the Territory to create a worldwide brand for the Product unless a Party has good cause to use a different brand name (such as for regulatory, inability to secure registration, or Third Party infringement reasons) in a country or territory where it is the Selling Party, informs the JCC thereof, and the JCC approves thereof (excepting the generic or international non-proprietary name, hereinafter, "Product Trademarks"); provided, that the Product Trademarks shall not use, be comprised of, or incorporate the [*] (hereinafter, "Other Marks") without SGI's or Genmab's, as applicable, prior Party Written Consent. For clarity,

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"Other Marks" includes [*]. The Product Trademarks shall be initially jointly owned by the Parties worldwide and the initial applications for registration for such Product Trademarks shall be filed and prosecuted by the Parties jointly using outside counsel mutually acceptable to the Parties (with the associated costs of engaging such outside counsel included in Trademark Costs); except that the domain names included in the Product Trademarks will be owned solely by and registered in the name of one Party (as determined by the JCC), and such Party shall be deemed the "Trademark Owner" (as defined below) with respect thereto. Upon registration of the Product Trademarks in the applicable country or territory, the Parties shall assign such Product Trademarks (a) to [*] (the applicable Party, the "Trademark Owner"). All registrations for Product Trademarks shall be maintained by the Trademark Owner (at its expense; provided, that Out of Pocket Costs of such maintenance for the Major Markets shall be treated as Trademark Costs). The Parties agree to handle Trademark Costs for the Product under this Agreement such that SGI or Genmab will pay its outside counsel, as applicable, and (i) to the extent such Trademark Costs are directly attributable or reasonably allocable to the Major Markets, the other Party will reimburse the paying Party [*] of such Trademark Costs paid to such outside counsel (ii) to the extent such Trademark Costs are directly attributable or reasonably allocable to the Royalty Territory, solely if Genmab was the paying party with respect to such Trademark Costs, SGI shall reimburse Genmab for all such costs paid to its outside counsel. Each Party agrees that it will use the trademark registration symbol ® or TM, as appropriate, in connection with the Product Trademarks. Genmab and SGI agree to cooperate with respect to execution and delivery of such additional instruments or documents as shall be necessary to ensure each Party's rights and interest in and to the Product Trademarks.

11.2.2 Each Party agrees to maintain suitable quality standards with respect to the Product it provides in connection with the Product Trademarks. Neither Party shall use outside the Collaboration any trademark that is substantially the same as or deceptively or confusingly similar to the Product Trademarks.

11.2.3 This Section 11.2 supersedes Section 14.6 of the Collaboration Agreement with respect to the Product.

11.3 Infringement of Trademarks.

11.3.1 Defense of Third Party Trademark Claims. Each Party shall notify the other Party promptly upon learning of any actual or alleged infringement, or of any unfair trade practices, trade dress imitation, passing off of counterfeit goods or like offenses or any such claims thereof relating to the Product Trademarks brought by a Third Party against a Party or any of its Affiliates (hereinafter "Trademark Infringement Claims"). Upon learning of such Trademark Infringement Claim, the Party or Parties against which such claim is made shall take all reasonable and appropriate steps to resolve the Trademark Infringement Claim, and give reasonable consideration to the other Party's suggestions regarding such Trademark Infringement Claim. All Out of Pocket Costs incurred in bringing, maintaining and prosecuting any action described in this Section 11.3.1 (including for outside counsel) shall be (a) included in [*] to the extent such Trademark Infringement Claim relates to the [*] Markets and (b) otherwise borne solely by [*] for the [*]. The non-resolving Party shall cooperate with the resolving Party in connection with any Trademark Infringement Claims, and all reasonable fees and expenses incurred for outside counsel and other reasonable Out of Pocket Costs incurred by such Party in providing such cooperation

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shall be (i) included in [*] to the extent such Trademark Infringement Claim relates to the [*] Markets and (ii) otherwise borne solely by [*] for the [*].

11.3.2 Enforcement of Product Trademarks. Each Party shall notify the other Party in writing promptly upon learning of any actual or alleged infringement by any Third Party of any Product Trademark of which it becomes aware. The Trademark Owner shall have the first right, but not the obligation, to control the prosecution of any such infringement in consultation with and subject to oversight by the JCC. If the Trademark Owner does not initiate an infringement action within [*] after learning of the infringement or within [*] prior to any applicable deadline for taking action, then the other Party shall have the right, but not the obligation, to bring such an action in consultation with and subject to oversight by the JCC. In the case of a jointly-owned trademark, neither Party shall have the right to settle any infringement action under this Section 11.3.2 in a manner that diminishes the rights or interests of, or imposes any liability on, the other Party without the prior Party Written Consent of such other Party. The expenses of defense, settlement and judgments in actions governed by this Section 11.3.2 shall be [*] (to the extent not reimbursed through recoveries from such litigation) to the extent related to the [*] Markets, and shall be borne solely by [*] to the extent related to the [*]. The costs and expenses of the Party bringing suit under this Section 11.3.2 shall be reimbursed first out of any damages or other monetary awards recovered in favor of Genmab or SGI (if such recovery is less than the Parties' aggregate costs and expenses incurred in such action, such recovery shall be allocated between the Parties on a pro rata basis based on their relative costs and expenses incurred in such action). The Party that does not control the action or suit hereunder shall cooperate with the controlling Party in connection with such action or suit. Any damages or other monetary awards remaining after payment of the Parties' expenses shall be allocated between the Parties in the same proportion as they share in Net Profit/Net Loss hereunder to the extent related to the [*] Markets, and shall be retained solely by [*] to the extent related to the [*].

11.4 Domain Names. Subject to Section 11.2.1, the Parties shall use a common domain name incorporating the same brand name for the Product worldwide. The Parties shall jointly select domain names and will coordinate filing and registering such names; provided, that all such registered domain names shall be owned solely by and registered in the name of one Party as provided in Section 11.2.1.

11.5 No Implied Licenses. No right or license under any Genmab Technology or SGI Technology or any Product Trademark or Other Mark is granted or shall be granted by implication as a result of the respective rights of the Parties under this Agreement. All such rights or licenses are or shall be granted only as expressly provided in this Agreement (or the Collaboration Agreement).

11.6 Defense of Third Party Patent Claims. Each Party shall notify the other Party promptly upon learning of any actual or alleged Patent infringement claim brought by a Third Party against a Party or any of its Affiliates with respect to activities conducted by such Party or its Affiliates for the Product hereunder (hereinafter "Patent Infringement Claims"). Upon learning of any Patent Infringement Claim, [*] shall take all reasonable and appropriate steps to resolve the Patent Infringement Claim, and give reasonable consideration to the other Party's suggestions regarding such Patent Infringement Claim. All Out of Pocket Costs incurred in bringing, maintaining and prosecuting any action described in this Section 11.6 (including for

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outside counsel) shall be (a) included in Patent Costs and included in the calculation of [*]. The non-resolving Party shall cooperate with the resolving Party in connection with any Patent Infringement Claims and all Out of Pocket Costs incurred for outside counsel and other Out of Pocket Costs incurred by such Party in providing such cooperation shall be (i) included in Patent Costs and included in the calculation of [*].

11.7 Amendment of Collaboration Agreement IP Provisions. For clarity, Article [*] of the Collaboration Agreement remain in full force and effect, subject to the following amendments:

11.7.1 Section [*] of the Collaboration Agreement is hereby amended and restated in its entirety as follows:

"[*] Subject to the oversight of the JSC under Section [*], Section [*], Section [*] and Section [*], in the event [*], each Party shall be responsible for and shall control the preparation, filing, prosecution, grant, maintenance and defense, of any patents and patent applications claiming [*] owned solely by it in accordance with Section [*] and [*], prepare, file, prosecute and maintain such patent rights in good faith consistent with its customary patent policy and its reasonable business judgment."

11.7.2 Section [*] of the Collaboration Agreement is hereby amended by inserting the following new Section [*] after Section [*]:

"[*] Notwithstanding the foregoing, the Parties agree that pursuant to the potential Commercialization of the Collaboration Product known as "Tisotumab Vedotin," which is defined as the "Product" in the Joint Commercialization Agreement between the parties dated October 19, 2020 ("Tisotumab Vedotin"), all (a) patent applications and patents listed under [*], and all patent applications and patents listed under [*], (b) [*], and (c) future patents issued from any such patent applications referred to in (a) or (b) above, and future patents issued from any continuation, continuation-in part [*], or divisional of any of the foregoing patent applications or any patent applications from which the patents in (a) or (b) issued, in each case to the extent Controlled by [*], and in each of (a) through (c) that are necessary or reasonably useful for the Development, manufacturing, or Commercialization of Tisotumab Vedotin (collectively, the [*]), shall be treated as if they were [*] pursuant to the procedures described in Section [*]."

11.7.3 Section [*] of the Collaboration Agreement is hereby amended [*] as follows:

"[*] shall have the right, [*], to determine the appropriate course of action to enforce patents claiming [*] owned solely by [*] in accordance with Section [*] and the [*] Patent Rights, or otherwise to abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce the [*] Patent Rights, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to the [*] Patent Rights. All monies recovered upon the final judgment or settlement of any such suit to enforce any [*] Patent Rights shall be

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retained by [*]. [*] shall fully cooperate with [*], in any action to enforce the [*] Patent Rights.

Notwithstanding the foregoing, the following shall apply if enforcement of the [*] Patent Rights arises in connection with a [*]: The Parties shall, subject to oversight of the JSC under Section 3.2.2(f), jointly determine the appropriate course of action (i) to enforce [*] and the [*] Patent Rights or otherwise to abate the infringement thereof, (ii) to take (or refrain from taking) appropriate action to enforce the [*] Patent Rights, (iii) to control any litigation or other enforcement action and (iv) to enter into, or permit, the settlement of any such litigation or other enforcement action for the [*] Patent Rights, in each of (i) through (iv) with respect to a [*]. The costs for any such actions shall be [*]. All monies recovered upon the final judgment or settlement of any such suit to enforce any [*] Patent Rights with respect to a [*] shall be [*]. Notwithstanding the foregoing, if the JSC cannot agree on enforcement of the [*] Patent Rights, with respect to a [*], the Party [*] shall have final decision-making authority with respect to enforcement [*].

In the case of an [*], if [*] fails to exercise its rights under this Section [*] to take any action to enforce the [*] Patent Rights or control any litigation with respect to the [*] Patent Rights with respect to the manufacture, use or sale by Third Parties of [*] within a period of [*] after the Parties receive reasonable notice of the infringement of the [*] Patent Rights, then [*] shall have the right to bring and control any such action [*], and permit the settlement of any such litigation or other enforcement action with respect to the [*] Patent Rights, so long as this does not adversely affect [*] rights under this Agreement. In such case, [*] recovered upon the final judgment or settlement of any such suit to enforce any [*] Patent Rights shall be [*]. In such a case, [*] shall cooperate fully with [*], in its efforts to enforce the [*] Patent Rights, including being joined as a party to such action if necessary. In no event may [*] assert an argument or settle a suit in a manner which would render a claim in the [*] Patent Rights invalid or unenforceable [*]."

11.7.4 Section [*] of the Collaboration Agreement is hereby amended [*] as follows:

"[*] shall have the right, [*], to determine the appropriate course of action to enforce [*] ([*] Patent Rights, and other than its interest in [*]), or otherwise to abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce such [*] Patents, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to such [*] Patents."

11.8 Patent Costs. The Parties agree to handle Patent Costs for the Product under this Agreement such that SGI or Genmab [*].

11.9 Court or Government Order or Decree. Notwithstanding any other provision in this Agreement, neither Party shall be required to take any action pursuant to this ARTICLE 11 that it reasonably determines in its sole judgment and discretion conflicts with or violates any court or government order or decree or any agreement with any Governmental Authority that it is then subject to or otherwise may create legal liability on the part of it.

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ARTICLE 12
AMENDMENT TO EXCLUSIVITY PROVISIONS OF COLLABORATION AGREEMENT

12.1 Overview. Without limiting any other amendments to the terms or conditions of the Collaboration Agreement that may be contained in this Agreement, the Parties agree that the Collaboration Agreement is hereby further amended as provided in this ARTICLE 12.

12.2 Amendments to Section 1.1 of the Collaboration Agreement. Section 1.1 of the Collaboration Agreement is hereby amended by inserting the following definitions following Section 1.1.132 thereof:

"1.1.133 "Acquired Party" has the meaning set forth in Section 3.4.4(a).

1.1.134 "Cease Activities for the Competing Product" has the meaning set forth in Section 3.4.3(ii).

1.1.135 "Competing Party" has the meaning set forth in Section 3.4.3.

1.1.136 "Grace Period Activities" has the meaning set forth in Section 3.4.3(ii).

1.1.137 "Divest" means, with respect to a Competing Product, (a) the sale of all right, title and interest in such Competing Product, including all technology, intellectual property and other assets relating solely thereto, to a Third Party, without the retention or reservation of any rights, license or interest (other than solely an economic interest) by the selling entity or its Affiliates; or (b) the complete termination or withdrawal of such Competing Product, or shut-down of such development program for such Competing Product, such that no technology, intellectual property or other asset solely relating thereto is used by the terminating entity or its Affiliates. "Divestiture" shall have a correlative meaning.

1.1.138 "Divestment Period" has the meaning set forth in Section 3.4.3(i).

1.1.139 "Genmab Sensitive Information" has the meaning set forth in Section 3.4.4(c).

1.1.140 "Required Notice Date" means, with respect to a Competing Product that a Competing Party obtains ownership, license, or other rights to as a result of a relevant transaction consummated by such Competing Party, [*] days after the consummation thereof.

1.1.141 "Segregate" means, with respect to a Competing Product, to use diligent efforts to segregate, consistent with best industry practices, the research, development, manufacture and commercialization activities relating to such Competing Product from research, Development, Manufacture and Commercialization with respect to any Licensed Product under this Agreement (including for clarity the "Product" as defined under the Joint Commercialization Agreement entered into between the Parties dated

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October 19, 2020 (the "Commercialization Agreement")), including using diligent efforts to ensure that: (a) no personnel involved in performing the research, development, manufacture or commercialization of such Competing Product have access to [*] (provided, that management personnel may [*]); and (b) no personnel involved in performing the research, Development, Manufacture or Commercialization of any Licensed Product have access to [*] (provided, that management personnel may [*]).

1.1.142 "SGI Sensitive Information" has the meaning set forth in Section 3.4.4(b)."

12.3 Amendments to Section 3.4 of the Collaboration Agreement. Section 3.4 of the Collaboration Agreement is hereby amended and restated in its entirety as follows:

"3.4 Exclusivity

3.4.1 Except as expressly set forth in this Agreement or the Commercialization Agreement, the Parties and their Affiliates shall work exclusively with each other to develop and commercialize Exclusive Products (for which the Opt-In Period has not yet expired) and Collaboration Products solely in accordance with the terms of this Agreement. Subject to the terms of this Agreement and the Commercialization Agreement, each Party shall be free to work alone or with Affiliates or Third Parties to research, develop, and commercialize any product that is not a Competing Product.

3.4.2 Except as expressly permitted in this Section 3.4, neither Party nor any of their respective Affiliates shall, directly or indirectly, perform research, conduct clinical development of, commercialize, or otherwise acquire rights to any Competing Product.

3.4.3 If a Party or any of its Affiliates, either as a result of an acquisition by such Party or its Affiliates of a Third Party or any of its business or assets, obtains ownership, license or other rights to a Competing Product (or, as a result of such acquisition, has as an Affiliate that has an ownership, license or other rights to a Competing Product), then such Party or its Affiliate (the "Competing Party") shall promptly notify the other Party in writing no later than the Required Notice Date that it is electing to:

(i) Divest itself of such Competing Product via a transaction in which such Party and its Affiliates no longer has an economic interest in the future sales of the Competing Product and notify the other Party in writing of such Divestiture; provided, that such Divestiture must be completed prior to (x) the expiration of [*] following the Required Notice Date in the case of a Competing Product that is [*], and (y) at least [*] prior to [*], in the case of a Competing Product that is [*] (the "Divestment Period"); or

(ii) (A) commit not to, and to cause its Affiliates not to, directly or indirectly, by itself or with a Third Party, market, promote, sell, manufacture or distribute for commercial sale such Competing Product, or (B) in the case of any such Competing Product with respect to which [*], cease engaging in such

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prohibited activities with respect to such Competing Product (in which event the Competing Party shall have a period of [*] after the Required Notice Date to sell off existing inventory or work-in-progress of the Competing Product) (the "Grace Period Activities") ((A) and (B) collectively, "Cease Activities for the Competing Product").

If the Competing Party notifies the other Party that it elects to Cease Activities for the Competing Product as set forth hereunder, the Competing Party shall immediately start to Cease Activities for the Competing Product. For clarity, if the Parties mutually agree in writing to an alternative arrangement (such as bringing the Competing Product under this Agreement or transitioning the Competing Party to a passive role hereunder), the Competing Party shall not be in breach of Section 3.4 to the extent it carries out the mutually agreed alternative arrangement. Moreover, in circumstances where the Competing Party notifies the other Party that it intends to Divest the Competing Product pursuant to Section 3.4.3(i) and fails despite using Commercially Reasonable Efforts to complete such Divestiture within the Divestment Period, the Competing Party shall not be in breach of this Section 3.4 if it Ceases Activities for the Competing Product after the end of the Divestment Period (provided, that in such circumstance the Competing Party shall have no further right to conduct the Grace Period Activities).

3.4.4 Change of Control

(a) Notwithstanding anything to the contrary herein, any intellectual property Controlled by any Person that becomes an Affiliate of a Party (the "Acquired Party") as a result of a Change of Control of such Acquired Party or its Affiliate shall not be Genmab Technology or SGI Technology, as applicable, unless (i) such technology or rights had been Controlled, prior to the Change of Control, by such Acquired Party or its Affiliate(s) that were Affiliate(s) prior to the Change of Control or (ii) with respect to any of the foregoing technology covered by patent rights, at least one named inventor was employed by such Acquired Party or its then Affiliate(s) immediately prior to the public announcement of the transaction(s) giving rise to such Change of Control.

(b) Following any Change of Control of Genmab or its Affiliates, in the event the applicable acquirer has, or has rights or an interest in, at the time of the Change of Control, a Competing Product, Genmab shall be required to, and shall cause its Affiliates to: (i) Segregate such Competing Product and (ii) establish reasonable firewalls to prevent disclosure of non-public plans or non-public information relating to the Development, Manufacturing or Commercialization of any Licensed Product or any Confidential Information of SGI (collectively, the "SGI Sensitive Information") beyond personnel of Genmab or its Affiliates who continue to actively perform obligations under this Agreement, and to prevent the dissemination of SGI Sensitive Information disclosed after the Change of Control of Genmab or its Affiliates to such acquirer or its Affiliates. For clarity, the foregoing will not apply to any SGI Sensitive Information that is not Confidential Information under Section 13.1 or "Confidential Information" (as such term is defined under the Commercialization Agreement). Notwithstanding

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the foregoing, following such Change of Control of Genmab or its Affiliates, Genmab will be allowed to provide information regarding the amount of financial payments (including the underlying reports provided hereunder) from SGI to Genmab hereunder to such acquirer or its Affiliates.

(c) Following any Change of Control of SGI or its Affiliates, in the event the applicable acquirer has, or has rights or an interest in, at the time of the Change of Control, a Competing Product, SGI shall be required to, and shall cause its Affiliates to (i) Segregate such Competing Product and (ii) establish reasonable firewalls to prevent disclosure of non-public plans or non-public information relating to the Development or Commercialization of any Licensed Product or any Confidential Information of Genmab (collectively, the "Genmab Sensitive Information") beyond personnel of SGI or its Affiliates who continue to actively perform obligations under this Agreement, and to prevent the dissemination of Genmab Sensitive Information disclosed after the Change of Control of SGI or its Affiliates to such acquirer or its Affiliates. For clarity, the foregoing will not apply to any Genmab Sensitive Information that is not Confidential Information under Section 13.1 or "Confidential Information" (as such term is defined under the Commercialization Agreement). Notwithstanding the foregoing, following such Change of Control of SGI or its Affiliates, SGI will be allowed to provide the information regarding the amount of financial payments (including the underlying reports provided hereunder) from Genmab to SGI hereunder to such acquirer or its Affiliates.

3.4.5 In the period either prior to SGI's first Opt-In Notice or after any relevant Opt-Out Date, Genmab may use antibody-drug conjugates targeted to Tissue Factor, including ADCs, in studies designed to evaluate, research, develop or commercialize an antibody-drug conjugate with a target other than Tissue Factor; provided, that such studies are non-clinical in nature. At any other time during the Term, neither Party may use antibody-drug conjugates targeted to Tissue Factor in such studies without the prior written consent of the other Party, such consent not to be unreasonably withheld. The Parties agree that any ongoing activities initiated prior to SGI's first Opt-In Notice may be finalized according to the contemplated plan.

3.4.6 Notwithstanding anything to the contrary in this Agreement, Genmab shall be permitted to develop and commercialize, alone or with a partner, a [*] with specificity against Tissue Factor for diagnostic purposes. Genmab shall ensure that any agreements with Third Parties pertaining to the development, commercialization or licensing of such products contain provisions permitting the Parties to use such products to support the development and commercialization of Licensed Products, if appropriate. At any time during the Term, Genmab shall be permitted to use a [*] with specificity against Tissue Factor for research purposes. Following an Opt-Out Notice by SGI or if SGI does not exercise its Opt-In Right for the first Exclusive Product, Genmab shall be permitted to develop, alone or with a partner, a [*] with specificity against Tissue Factor for any purpose. Following an Opt-Out Notice by SGI or if SGI does not exercise its Opt-In Right for the first Exclusive Product, Genmab shall, alone or with a partner, be permitted to commercialize such [*] with specificity against Tissue Factor for any purpose after [*] of

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the date of First Commercial Sale in a Major Market Country of an Exclusive Product or Genmab Product."

ARTICLE 13
CONFIDENTIALITY

13.1 Confidentiality.

13.1.1 Confidential Information. For purposes of this Agreement, "Confidential Information" means all Information, documents (including unpublished patent applications), trade secrets, or materials supplied by the other Party or any of its Affiliates (the "Disclosing Party") under this Agreement, whether disclosed orally, visually, in writing or in any tangible or electronic form or media, that is confidential or proprietary and is marked or otherwise identified as "Confidential" or which the receiving Party or any of its Affiliates (the "Receiving Party") should reasonably recognize as being confidential. Confidential Information may be owned by the Disclosing Party or held by the Disclosing Party under an obligation of confidentiality to a Third Party. The terms of this Agreement and Information related directly to the Product shall be the Confidential Information of both Parties; provided, that Drug Conjugation Technology (as such term is defined in the Collaboration Agreement) will be Confidential Information of SGI. Confidential Information of a Party may also include information relating to such Party's or its Affiliates' research programs, development, marketing, manufacturing, regulatory matters, business practices and finances. Information shall not be considered Confidential Information to the extent that such Information:

(a) has been published or otherwise entered the public domain other than by breach by the Receiving Party of this ARTICLE 13 or directly or indirectly under any other agreement between the Parties that imposed obligations of confidentiality;

(b) has been disclosed to the Receiving Party by a Third Party that is not breaching any duty of confidentiality by disclosing the same; provided, that such Information was not obtained by such Third Party directly or indirectly from the Disclosing Party on a confidential basis;

(c) prior to disclosure by the Disclosing Party under this Agreement, the Collaboration Agreement or directly or indirectly under another agreement between the Parties that imposed obligations of confidentiality, was already in the possession of the Receiving Party, as demonstrated by the Receiving Party by competent written evidence; or

(d) was developed independently of and without reference to the Disclosing Party's Confidential Information, as demonstrated by the Receiving Party by competent written evidence.

13.1.2 Non-Disclosure Obligations. Except as otherwise provided in this ARTICLE 13, during the Term and for a period of [*] thereafter, each Party shall maintain in confidence, and use only for purposes as expressly authorized and contemplated by this Agreement, all Confidential Information supplied by or on behalf of the other Party or its Affiliates under this Agreement. Each Party shall use at least reasonable care, and in no event less than the

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same standard of care as it uses to protect its own Confidential Information, to ensure that its and its Affiliates' employees, agents, consultants and clinical investigators only make use of the other Party's or its Affiliates' Confidential Information for purposes as expressly authorized and contemplated by this Agreement or the Collaboration Agreement and do not make any unauthorized use or disclosures of such Confidential Information.

13.1.3 Permitted Disclosures. Notwithstanding Section 13.1.2, Confidential Information may be disclosed by the Receiving Party solely to the extent such Confidential Information:

(a) is permitted to be disclosed by prior written consent of the other Party;

(b) is disclosed in the filing, prosecution or maintenance of patents solely in accordance with this Agreement or the Collaboration Agreement, provided, that (i) such disclosure may be only to the extent reasonably necessary for such purpose and (ii) the Receiving Party complies with the obligations set forth in Section 13.1.2;

(c) is disclosed to a Regulatory Authority in accordance with this Agreement or as required by the Applicable Law to obtain or maintain a Regulatory Approval; provided, that such disclosure may be only to the extent reasonably necessary for such purpose;

(d) is deemed necessary by the Receiving Party to be disclosed to such Party's financial advisors, attorneys or independent accountants for the sole purpose of enabling such financial advisors, attorneys or independent accountants to provide professional advice to the Receiving Party; provided, that such Third Parties are bound by confidentiality and non-use obligations customary for the type of professional and are advised that the information being disclosed is confidential;

(e) is deemed necessary by the Receiving Party to be disclosed to accredited investors, lenders or bona fide potential acquirers or merger candidates in the context of due diligence investigations of such Party solely for the purpose of evaluating a potential business relationship; provided, that such Third Parties are bound by confidentiality and non-use obligations (i) customary for the type of recipient in the case of all recipients who are not potential acquirers or merger candidates, and (ii) contained in this Agreement, in the case of potential acquirers or merger candidates, but in no event pursuant to (i) or (ii) for a term of less than ten (10) years, and are advised that the information being disclosed is confidential;

(f) is deemed necessary by the Receiving Party to be disclosed to such potential Third Party(ies) for a Commercial License or Third Party License Agreement as permitted hereunder; provided, that any such potential Third Party is bound by obligations of confidentiality and limitations on use of such Confidential Information contained herein;

(g) is disclosed to a potential or bona fide collaborator or manufacturing, development or sales contractor or partner (including any Approved Subcontractor) but only to the extent directly relevant to the collaboration, contract or partnership;

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provided, that such collaborator, contractor or partner is bound by obligations of confidentiality and limitations on use of such Confidential Information contained herein; or

(h) is disclosed in accordance with Section 13.1.4.

Notwithstanding the disclosures permitted under subsections (a)-(h), such Confidential Information shall remain otherwise subject to the non-disclosure and non-use provisions of this ARTICLE 13.

13.1.4 Compelled Disclosure. Without limiting Section 13.1.3, if a Party is required by Applicable Law or the rules of any Securities Exchange to disclose Confidential Information of the other Party or any of its Affiliates, the Party being compelled shall (if not prohibited by Applicable Law from doing so) promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Without limiting Section 13.1.3, each Party agrees that it shall cooperate fully and in a timely manner with the other Party with respect to all disclosures to the Securities and Exchange Commission and any other governmental or regulatory agencies or Securities Exchanges, including requests for confidential treatment of Confidential Information of either Party included in any such disclosure.

13.2 Publicity. Neither SGI nor Genmab will, without the prior written consent of the other Party, issue any press release or make any other public announcement or furnish any statement to any Person (other than either Parties' respective Affiliates) concerning the existence of this Agreement, its terms and the transactions contemplated hereby, except for disclosures made in compliance with ARTICLE 13.

13.3 Securities Filings. In the event either Party proposes to file with the U.S. Securities and Exchange Commission or the securities regulators of any state or other jurisdiction under the Securities Act of 1933, the Exchange Act, or any other applicable securities law (the "Securities Exchanges") a registration statement or any other disclosure document which describes or refers to this Agreement, such Party shall notify the other Party of such intention and shall provide the other Party with a copy of relevant portions of the proposed filing not less than [*] Business Days prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto relating to this Agreement, and shall use reasonable efforts to obtain confidential treatment of this Agreement that the other Party requests be kept confidential, consistent with such Party's disclosure obligations under applicable securities laws.

13.4 Publications. Except as otherwise permitted pursuant to this ARTICLE 13, neither Party may publish, present or announce results of the Development of the Product either orally or in writing (a "Publication") without complying with the provisions of this Section 13.4. The other Party shall have [*] days from receipt of a proposed Publication to provide comments or proposed changes to the publishing Party. The publishing Party shall take into account the comments or proposed changes made by the other Party on any Publication and shall agree to designate employees or others acting on behalf of the other Party as co-authors on any Publication describing results to which such persons have contributed in accordance with standards applicable to authorship of scientific publications. If the other Party reasonably

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determines that the Publication would entail the public disclosure of such Party's Confidential Information or of a patentable invention, submission of the concerned Publication to Third Parties shall be delayed for such period as may be reasonably necessary for deleting any such Confidential Information of the other Party (if the other Party has requested deletion thereof from the proposed Publication) or the drafting and filing of a patent application covering such invention; provided, such additional period shall not exceed [*] days from the date the publishing Party first provided the proposed Publication to the other Party. In addition, any publications or presentations in any medium with respect to the Product or activities under this Agreement must comply with the publications charter agreed by the Parties under the Collaboration Agreement, as such charter may be updated or amended by the JMAT from time to time consistent with this Section 13.4 and the other terms and conditions of this Agreement (the "Publication Charter"). As amended, such Publication Charter shall apply to the Product, only, and not to any other Licensed Product under the Collaboration Agreement. In the event of a conflict between the terms of the Publication Charter and the terms of this Agreement, the terms of this Agreement shall prevail.

13.5 Existing Confidentiality Agreement. The Parties acknowledge that Article 13 of the Collaboration Agreement contains confidentiality and non-use provisions that shall remain in full force and effect solely with respect to information not related to the Product and the confidentiality provisions in this Agreement shall govern all information related to the Product from and after the Effective Date. Notwithstanding the foregoing, in the event of any conflict between the terms of Article 13 of the Collaboration Agreement and the terms of this Agreement, the terms of this Agreement shall control with respect to the matters related to the Product.

ARTICLE 14
TERM AND TERMINATION

14.1 Term. The term of this Agreement (the "Term") shall become effective on the Effective Date and shall remain in effect until expired or terminated as provided in this ARTICLE 14.

14.2 Expiration. This Agreement shall expire on country-by-country basis, on the date of complete and permanent cessation of Development, Commercialization and any other sale of Product in or for such country. For clarity, this Agreement shall expire in its entirety upon complete and permanent cessation of Development, Commercialization and any other sale of Product in all countries in the Territory. Upon expiration of this Agreement with respect to a country, the Collaboration Agreement will automatically terminate with respect to the Product with respect to such country, and neither Party shall Develop, Commercialize or otherwise sell the Product in or for the relevant country without the prior written agreement of the other Party.

14.3 Material Breach.

14.3.1 Breach. If either Party (the "Non-Breaching Party") believes that the other Party (the "Breaching Party") has materially breached its obligations under this Agreement, then the Non-Breaching Party may deliver notice of such material breach to the Breaching Party (a "Default Notice"). Such Default Notice may include an allegation from the Non-Breaching

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Party that the alleged material breach by the Breaching Party [*] (a "Fundamental Breach") or is a material breach of the Agreement affecting only (a) [*], (b) [*], (c) [*], or (d) [*] (each of (a) through (d), an "Affected Region" and the material breach with respect to such Affected Region, a "Regional Material Breach"). For clarity, it is possible that a material breach of this Agreement by a Party with respect to one or more countries may constitute a Fundamental Breach of this Agreement if the relevant material breach fundamentally frustrates the purpose of the Agreement as a whole. If the Breaching Party does not dispute that it has materially breached its obligations under this Agreement, then if the Breaching Party fails to cure such breach within [*] days after receipt of the Default Notice, or if such cure cannot reasonably be fully achieved within such [*] period and the Breaching Party has failed to commence curing such breach using diligent efforts to cure such breach as soon as reasonably practicable (not to exceed a total of [*] additional days), then, Section 14.3.2 shall apply. If a cure cannot reasonably be fully achieved within [*] days of receipt of a Default Notice and the Breaching Party has commenced using diligent efforts to cure such breach in accordance with this Section 14.3.1, Section 14.3.2 shall not apply for such time as is reasonably necessary to fully achieve the relevant cure so long as the Breaching Party is using diligent efforts to cure such breach; provided, that in no event shall the cure period extend for more than [*] after the date upon which the breaching Party receives the notice of such material breach from the other Party. If the Breaching Party disputes that it has (i) materially breached its obligations under this Agreement, (ii) failed to cure such breach, or (iii) failed to commence curing such breach using diligent efforts to cure such breach as provided in this Section 14.3.1, in each case, such dispute shall be resolved in accordance with ARTICLE 16. If, as a result of the application of such arbitration procedures, the Breaching Party is determined to be in material breach of its obligations under this Agreement (including, if applicable, a Fundamental Breach or a Regional Material Breach) and has failed to cure such breach within the foregoing time period as applicable (an "Adverse Ruling"), then, if the Breaching Party fails to complete the actions specified by the Adverse Ruling to cure such material breach within [*] after such ruling, or if such compliance cannot be fully achieved within such [*] and the Breaching Party has failed to commence compliance or has failed to use diligent efforts to achieve full compliance as soon thereafter as is reasonably possible, then Section 14.3.2 shall apply. During the pendency of any such dispute, all rights, remedies and cure periods relating to the dispute and any alleged breach shall be tolled, and all of the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.

14.3.2 Non-Breaching Party Right.

(a) Subject to Section 14.3.1, in the event of a Fundamental Breach, then upon written notice by the Non-Breaching Party, the Breaching Party will be deemed to have provided an Opt-Out Notice for the Product for purposes of Section 5.10 of the Collaboration Agreement and Sections 5.10.3 and 5.10.4 of the Collaboration Agreement shall apply. If a Fundamental Breach occurs and the Non-Breaching Party exercises its rights pursuant to Section 14.3.1 with respect thereto, then the second, third and fourth sentences of Section 5.10.3 of the Collaboration Agreement shall not apply, but instead the remainder of this Section 14.3.2(a) shall apply: The Breaching Party will not be refunded or repaid any amounts it has paid for the Development or Commercialization of the Product. In addition, the Breaching Party will remain responsible for its share of Development Costs and Allowable Expenses incurred with respect to the Product through [*] following the date of the Non-Breaching Party's exercise of its rights pursuant to this Section 14.3.2(a), to the extent such costs and expenses were incurred pursuant to

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applicable Approved Plans. Furthermore, for [*] after the date of such termination, the Breaching Party shall provide development, consultation or support work for the Product, as reasonably requested by the Non-Breaching Party, and the Non-Breaching Party shall reimburse the Breaching Party's FTE Costs for such work at the annual rate per FTE as in force between the Parties at such date.

(b) Subject to Section 14.3.1, in the event of a Regional Material Breach, then upon written notice by the Non-Breaching Party, the Affected Region(s) shall be deemed part of (i) if Genmab is the Non-Breaching Party, the "Genmab Royalty Territory" (operating mutatis mutandis as if such Affected Region(s) were included in the Royalty Territory except that Genmab would have the rights and obligations as if Genmab were SGI under this Agreement with respect to the Product in the Affected Region) for all purposes under this Agreement (and shall no longer be a Genmab Major Market, SGI's Major Market(s) or Royalty Territory, as applicable), and (ii) if SGI is the Non-Breaching Party, the Royalty Territory for all purposes under this Agreement (and shall no longer be Genmab's Major Market or SGI's Major Market(s)) and shall be treated in the same manner as any other countries in the Royalty Territory; provided, however, that in each of (i) and (ii), as applicable, all amounts otherwise payable to the Breaching Party with respect to Net Sales of the Product in the Affected Region that would apply pursuant to Section 5.2 shall be reduced by [*]; provided, further, that in no event shall the royalty rates set forth in Section 5.2.1 be reduced pursuant to Section 5.2.2, Section 5.2.3 and this Section 14.3.2(b) by more than [*], in the aggregate.

(c) If the Non-Breaching Party exercises its rights pursuant to Section 14.3.2(b), then promptly thereafter, the Parties will work together to and complete a transfer and assignment to the Non-Breaching Party of all regulatory documents, contracts, licenses, collaborations, materials and information that are reasonably necessary for the Non-Breaching Party to exercise such rights, which transfer and assignment shall be at the Breaching Party's sole cost and expense (which shall include the FTE Costs and Out of Pocket Costs incurred by the Non-Breaching Party to effect such transfer and assignment). In such case, the Breaching Party shall use Commercially Reasonable Efforts to transition all activities to be transferred or assigned to the Non-Breaching Party pursuant to this Section 14.3.2(c) as promptly as practicable.

(d) No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law or equity. Without limiting Section 14.3.1 or ARTICLE 16, in addition to the other rights of the Non-Breaching Party under this Section 14.3.2, the Non-Breaching Party may offset against amounts payable to the Breaching Party pursuant to this Agreement any damages resulting from such material breach.

14.3.3 No Termination. For clarity, unless otherwise expressly set forth in Section 14.3.2, the Parties agree that this Agreement will not be terminated pursuant to this Section 14.3 and the Breaching Party shall continue to be obligated to perform any activities not assumed by the Non-Breaching Party pursuant to Section 14.3.2 and shall continue to share in Net Profit/Net Loss or receive or pay royalties with respect to the Royalty Territory, as applicable, as set forth in this Agreement (subject to any adjustment made pursuant to Section 14.3.2 or as a result of dispute resolution hereunder).

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14.4 Termination of Co-Funding; Out-License of Product. For clarity, Section 5.10 of the Collaboration Agreement continues to apply to the Product; provided, the Opt-Out Date for the Product will be effective [*] after the Non-Continuing Party provides written notice to the other Party (such notice being irrevocable once provided), and the Continuing Party shall have the right to determine whether it will assume sole responsibility for Development and Commercialization of the Product. If the Continuing Party so elects, then, on and after the effective date of termination, the Product shall be treated as a Genmab Product (if Genmab is the Continuing Party) or an SGI Product (if SGI is the Continuing Party) and the terms of the Collaboration Agreement shall apply with respect to Product (including Section 5.10 of the Collaboration Agreement and the payment of royalties and milestones pursuant to Article 10 of the Collaboration Agreement).

14.5 Termination for Insolvency; Bankruptcy. Either Party may terminate this Agreement if, at any time, the other Party (a) shall file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, (b) proposes a written agreement of composition or extension of its debts, (c) shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within [*] days after the filing thereof, (d) shall propose or be a party to any dissolution or liquidation, or (e) shall make an assignment for the benefit of its creditors. Notwithstanding the foregoing, the Parties intend for this Agreement and the licenses granted herein to come within Section 365(a) of the United States Bankruptcy Code, and notwithstanding the bankruptcy or insolvency of SGI, this Agreement and the licenses granted herein shall remain in full force and effect so long as Genmab shall remain in material compliance with the terms and conditions hereof.

14.6 Remedies. Except as otherwise expressly provided herein, termination of this Agreement (either in its entirety or with respect to one (1) or more countries or other jurisdiction(s)) in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

14.7 Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, ARTICLE 1 (to the extent defined terms are used in any other surviving provisions), the first sentence of Section 3.7.5, Section 3.7.6, Section 4.5, Section 5.7 (and with respect to amounts owed or rights accrued prior to termination or expiration of this Agreement, Sections 5.1-5.6), Section 8.1.2, the last sentence of Section 10.2, Section 10.3, Section 11.1, Section 11.2 (with respect to ownership of Product Trademarks and use of Other Marks), Section 11.5, Section 11.7, ARTICLE 12, ARTICLE 13, this ARTICLE 14, ARTICLE 15, ARTICLE 16 and ARTICLE 17 of this Agreement shall survive the termination or expiration of this Agreement for any reason. For the avoidance of doubt, (a) the license granted by Genmab to SGI under Section 2.4.2 of the Collaboration Agreement with respect to the Product is subject to the terms and conditions of this Agreement in all respects, including with respect to the payment of royalties hereunder during the Royalty Term on a country-by-country basis, (b) such license with respect to the

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Product for the Royalty Territory shall survive the expiration of the Royalty Term under this Agreement on a country-by-country basis as a royalty-free, fully paid-up license, and (c) references to the "Commercialization Plan" in Section 2.4.2 of the Collaboration Agreement shall be deemed to be references to this Agreement. For the further avoidance of doubt, (i) the license granted by SGI to Genmab under Section 2.1.2 of the Collaboration Agreement with respect to the Product is subject to the terms and conditions of this Agreement in all respects, including (in the event that one or more Affected Region(s) have been deemed part of the Genmab Royalty Territory pursuant to Section 14.3.2(b)) with respect to the payment of royalties hereunder during the Royalty Term on a country-by-country basis, (ii) such license with respect to the Product for the Genmab Royalty Territory shall survive the expiration of the Genmab Royalty Term under this Agreement on a country-by-country basis as a royalty-free, fully paid-up license, and (iii) references to the "Commercialization Plan" in Section 2.1.2 of the Collaboration Agreement shall be deemed to be references to this Agreement.

ARTICLE 15
INDEMNIFICATION

15.1 Indemnification. Subject to Section 15.3, each Party shall defend, indemnify and hold harmless the other Party, its Affiliates and their respective directors, officers, employees and agents (collectively, such Party's "Indemnitees") from and against all liabilities, losses, damages, and expenses, including reasonable attorneys' fees and costs (collectively, "Losses"), resulting from all Third Party claims, suits, actions, or demands (collectively, the "Claims") to the extent that such Losses are incurred, relate to or arise out of (a) the material breach of any provision of this Agreement or any other agreement between the Parties with respect to the Product by the indemnifying Party or its Affiliate (or the inaccuracy of any representation or warranty made by such Party in this Agreement), (b) the gross negligence, recklessness or willful misconduct of the indemnifying Party or its Affiliate in connection with the exercise of its rights or the performance of its obligations under this Agreement, or (c) solely with respect to SGI as the indemnifying Party, SGI's Development, Manufacturing, and Commercialization of the Product in the Royalty Territory.

15.2 Indemnification Procedure.

15.2.1 A Party believing that it or its Indemnitees are entitled to indemnification under Section 15.1 (an "Indemnified Party") shall give prompt written notification to the other Party (the "Indemnifying Party") of the commencement of any Claim for which indemnification may be sought or, if earlier, upon the assertion of any such Claim by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Claim as provided in this Section 15.2 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually materially prejudiced as a result of such failure to give notice). Subject to any written agreement by the Parties to the contrary, within [*] after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Claim with counsel reasonably satisfactory to the Indemnified Party. If a Party believes that a Claim presented to it for indemnification is one as to which the Party seeking indemnification is not entitled to indemnification under Section 15.1, it shall so notify the Party seeking indemnification.

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15.2.2 If the Indemnifying Party elects to assume the defense of such Claim, the Indemnified Party may participate in such defense with its own counsel, with the fees and expenses to be paid by the Indemnified Party, unless the representation of such Indemnified Party by the counsel retained by the Indemnifying Party would be inappropriate due to actual differing interests between such Indemnified Party and any other party represented by such counsel in such proceedings, in which case the reasonable fees and expenses of such counsel shall be paid by the Indemnifying Party.

15.2.3 In any event, the Indemnifying Party shall keep the other Party reasonably apprised of the status of such Claim and the defense thereof (including by providing copies of pleadings and such other documents, information, and correspondence reasonably requested by the Indemnified Party) and shall consider in good faith recommendations made by the Indemnified Party with respect thereto.

15.2.4 The Indemnified Party shall not agree to any settlement of such Claim without the prior Party Written Consent of the Indemnifying Party. The Indemnifying Party shall not agree to any settlement of such Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party or adversely affects the Indemnified Party without the prior Party Written Consent of the Indemnified Party, which shall not be unreasonably withheld, conditioned or delayed.

15.3 Treatment of Manufacturing Losses. Notwithstanding anything to the contrary contained in this Agreement or the Collaboration Agreement, the Parties agree to share equally in that portion of Manufacturing Losses that is included as Allowable Expenses or Development Costs hereunder.

15.4 No Consequential or Punitive Damages. EXCEPT (A) FOR WILLFUL MISCONDUCT, (B) FOR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 13, AND (C) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 15 OR UNDER ANY RELATED MANUFACTURING AGREEMENT, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING BUSINESS INTERRUPTION, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE, IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS AGREEMENT OR ANY RELATED MANUFACTURING AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY OR THE USE OF THE PRODUCT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

15.5 Effect on Collaboration Agreement. For clarity, the provisions of this ARTICLE 15 shall supersede the provisions of Section 18.2 of the Collaboration Agreement with respect to any right to indemnification by either Party for Claims to the extent that such Claims relate to or arise out of this Agreement or the performance of obligations under this Agreement with respect to the Product.

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ARTICLE 16
DISPUTE RESOLUTION

16.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise that relate to decisions to be made by one or more of the Committees provided for herein or to the Party's respective rights or obligations hereunder. It is the desire of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to arbitration or litigation. To accomplish this objective, the Parties agree that, except for disputes regarding Party Tactical Matters or other matters for which a Party has final decision-making authority hereunder or as otherwise expressly provided in this Agreement, the dispute resolution procedures set forth in Section 23.3 of the Collaboration Agreement shall apply if and when a dispute arises under this Agreement; provided, that if such dispute is regarding a matter to be decided or agreed upon by a Committee as set forth herein, then the terms of Section 2.10.5 or Section 3.5.2, as applicable, shall first apply. For clarity, any dispute as to whether or not a matter (a) is a Party Tactical Matter, (b) requires Joint Committee Consent, (c) is a matter to which Section 2.10.5 applies, or (d) is subject to a Party's final decision-making authority hereunder shall be resolved, in each case ((a) through (d)), in accordance with this Section 23.3 of the Collaboration Agreement; except, that with respect to all dispute resolution procedures for matters hereunder to be resolved in accordance with Section 23.1 of the Collaboration Agreement, notwithstanding any provision in Section 23.1 of the Collaboration Agreement to the contrary, (i) the Parties agree that they will not challenge the jurisdiction or authority of the arbitration panel to decide the dispute or the arbitrability or admissibility of the relevant dispute and (ii) any dispute submitted to the arbitrator(s) that fell within the decision-making responsibilities of any Committee, Team, or Working Group in accordance with the terms of this Agreement, the arbitrator(s) must render their decision applying the substantive law of the state of New York and based on the principles of maximizing the value and reasonable commercial potential of the Product.

ARTICLE 17
MISCELLANEOUS

17.1 [*]. To the extent permissible under Applicable Law, each Party agrees that, during the Term, neither it nor any of its Affiliates that participates in or is responsible for activities for the Product pursuant to this Agreement shall [*] conducted by the other Party or any of its Affiliates under this Agreement [*] with such other Party or Affiliate and [*]. For purposes of the foregoing, [*]. This Section 17.1 shall not restrict either Party or any of its Affiliates from [*] or [*].

17.2 Maintenance of Records. Each Party shall, and shall require its Affiliates to, and shall use Commercially Reasonable Efforts to cause its permitted sublicensees and Approved Subcontractors to, keep and maintain accurate and complete records of activities performed by or on behalf of such Party or any of its Affiliates, permitted sublicensees and Approved Subcontractors in connection with its or their activities under this Agreement (including records for Patent purposes), as well as all records required by Applicable Law with respect to the Product, and shall make copies of such records available to the other Party upon request. The Parties' and their Affiliates' obligations under this Section 17.2 shall continue for the longer of

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(a) five (5) years following the activity with respect to which the applicable records relate and (b) any applicable time period under Applicable Law.

17.3 Force Majeure. No Party (or any of its Affiliates) shall be held liable or responsible to the other Party (or any of its Affiliates), or be deemed to have defaulted under or breached the Agreement, for failure or delay by such Party (or any of its Affiliates) in fulfilling or performing any term of the Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party (or any of its Affiliates), including fire, floods, embargoes, war, acts of war (whether war be declared or not), insurrections, epidemics, pandemics, riots, civil commotions, acts of God, earthquakes, or omissions or delays in acting by any Governmental Authority ("Force Majeure"); provided, however, that the affected Party shall (a) promptly notify the other Party in writing of the existence of the Force Majeure, and (b) exert all Commercially Reasonable Efforts to eliminate, cure or overcome any such Force Majeure and to resume performance hereunder promptly. Notwithstanding the foregoing, to the extent that an event of Force Majeure continues for a period in excess of [*], the affected Party shall promptly notify in writing the other Party of such continued event of Force Majeure and the Parties shall negotiate in good faith (i) a resolution of the event of Force Majeure, if possible, (ii) an extension by mutual agreement of the time period to resolve, eliminate, cure, or overcome such Force Majeure, (iii) an amendment of this Agreement to the extent reasonably possible, or (iv) an early termination of this Agreement. If the Parties do not reach such resolution within an additional [*] period (or such period is not extended by mutual agreement of the Parties), the non-affected Party may terminate this Agreement on [*] days advance written notice to the other Party. This Section 17.3 supersedes Section 19.1 of the Collaboration Agreement with respect to the Product.

17.4 Assignment. This Agreement may not be assigned or otherwise transferred, nor, except as expressly provided hereunder, may any right or obligations hereunder be assigned, transferred or delegated to any Third Party by either Party without the consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed; provided, however, that either Party may, without such consent but with notification, assign this Agreement and its rights and obligations hereunder [*]. Any permitted assignee shall assume all rights and obligations of its assignor under this Agreement. Any attempted assignment of this Agreement not in accordance with this Section 17.4 shall be void and of no effect. This Agreement shall be binding on, and inure to the benefit of, each Party, its successors and permitted assigns. This Section 17.4 expressly supersedes Section 20.1 of the Collaboration Agreement and shall apply mutatis mutandis with respect to the assignability of the Collaboration Agreement. Additionally, this Agreement may only be assigned together with the Collaboration Agreement (in its entirety or in its entirety with respect to the Product), and the Collaboration Agreement (in its entirety or in its entirety with respect to the Product) may only be assigned together with this Agreement.

17.5 Severability. Each Party hereby agrees that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties hereto shall substitute, by mutual Party Written Consent, valid provisions for such invalid provisions, in their economic effect, are sufficiently similar to the invalid provisions that it can be reasonably

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assumed that the Parties would have entered into this Agreement based on such valid provisions. In case such alternative provisions cannot be agreed upon, the invalidity of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid provisions.

17.6 Insurance. The insurance provisions of Article 22 of the Collaboration Agreement shall apply to the activities conducted hereunder.

17.7 Notices. All notices, consents or waivers under this Agreement shall be in writing and will be deemed to have been duly given when: (a) delivered in person; or (b) delivered by first class air mail or internationally recognized courier service, postage prepaid, addressed to the other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the address to the other Party in accordance with this Section 17.7. For clarity, this Section 17.7 is not intended to apply to day-to-day business communications made in the ordinary course.

For Genmab:

Genmab A/S
Attention: Head of Legal
Email: [*]

the address of Genmab as registered in the Danish Central Business Register (or any successors hereof)

or

the address of Genmab as registered at the Genmab's official homepage (currently www.genmab.com)

Invoices to Genmab: [*]

For SGI:

Seagen Inc.
21823 30th Drive S.E.
Bothell, WA 98021
Telephone: +1 (425) 527-4000
Facsimile: [*]
Email: [*]
Attention: General Counsel

With copies of invoices to:

Accounts Payable
21823 – 30th Drive SE

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Bothell, WA 98021
Email: [*]

17.8 Governing Law. The Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflict of law principles thereof that may dictate application of the laws of any other state or the United States.

17.9 Headings; Construction.

17.9.1 Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between each of them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption shall apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

17.9.2 The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include," "includes" and "including," the phrase "for example" and the abbreviation "e.g.," shall each be deemed to be followed by the phrase "without limitation." The word "will" shall be construed to have the same meaning and effect as the word "shall." The word "any" shall mean "any and all" unless otherwise clearly indicated by context. The word "or" is used in the inclusive sense (and/or) unless the context otherwise requires.

17.9.3 Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Applicable Law herein shall be construed as referring to such Applicable Law as from time to time enacted, repealed or amended, (c) any reference herein to any Person shall be construed to include the Person's successors and permitted assigns, (d) the words "herein," "hereof" and "hereunder," and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) references to "drugs" or pharmaceutical products or therapies include biological products or therapies, and (f) all references herein to Articles, Sections or Schedules, unless otherwise specifically provided, shall be construed to refer to Articles, Sections and Schedules of this Agreement. As used herein, the reference to an Article refers to all of the Sections under that Article.

17.9.4 The headings of Articles and Sections of this Agreement are for ease of reference only and shall not affect the meaning or interpretation of this Agreement in any way.

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17.10 No Third Party Beneficiaries. No Person other than Genmab, SGI and their respective Affiliates, successors and permitted assignees hereunder, shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

17.11 Entire Agreement; Amendment. This Agreement, together with the Schedules hereto, the Collaboration Agreement and the supply agreements, quality agreements, and pharmacovigilance agreements referenced herein, together with the exhibits and schedules thereto, contains the entire understanding of the Parties with respect to the specific subject matter hereof. All other express or implied agreements and understandings, either oral or written, heretofore made are expressly superseded. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties.

17.12 Relationship Between Agreements.

17.12.1 To the extent the terms and conditions of this Agreement conflict with the terms of the Collaboration Agreement or the supply agreements, quality agreements, pharmacovigilance agreements, and data protection agreements referenced herein, the terms and conditions of this Agreement shall prevail with respect to the Product; provided, that (a) the terms and conditions of such pharmacovigilance agreements shall prevail solely with respect to Product safety matters in accordance with Section 8.2, (b) the terms and conditions of such quality agreements shall prevail with respect to Product quality matters, and (c) the terms and conditions of such data protection agreements shall prevail with respect to personal data.

17.12.2 Notwithstanding anything to the contrary, the Collaboration Agreement may not be terminated with respect to the Product for so long as this Agreement continues to survive.

17.13 Independent Contractors. Notwithstanding anything contained herein to the contrary, SGI and Genmab each agree and acknowledge that they shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture, agency, or any type of fiduciary relationship. Neither SGI nor Genmab shall have the authority to make any statements, representations or commitments of any kind, or take any action, which shall be binding on the other Party, without the prior Party Written Consent of the other Party to do so.

17.14 Affiliates.

17.14.1 Except as provided in this Section 17.14, either Party may perform any or all of its obligations under this Agreement through one or more Affiliates (but only for so long as such Person is and remains an Affiliate of such Party); provided, that such Party shall remain fully liable for the obligations under this Agreement and any acts or omissions of such Affiliates. Each Party shall cause its respective Affiliates to comply fully with the provisions of this Agreement to the extent such provisions specifically relate to, or are intended to specifically relate to, such Affiliates, as though such Affiliates were expressly named as joint obligors hereunder. In addition, notwithstanding any limitations in the Collaboration Agreement, each Party shall have the right to extend the rights, licenses, immunities and obligations granted in this Agreement and the Collaboration Agreement to one or more of its Affiliates (but only for so long as such Person

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is and remains an Affiliate of such Party) and any such extension to Affiliates under the Collaboration Agreement prior to the Effective Date is hereby deemed approved. All applicable terms and provisions of this Agreement and the Collaboration Agreement shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to the extending Party.

17.14.2 To the extent required by Applicable Law, the Parties shall cause their relevant local Affiliates in any country in the Territory to enter into local agreements to implement the arrangements provided for in this Agreement. Such implementing agreements shall be in forms mutually agreed by the Parties and shall be, in all material respects, consistent with the terms and conditions of this Agreement, including by having termination provisions that are not inconsistent with ARTICLE 14.

17.15 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

17.16 Fees and Expenses. Except as otherwise specified in this Agreement, each Party shall bear its own costs and expenses (including investment banking and legal fees and expenses) incurred in connection with this Agreement and the transactions contemplated hereby.

17.17 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by delivery of electronically scanned copies of original signatures delivered by electronic mail, and such signatures shall be deemed to bind each Party as if they were original signatures; provided, that each Party shall also provide the other Party a hard copy of the executed Agreement.

{Signature Pages Follow}

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IN WITNESS WHEREOF, the Parties have caused this Joint Commercialization Agreement to be executed by their duly authorized representatives as of the Effective Date.

GENMAB A/S

By: _____
Jan van de Winkel
President & CEO

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IN WITNESS WHEREOF, the Parties have caused this Joint Commercialization Agreement to be executed by their duly authorized representatives as of the Effective Date.

SEAGEN INC.

By: _____
Clay B. Siegall, Ph.D.
President and Chief Executive Officer

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SCHEDULE 1.6
APPROVED SUBCONTRACTORS

For SGI:

Approved Subcontractor	Services/Functions:
[*]	[*]

For Genmab:

Approved Subcontractor	Clinical Trial(s)	Services/Functions
[*]	[*]	[*]

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SCHEDULE 1.44
EUROPE

The United Kingdom:

- England
- Scotland
- Wales
- Northern Ireland

EU:

- Austria
- Belgium
- Bulgaria
- Croatia
- Republic of Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden

EFTA:

- Iceland
- Liechtenstein
- Norway
- Switzerland

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SCHEDULE 3.1
GENMAB US ACTIVITIES

	US Commercialization and Medical Affairs Activities
1. Commercialization	▪ Genmab fields fifty percent (50%) of the Parties' aggregate Sales Representatives for the Product in the United States, as determined on an FTE basis.
2. Medical Affairs	▪ Genmab fields fifty percent (50%) of the Parties' aggregate MSLs for the Product in the United States, as determined on an FTE basis.
3. First and Second Line Management	▪ [*].

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SCHEDULE 5.3.4
CERTAIN U.S. FEDERAL INCOME TAX MATTERS

Section 1.1. Tax Partnership. The activities of the Partners pursuant to the Agreement in respect of the Development and Commercialization of the Product are deemed to be conducted by the Tax Partnership; provided that the activities of SGI and Genmab with respect to the Royalty Territory are deemed to be activities conducted by SGI and Genmab outside of the Tax Partnership. The partners of the Tax Partnership are SGI and Genmab (the "Partners"). The Tax Partnership, and the rights and obligations set forth in this Schedule 5.3.4, shall be effective beginning on the Tax Partnership Formation Date and shall remain in existence until the Agreement is terminated.

Section 1.2. Definitions. Capitalized terms used, but not defined, herein will have the meanings ascribed to them in the Agreement. For purposes of this Schedule 5.3.4:

(a) "Adjusted Capital Account" has the meaning set forth in Section 1.4(d) of this Schedule 5.3.4.

(b) "Book" means the method of accounting prescribed for compliance with the capital account maintenance rules set forth in Section 1.704-1(b)(2)(iv) of the Treasury Regulations, as distinguished from any accounting method which a Partner may adopt for other purposes such as financial reporting.

(c) "Budget Act" means Section 1101 of the Bipartisan Budget Act of 2015 and any Sections of the Tax Code or Treasury Regulations promulgated thereunder and with respect thereto, each as amended from time to time, and other guidance that may be promulgated in the future relating thereto.

(d) "Capital Account" has the meaning set forth in Section 1.4(a) of this Schedule 5.3.4.

(e) "Capital Contribution" means, for each Partner, such Partner's cash or property deemed contributed to the Tax Partnership.

(f) "Designated Individual" has the meaning set forth in Section 1.9(c) of this Schedule 5.3.4.

(g) "Fiscal Year" means the calendar year.

(h) "Gross Asset Value" means, with respect to any asset of the Tax Partnership, the asset's adjusted basis for federal income tax purposes, adjusted to reflect any adjustments required or permitted by Sections 1.704-1(b)(2)(iv)(d) through (g), (m) and (s) of the Treasury Regulations, as mutually agreed upon by the Partners; provided, that in the case of any asset (other than cash) deemed contributed to the Tax Partnership, the initial Gross Asset Value of such property shall be equal to the fair market value of such asset as of the date of contribution, as mutually agreed upon by the Partners.

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(i) "Net Income" and "Net Losses" shall mean the Book income, gain, loss, deductions and credits of the Tax Partnership in the aggregate or separately stated, as appropriate, as of the close of each Taxable Year on the Tax Partnership's tax return filed for federal income tax purposes (or other allocation period).

(j) "Partners" has the meaning set forth in Section 1.1 of this Schedule 5.3.4.

(k) "Partnership Representative" has the meaning set forth in Section 1.9(c) of this Schedule 5.3.4.

(l) "Tax Code" means the U.S. Internal Revenue Code of 1986, as amended.

(m) "Taxable Year" means the Tax Partnership's Fiscal Year or such other year as may be required by Section 706 of the Tax Code.

(n) "Treasury Regulations" means regulations (whether in final, proposed or temporary form) promulgated by the U.S. Department of the Treasury under the Tax Code, as amended.

Section 1.3. Capital Contributions.

[*]

Section 1.4. Capital Accounts.

[*]

Section 1.5. Distributions.

[*]

Section 1.6. Allocation of Net Income or Net Losses. [*].

Section 1.7. Regulatory Allocations.

[*]

Section 1.8. Tax Allocations.

[*]

Section 1.9. Tax Reports, Tax Elections, Partnership Representative and Designated Individual.

[*]

Section 1.10. Tax Information Sharing. [*].

Section 1.11. Tax Position. [*].

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Section 1.12. Termination of Tax Partnership. [*].

Section 1.13. Costs and Expenses. [*].

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SCHEDULE 6.3
MANUFACTURING

Existing CMO Agreements:

NAME OF THIRD PARTY CMO	ROLE	RELATIONSHIP PARTY	AGREEMENT
[*]	[*]	[*]	[*]

Pending CMO Agreements:

NAME OF THIRD PARTY CMO	ROLE	RELATIONSHIP PARTY	STATUS
[*]	[*]	[*]	[*]

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Exhibit 10.16

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED

COMMERCIAL SUPPLY AGREEMENT
SGD-1006

This Commercial Supply Agreement (this "Agreement"), effective as of the 1ST day of DECEMBER 2010 (the "Effective Date"), is entered into by and between:

Seattle Genetics, Inc., a company incorporated under the laws of Delaware, with its principal office located at 21823 - 30th Drive S.E., Bothell, Washington 98021 ("Company"); and

SAFC, an operating division of Sigma-Aldrich, Inc., a company incorporated under the laws of the State of Wisconsin, USA, with its principal office located at 3050 Spruce Street, St. Louis, Missouri 63103 ("SAFC").

Company and SAFC are hereinafter sometimes referred to separately as a "Party" or together as the "Parties".

RECITALS

WHEREAS, Company is engaged in the research and development of products, including SGD-1006 and the Finished Product, brentuximab vedotin (or SGN-35) (as such terms are hereinafter defined),

WHEREAS, SAFC develops, manufactures and sells a broad range of biochemicals and organic chemicals globally for use in pharmaceutical development and as key components in pharmaceutical and other high technology manufacturing;

WHEREAS, Company desires to engage SAFC to manufacture SGD-1006 at commercial scale for use in the Finished Product; and

WHEREAS, SAFC is willing to manufacture and supply to Company SGD-1006 upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the above premises and the mutual covenants and agreements contained herein, the Parties hereby agree as follows:

1. Definitions and Interpretation

1.1 "Affiliate" means any entity controlling, controlled by or under common control with either Party hereto. For purpose of this definition, "control" shall mean ownership of over fifty percent (50%) of the equity, the outstanding voting securities or other ownership interest of an entity, or the right to receive over fifty percent (50%) of the profits or earnings of an entity. In the case of non-stock organizations, the term "control" shall mean the power to control the distribution of profits.

1.2 "Analytical Methods" shall mean the set of validated analytical methods related to the Manufacturing of the SGD-1006 as provided by Company, or developed on behalf of Company, by SAFC.

1.3 "Applicable Laws" shall mean all laws, statutes, ordinances, codes, rules and regulations which have been enacted by a Regulatory Agency and/or are applicable to the Manufacture of SGD-1006.

1.4 "Batch or batch size" shall have the meaning of [*] of SGD-1006 or other quantities that may be mutually agreed to by both parties in the future.

1.5 "Batch Record" or "Master Batch Record" means the mutually agreed upon final batch production and control records for SGD-1006 prepared in accordance with Q7A guidelines.

1.6 "Commencement Date" means the date Company issues its initial binding written purchase order for the commercial supply of SGD-1006 under Section 3.2 below.

1.7 "Commercial Forecast" shall have the meaning set forth in Section 3.1 hereof.

1.8 "Compliance Level" shall have the meaning set forth in Section 2.9(b) hereof.

1.9 "Confidential Information" shall mean all the technical information, whether tangible or intangible, including (without limitation) any and all data, techniques, discoveries, inventions, processes, know-how, patent applications, inventor certificates, trade secrets, methods of production and other proprietary information, that either Party or any Affiliate of a Party has ownership rights to (as either owner, licensee or sub-licensee), or may hereafter obtain rights.

1.10 "Current Good Manufacturing Practices" or "cGMP" shall mean the FDA's current good manufacturing practices, as first published in the Federal Register and then specified in the Code of Federal Regulations and FDA's guidance documents, applicable to the manufacture of SGD-1006 and all successor regulations and guidance documents thereto, as well as the comparable practices, regulations and documents of any other comparable Regulatory Agency, as in effect from time to time, including the guidance document developed by the International Conference on Harmonization known as "Q7A Good Manufacturing Practice Guidance".

1.11 "Deviation" shall have the meaning set forth in the Quality Agreement.

1.12 "EMA" shall mean the European Medicines Agency of the European Union.

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1.13 "Facility" shall mean SAFC's facility located at [*].

1.14 "Failure to Supply" shall have the meaning set forth in Section 2.10(a) hereof.

1.15 "FDA" shall mean the United States Food and Drug Administration, and any successor thereto.

1.16 "Finished Product", "SGN-35" or "brentuximab vedotin" shall mean the finished dosage form drug product that contains the SGD-1006 as an active ingredient, in vials, labelled and packaged, ready for commercial sale.

1.17 "Fully Burdened Manufacturing Cost" shall have the meaning set forth in Section 5.5(b) hereof.

1.18 "Intellectual Property" means all inventions, discoveries, improvements, design rights, patents, trademarks, copyrights, trade secrets, know-how, and all other intellectual and industrial property rights of every kind and nature however designated, whether arising by operation of law, contract, license or otherwise, and any equivalents thereof, which are made, developed, conceived, reduced to practice, or created by or on behalf of a Party, or jointly by a Party with the other Party or with a third party, in connection with a Party's performance under this Agreement. Intellectual Property also means and includes all applications, registrations, renewals, extensions, continuations, continuations-in-part, divisions or reissues of any of the foregoing, now or hereafter existing, made or in force, and including any and all rights in any of the foregoing.

1.19 "Laboratory" shall have the meaning set forth in Section 4.2 hereof.

1.20 "Manufacture, Manufacturing or Manufactured" means all activities related to the manufacturing of SGD-1006, or any ingredient thereof in accordance with the terms and conditions of this Agreement and the Quality Agreement, which may include manufacturing SGD-1006 or supplies for development or commercial sale, packaging SGD-1006, in-process and final testing and release of SGD-1006, or any component or ingredient thereof, quality assurance activities related to manufacturing and release of SGD-1006 and regulatory activities related to any of the foregoing.

1.21 "Manufacturing Process" shall mean the instructions, specifications for raw materials and excipients, formulae, procedures, tests and standards developed, established and described by Company or developed by or for Company's use in Manufacturing SGD-1006.

1.22 "Marks" shall have the meaning set forth in Section 11.4 hereof.

1.23 "Minimum Lead Time" shall have the meaning set forth in Section 3.2(a) hereof.

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1.24 "OOS" (Out of Specification) shall have the meaning set forth in the Quality Agreement.

1.25 "Qualified Alternate Facility" shall have the meaning set forth in Section 2.9(a)(i) hereof.

1.26 "Quality Agreement" means the Quality Agreement between Company and SAFC attached hereto and incorporated herein by reference as Appendix 1.

1.27 "Regulatory Agency" means the FDA, the EMA, or any comparable national or territorial regulatory entity having substantially the same functions.

1.28 "[*]" has the meaning set forth in Section 2.9(a).

1.29 "SGD-1006" shall mean vcMMAE, in all instances meeting the Specifications, manufactured and sold by SAFC to Company.

1.30 "SGD-1006 Requirements" shall have the meaning set forth in Section 4.1 hereof.

1.31 "Specifications" shall mean Manufacturing and SGD-1006 specifications set forth in Appendix 2 hereto and/or in the Quality Agreement (and any attachments thereto), and including the Manufacturing Process.

1.32 "Term" shall have the meaning set forth in Section 9.1 hereof.

1.33 "Third Party Designee" shall have the meaning set forth in Section 2.9(a).

1.34 "[*]" shall have the meaning set forth in Section 2.10(b) hereof.

2. Manufacture and Supply of SGD-1006

2.1 General Conditions of Supply. During the Term, SAFC shall Manufacture at the Facility and supply SGD-1006 to Company, and Company shall purchase SGD-1006 from SAFC in such quantities as Company may order from time to time, subject to the limitations and requirements set forth herein.

2.2 Specifications. At all times during the Term, SAFC shall Manufacture the SGD-1006 in accordance with cGMP, the Specifications and the Quality Agreement.

2.3 Quality Control and Release. The quality control(s) and the release(s) of SGD-1006 (including documentation) shall be done by SAFC in accordance with the Quality Agreement and this Agreement. Company shall have the right to reject SGD-1006 that does not meet cGMPs and the quality control and release testing requirements agreed upon by SAFC and Company in the Quality Agreement or this Agreement.

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2.4 Inspections. Inspections of SAFC's facilities used in the Manufacture of the SGD-1006, including the Facility, shall be conducted as specified in the Quality Agreement. Subject to the limitations and qualifications set forth in the Quality Agreement, upon reasonable prior notice, SAFC shall permit Company's representatives and partners (licensees) to visit and audit SAFC's facilities used in the Manufacture of the SGD-1006 to observe the Manufacturing of SGD-1006, to discuss the Manufacturing of SGD-1006 with appropriate officials of SAFC and to inspect and audit records relevant to the Manufacturing of the SGD-1006.

2.5 Person in the Plant. SAFC shall permit representatives of Company (limited to a reasonable number of qualified persons) during normal business hours with reasonable advance notice (not less than [*]) and subject to the confidentiality undertakings provided below, to observe manufacturing or packaging for shipment of the SGD-1006 pursuant to this Agreement. The limit on number of qualified persons shall not apply during the pre-approval period for qualification Batches. Company agrees that Company's representatives shall comply with SAFC's reasonable rules, regulations and safety procedures and cGMP while on SAFC's premises. Company's representatives may include employees of its Affiliates, licensees or sublicensees. In addition, SAFC shall provide reasonable accommodations for Company's representatives, including a desk and access to the internet, phones, copiers, fax machines and other miscellaneous office equipment as requested.

2.6 Changes to Specifications and Process. The Specifications shall be amended only as agreed upon in writing by Company and SAFC; provided, however, that the Parties agree to cooperate to amend or supplement the Specifications to the extent reasonably necessary to comply with changes in applicable laws and/or regulations or the requirements of applicable Regulatory Agencies or as Company may reasonably request from time to time (provided such request is made in good faith). Notwithstanding anything to the contrary, SAFC shall not make any Specification changes, Manufacturing Process changes or Facility changes with respect to the manufacture of the SGD-1006 without prior written permission from Company. SAFC shall follow the change control procedures set forth in the Quality Agreement for any proposed changes in the Specifications and/or Manufacturing Process. SAFC acknowledges that any such change(s) shall, in each case, comply with cGMP, this Agreement, the Quality Agreement and Applicable Laws. In the event such amendment (whether as a result of changes in Applicable Laws or the requirements of Regulatory Agencies or at Company's reasonable and good faith request or otherwise) requires additional cost or schedule adjustments for the Manufacture of the SGD-1006 hereunder, Company and SAFC shall agree in good faith on an equitable adjustment to price and/or schedule, as appropriate. Any such amended Specifications shall be reflected in and attached hereto as an amended and restated Appendix 2. In the event the parties are unable to agree on such equitable adjustment, SAFC may refuse to implement the change, in which event, Company may [*] upon notice to SAFC.

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2.7 Documentation.

(a) General. Upon completion of Manufacture of each batch of SGD-1006, SAFC shall provide to Company accurate documentation related to the Manufacturing of SGD-1006 including: a certificate of analysis, certificate of compliance, Deviations, the Batch Record, and any other information specified in the Quality Agreement.

(b) Batch Records. The Batch Records and Master Batch Records shall be treated as Confidential Information of Company and shall not be used or disclosed by SAFC other than for the purposes of permitting SAFC to exercise its rights or fulfil its obligations under this Agreement and, where necessary, for disclosure to the relevant Regulatory Agencies in order to comply with regulatory requirements relating to the Manufacturing of SGD-1006 by SAFC.

(c) Retention of Documentation. All documentation related to the Manufacturing of SGD-1006 shall be archived with SAFC after Manufacturing in accordance with SAFC's document retention policies or as specified in the Quality Agreement. Company shall be contacted before destruction of any SGD-1006 specific records and shall be given the option to retain such documents.

2.8 Safety of SGD-1006. Each Party shall notify the other Party of any unusual health or environmental occurrence, including any safety or toxicity problems, relating to SGD-1006 promptly but no later than within [*].

2.9 Purchase Commitment.

(a) During the Term and upon the terms and subject to the conditions of this Agreement Company, for and on behalf of itself, its Affiliates, sublicensees, licensees, contractors and collaborators, as well as for and on behalf of those third parties that are designated by Company and agreed upon by SAFC (such consent not to be unreasonably withheld) ("Third Party Designees"), which shall be deemed to include Millennium Pharmaceuticals, Inc. and its Affiliates, agrees to purchase from SAFC at least the Compliance Level of the SGD-1006, provided that SAFC is able to supply such SGD-1006 in accordance with this Agreement. Notwithstanding the foregoing, Company shall [*].

Company hereby agrees that SAFC may qualify, as the [*], at Company' sole discretion, if SAFC:

(i) can demonstrate its ability to supply [*] of Company's, its Affiliates', subsidiaries', licensees', sublicensees', collaborators', Third Party Designees' and contractors' [*]; provided, that for purposes of this definition, SAFC's facility in [*] shall be [*] from the Facility ("Qualified Alternate Facility");

(ii) demonstrates that [*]; and

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(iii) mutually agrees with Company on a [*].

(b) In the event that SAFC intends to [*] at any time during the Term, then [*]. During the Term, Company, its Affiliates, sublicensees, Licensees, contractors, collaborators, and Third Party Designees, shall purchase SGD-1006 at the [*]. [*].

(c) Notwithstanding anything to the contrary, Company shall have the right to require SAFC to manufacture SGD-1006 for and supply SGD-1006 directly to Company's Affiliates, sublicensees, licensee, contractors, collaborators and Third Party Designees; provided, however, that if Company requires SAFC to supply such SGD-1006, Company shall [*] with respect to such orders. The manufacture and supply of SGD-1006 to such Affiliates, sublicensees, licensees contractors, collaborators and Third Party Designees will be in accordance with the terms and conditions of this Agreement, including without limitation the [*], provided that SAFC will continue to invoice [*], and Company, its Affiliates, sublicensees, licensee, contractors, collaborators and Third Party Designees shall furnish SAFC with forecasts and orders which include forecasts and orders for all such Affiliates, sublicensees, collaborators and Third Party Designees. Company shall also designate the delivery destination for the SGD-1006, and Company shall pay SAFC directly for orders of SGD-1006 that have been accepted by such Affiliate, sublicensee, licensee, contractors, collaborator or Third Party Designee. All SGD-1006 supplied to Affiliate, sublicensee, licensee, contractors, collaborator or Third Party Designee shall provide such Affiliate, sublicensee, licensee, contractors, collaborator or Third Party Designee the [*], such as conformance to the [*], as is available to Company hereunder.

2.10 Delay; [*].

(a) If SAFC is or will be unable, for any reason (including an event of Force Majeure under Section 11.17 hereof), to supply the SGD-1006 in accordance with the quantities and/or delivery dates specified by Company in a purchase order received by SAFC ("Failure to Supply"), SAFC shall [*] notify Company in writing of such circumstance. If the quantities are within [*] of the Commercial Forecast and such delivery dates meet the [*] requirements herein then within [*] of such notice of Failure to Supply, SAFC shall provide Company the cause of such Failure to Supply and shall propose a plan of remediation.

(b) If such Failure to Supply will continue or does continue for a period of [*], and SAFC is unable in the Facility or any Qualified Alternate Facility to Manufacture the SGD-1006 in [*], then Company may, at its discretion and upon written notice to SAFC (i) [*], without being deemed to be in [*] of this Agreement, and/or (ii) if such [*] pursuant to Section [*], provided that the period of Failure to Supply shall count towards the notice period requirement in such Section [*]. In the event of 2.10(b)(i) or (ii) above, upon Company's request, SAFC shall [*], at [*], in order to allow Company to promptly resume its supply of SGD-1006 by way of [*].

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(c) SAFC shall promptly notify Company when SAFC can resume supply of SGD-1006 in accordance with this Agreement and provide Company with a firm date for delivery of the SGD-1006 in accordance with Company's needs. Upon receipt of notice, Company, at its discretion, may continue production of the SGD-1006 if Company is self-manufacturing the SGD-1006 or continue the contract with [*] under the terms and conditions of that contract; but Company will use reasonable commercial efforts to resume supply from SAFC to the Compliance Level within [*].

3. Forecasts, Release, Purchase Orders, Delivery and Storage

3.1 Forecasts. Reasonably in advance of the Commencement Date, Company shall determine its initial estimated purchases of the SGD-1006 from SAFC under this Agreement and shall deliver to SAFC a written, non-binding, [*] forecast (the "Commercial Forecast") of such estimated quantities. The Commercial Forecast shall cover each of the next succeeding [*]. After delivery of the initial Commercial Forecast, the Commercial Forecast shall be updated by Company on a [*], which update shall include the next [*] of the previous Commercial Forecast. Although the Commercial Forecast is non-binding, Company understands that SAFC shall use the Commercial Forecast for planning purposes (including raw material acquisitions and investment in equipment and other resources) in order to make available the production capacity required to Manufacture and supply the forecasted amounts of the SGD-1006 within the time frames specified therein. For the avoidance of doubt, until such a time when SAFC has approval from Company to manufacture the raw materials and intermediates required in the manufacture of SGD-1006, Company will be responsible for insuring that all raw materials and intermediate are supplied in sufficient quantity and in a timeframe that will not prevent SAFC from meeting its delivery obligations.

3.2 Initial Commercial Supply; Purchase Orders.

(a) To initiate SAFC's Manufacture and supply of commercial quantities of the SGD-1006 under this Agreement, Company must issue a binding written purchase order for its purchase of SGD-1006 at [*] prior to the scheduled shipment of SGD-1006 thereunder or such shorter time as may be agreed upon by the Parties in writing (the "Minimum Lead Time").

(b) Within [*] of receipt of a purchase order, SAFC shall notify Company in writing of its acceptance of the purchase order. If SAFC fails to respond [*] of receipt of the purchase order, the purchase order shall be deemed accepted.

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(c) If a purchase order [*] of the Commercial Forecast or does not meet the Minimum Lead Time, SAFC will be required only to use commercially reasonable efforts to fill such excess or accommodate such shorter lead-time.

(d) For each such purchase of SGD-1006, the purchase order shall specify: (i) quantity requested; (ii) the requested delivery date; and (iii) shipping instructions and address.

(e) Each purchase order shall give rise to a contract for the purchase of such SGD-1006 under the terms and conditions set forth in this Agreement, to the exclusion of any additional or contrary terms set forth in any purchase order, unless otherwise explicitly agreed to in writing by the Parties.

3.3 Release of SGD-1006. SAFC shall notify Company when (i) the Manufacture of SGD-1006 is complete, (ii) all Batch Records have been reviewed by SAFC, (iii) all testing is completed, reviewed, and SGD-1006 meets Specifications (certificate of analysis), (iv) all Deviations have been adequately reviewed and approved, and (v) SGD-1006 has been released by SAFC in accordance with the Quality Agreement. SAFC shall ensure that release occurs within [*] after Manufacturing is complete. This does not include the Company review of manufacturing documentation including batch records, deviations, test data, etc which is required prior to Company release.

3.4 Delivery, Title and Risk of Loss. All SGD-1006 supplied by SAFC hereunder shall be supplied [*] within the meaning of Incoterms 2000, using validated shipping methods. Delivery of the SGD-1006 to the [*] shall constitute delivery to Company. [*]. SAFC shall not ship any SGD-1006 that does not conform to the Specifications. Each shipment of SGD-1006 shall be accompanied by all documentation described in Section 2.7(a).

3.5 Packaging. SAFC will preserve, package, handle, and pack all SGD-1006 so as to protect the SGD-1006 from loss or damage, in conformance with standard commercial practices, the Specifications, the Quality Agreement, Applicable Laws, Company SOPs, and other applicable standards.

3.6 Storage. SAFC shall hold all SGD-1006 under the storage conditions established pursuant to the Quality Agreement and in accordance with cGMP. SAFC shall store the SGD-1006 for a period not to exceed [*], at its own cost, after the SGD-1006 has been released in accordance with Section 3.3 above. Any SGD-1006 held by SAFC beyond [*] from the release date shall be subject to SAFC's standard storage charges.

4. Rejection, Defects and Non-Conforming Goods

4.1 Nonconforming SGD-1006. Within [*] from the date SAFC delivers SGD-1006 in accordance with all the requirements of Section 3.4, to Company or to a third party designated by Company (after SGD-1006 release), Company shall have the right to report any shortages in shipment, and determine whether such SGD-1006

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conforms to the warranties set forth in Section 6.2, including but not limited to cGMP, the applicable Specifications and generally to the requirements according to the Quality Agreement (collectively the "SGD-1006 Requirements"). Any claim by Company that SGD-1006 does not meet SGD-1006 Requirements or is in shortage shall be made in writing to SAFC within such [*] period and shall be accompanied by a detailed report of analysis or report of short SGD-1006 prepared by or on behalf of Company. If a defect in SGD-1006 could not have been ascertained by Company upon reasonable inspection and analysis of the SGD-1006, then the [*] time period referred to herein shall not apply; provided that (i) Company notifies SAFC promptly upon having reason to know of such defect (but in any event no later than [*] from the date of delivery) and (ii) the limitation on remedy and liability set out in Section 4.3 below shall apply with respect thereto. Subject to the provisions of Section 4.2, Company has the right to reject and return, [*], any portion of any shipment of SGD-1006 that fails to comply with all of the SGD-1006 Requirements, without invalidating any remainder of such shipment.

4.2 Disagreement Concerning Fulfilment of SGD-1006 Requirements. In the event of a disagreement concerning the fulfilment of SGD-1006 Requirements, Company and SAFC shall agree on an independent testing laboratory or consultant of recognized standing in the industry ("Laboratory") to determine whether any such SGD-1006 met the SGD-1006 Requirements. The findings of the Laboratory shall be binding. The expenses related to such testing shall be borne by [*] only if the testing confirms that SGD-1006 Requirements are not fulfilled (unless the nonconformity is directly attributable to [*]), and otherwise by [*]. During any period that the Parties are in dispute regarding the conformity of the SGD-1006, SAFC shall, if requested by Company, [*], and Company shall [*] of SGD-1006 and the replacement shipment of SGD-1006 if the Laboratory confirms the conformity of the original shipment, otherwise, [*] shall bear the cost for the [*] if Laboratory confirms the non-conformity of the original shipment.

4.3 Remedies for Non-Conforming Product or Shortage. If any SGD-1006 delivered to Company fails to conform to SGD-1006 Requirements, or if there is any shortage of SGD-1006 in the shipment, SAFC shall, at Company's election, [*] with [*] that conforms to the [*] within [*] from the date all required Raw Materials are provided to SAFC by Company, or issue Company [*] paid for such non-conforming SGD-1006 or shorted SGD-1006. Company will [*] for each batch supplied to SAFC and [*]. Pursuant to written directions from SAFC, Company shall either return the non-conforming SGD-1006 to SAFC or destroy it, in each case, [*]. If Company is directed to destroy non-conforming SGD-1006, then Company shall provide SAFC a certificate certifying such destruction. Except as provided for under Section 6.6 hereof regarding SAFC's indemnification obligations for third party claims, the remedy described in this Section 4.3 shall be Company's sole remedy and SAFC's only liability for SGD-1006 failing to meet the SGD-1006 Requirements or short SGD-1006.

4.4 Deviations and OOS. At the request of one Party, each Party shall cooperate with the other Party in the investigation and response to any SGD-1006 complaints concerning Deviations and OOS, which may relate to a Party's role in the Manufacture of SGD-1006 (in addition to complying with the corresponding provisions in the Quality Agreement).

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5. Sales Prices and Terms of Payment

5.1 Currency. Except as otherwise expressly indicated, all references to "$" or to "dollars" in this Agreement shall be read as referring to the legal tender of the United States of America.

5.2 Sales Prices. The sales prices for SGD-1006 Manufactured under this Agreement and released by SAFC's quality assurance department shall be the sales prices set forth in Appendix 3. The sales prices are to be understood as packaged and ready for further processing at the facility of Company or of a third party designated in writing by Company, excluding costs of shipping, insurance and freight and further excluding applicable sales or other taxes (which will be applied as set forth in Section 5.6 hereof). All prices are quoted in United States Dollars.

5.3 Invoices and Payments. SAFC shall invoice Company at the time of delivery (or authorized partial delivery) of the SGD-1006. Company shall make all payments of undisputed amounts in accordance with the SAFC invoices. Further, all payments of undisputed amounts made hereunder are due within [*] from the date of the SAFC invoice unless Company has provided notice under Section 4 above of defects, rejection or non-conforming SGD-1006. Payments shall be made to SAFC in accordance with the instructions on the invoice. All payments hereunder shall be made in United States Dollars.

5.4 Overdue Payments. Company shall pay interest on all past-due undisputed amounts at a rate of interest equal to the lesser of [*] or the maximum rate permitted by applicable law.

5.5 Price Adjustment. Notwithstanding any other provision of this Agreement to the contrary, each year of the Term following the [*] of the Term, with [*] prior written notice to Company, and in addition to any other price adjustment that may be permitted by this Agreement or otherwise agreed to by the Parties, [*] for such year by the percentage increase in the [*] as reported by the U.S. Department of Labor Bureau of Labor Statistics from the Effective Date to the time of such written notice to Company reflecting such price increase.

5.6 Taxes.

(a) If Company must withhold from any payment to SAFC under this Agreement any taxes required to be withheld by Company under the applicable laws of any country, state, territory or jurisdiction, such amount shall be paid to the appropriate taxing authorities. Upon request, Company shall provide SAFC with documentation of such withholding as is reasonably available to allow SAFC to document such tax withholdings for purposes of claiming tax credits and similar benefits.

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(b) Any use tax, sales tax, excise tax, duty, custom, inspection or testing for, or any other tax, fee or charge of any nature whatsoever imposed by, any governmental authority, on or measured by the transaction between Company and SAFC shall be paid by Company in addition to any other amounts due hereunder.

6. Recall, Warranties, Indemnification and Insurance

6.1 Recall.

(a) Company shall be responsible for conducting any recall of Finished Product, and SAFC shall co-operate with and give all reasonable assistance to Company in conducting any such recall to the extent it relates to the SGD-1006. SAFC shall bear the expense of any recall resulting from [*] and/or of the [*] and/or from [*]. Otherwise, Company shall bear such expenses. Notwithstanding the foregoing, to the extent such recall or similar action is due to [*]or from their [*], then each Party shall share in such costs in proportion to the damages or losses caused by [*]. In the event of such recall or similar action, each Party shall use commercially reasonable efforts to mitigate the costs associated therewith.

(b) In the case of a disagreement as to the existence or level of nonconforming SGD-1006 in connection with a recall under Section 6.1(a) above, then the matter shall be referred to the Laboratory in accordance with Section 4.2 above. The decision of the Laboratory shall be final and binding on the Parties with regards to nonconforming SGD-1006, except to the extent the basis for such recall relates primarily to a violation of cGMP or [*], in which case such disagreement shall be resolved by binding arbitration in accordance with Section 10.3.

6.2 SAFC Representations and Warranties. SAFC hereby represents and warrants as follows:

(a) (i) The execution, delivery and performance of this Agreement does not conflict with, violate or breach any agreement to which SAFC is a party or SAFC's constituent documents, (ii) SAFC is not prohibited or limited by any law or agreement (to which it is a party) from entering into this Agreement and (iii) the performance of this Agreement will not create any conflict with any other business or activity engaged in by SAFC;

(b) The SGD-1006 shall be Manufactured and shipped in compliance with cGMP, the Specifications and all other Applicable Laws;

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(c) All SGD-1006 delivered by SAFC hereunder: will conform to the Quality Agreement, the applicable Purchase Order and the Specifications, will not be adulterated or misbranded within the meaning of the U.S. Food, Drug, & Cosmetic Act, or any other Applicable Laws and will be manufactured at the Facility which is in compliance with cGMP; and

(d) SAFC will have obtained and maintained in effect all such approvals and permits as may be required under Applicable Laws to operate the Facility for the purposes of Manufacturing SGD-1006 under the Quality Agreement and under this Agreement;

(e) Unencumbered title to all SGD-1006 will be conveyed to Company upon delivery;

(f) The Batch Records shall conform with the Specifications;

(g) If any [*] and/or intellectual property rights are incorporated into the Manufacturing of SGD-1006, the use of such inventions and/or rights shall not [*];

(h) Neither SAFC, nor any of its employees or agents working hereunder, has ever been, is currently, or is the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred Entity or Individual, an Excluded Entity or Individual or a Convicted Entity or Individual. SAFC further covenants, represents and warrants that if, during the term of this Agreement, it, or any of its employees or agents working hereunder, becomes or is the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred Entity or Individual, an Excluded Entity or Individual or a Convicted Entity or Individual, SAFC shall immediately notify Company, and Company shall have the right to immediately terminate this Agreement upon notice. For purposes of this provision, the following definitions shall apply:

A "Debarred Individual" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) (or any comparable law of the EMA or any country in the world, as each may be amended from time to time) from providing services in any capacity to a person that has an approved or pending drug product application.

A "Debarred Entity" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) (or any comparable law of the EMA or any country in the world, as each may be amended from time to time) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

An "Excluded Individual" or "Excluded Entity" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, (or any comparable international programs) or (ii) an individual or entity, as applicable, who has been excluded, debarred, suspended or is

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otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration ("GSA"), or any comparable international programs.

A "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a – 7(a) (or any comparable law of the EMA or any country in the world, as each may be amended from time to time), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

6.3 Company Representations and Warranties. Company represents and warrants that (i) the execution, delivery and performance of this Agreement does not conflict with, violate or breach any agreement to which Company is a party or Company's constituent documents, (ii) Company is not prohibited or limited by any law or agreement to which it is a party from entering into this Agreement and (iii) the performance of this Agreement will not create any conflict with any other business or activity engaged in by Company.

6.4 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY, WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF NON-INFRINGEMENT.

6.5 Company Indemnification. Company shall indemnify, defend and hold harmless SAFC, its Affiliates and its or their directors, officers and employees from all actions, losses, demands, costs and liabilities arising from any third party claim (including reasonable attorney's fees) to which SAFC is or may become subject insofar as they arise out of or are alleged or claimed to arise out of:

(a) any breach by Company of any of its material obligations or representations and warranties under this Agreement;

(b) any negligent act or omission or willful misconduct by Company, its Affiliates or its or their directors, officers, employees, agents or subcontractors;

(c) SAFC strictly following any of Company developed procedures as described in the Analytical Methods, the Manufacturing Process and the Specifications;

(d) Company's conversion of the SGD-1006 into the Finished Product;

(e) the labeling, marketing, distribution or sale by Company of the SGD-1006 or the Finished Product;

(f) the use or consumption of the SGD-1006 or any related Finished Product; or

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(g) the infringement by Company of patents or proprietary rights of any third party, which are incorporated into the Finished Product;

in each case except that Company shall have no obligation to indemnify, defend or hold harmless SAFC, its Affiliates and its or their directors, officers and employees for any breach of its material obligations or representations and warranties under this Agreement, or for any negligent acts or omissions or willful misconduct by SAFC or its Affiliates and its or their directors, officers, employees, agents or permitted subcontractors associated with its obligations under this Agreement or to the extent its an indemnifiable obligation of SAFC set forth in Section 6.6 below.

6.6 SAFC Indemnification. SAFC shall indemnify, defend and hold harmless Company, its Affiliates and its licensees or sublicensees, contractors, collaborators, Third Party Designees or each of their directors, officers and employees from all actions, losses, demands, costs and liabilities arising from any third party claim (including reasonable attorney's fees) to which Company or such entities is or may become subject insofar as they arise out of or are alleged or claimed to arise out of:

(a) any breach by SAFC of any of its material obligations or representations and warranties under this Agreement or the Quality Agreement;

(b) any negligent act or omission or willful misconduct by SAFC, its Affiliates or its or their directors, officers, employees, agents or subcontractors;

(c) SAFC's negligence or willful misconduct in the development, testing, use, storage, handling, packaging, labeling, Manufacture, storage or delivery of SGD-1006, formulations containing SGD-1006 or its Raw Materials;

(d) any manufacturing procedures, methods or techniques (or component thereof) that are incorporated into the Manufacturing Process or Specifications by SAFC for which Company did not provide written consent; or

(e) [*] by SAFC of [*] of [*] without Company's written consent or for which SAFC was [*];

in each case except that SAFC shall have no obligation to indemnify, defend, or hold harmless Company, its Affiliates and its licensees or sublicensees or their directors, officers and employees for any breach of its material obligations or representations and warranties under this Agreement, or for any negligent acts or omissions or willful misconduct by Company or its Affiliates and its or their directors, officers, employees, agents or permitted subcontractors associated with its obligations under this Agreement or to the extent its an indemnifiable obligation of Company set forth in Section 6.5 above.

6.7 Indemnification Procedure. Either Party intending to seek indemnification from the other Party under Sections 6.5 or 6.6 above, as the case may be, shall give the other Party prompt notice of any such claim or lawsuit (including a copy thereof) served upon it and shall fully cooperate with the other Party and its legal

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representatives in the investigation of any matter which is the subject of indemnification. Such Party seeking indemnification shall not unreasonably withhold its approval of the settlement of any claim, liability or action covered by the above indemnification provisions. Notwithstanding the foregoing, the failure to give timely notice to the indemnifying Party shall not release the indemnifying Party from any liability to the Party seeking indemnification to the extent the indemnifying Party is not prejudiced thereby.

6.8 Company Insurance. Without limiting its liability under this Agreement (except as may be otherwise expressly provided in this Agreement), during the Term and for [*] after the expiration or termination of this Agreement, Company shall obtain and maintain commercial general liability/product liability insurance with limits of not less than [*] per occurrence for general liability and product liability. With respect to all insurance coverage required under this Section 6.8, (i) Company shall, promptly upon SAFC's request, furnish SAFC with certificates of insurance evidencing such insurance and (ii) all policies shall include provisions for at least thirty [*] prior written notice of cancellation. SAFC, upon request, shall be named as an additional insured under the policies of insurance required by this Section 6.8.

6.9 SAFC Insurance. Without limiting its liability under this Agreement (except as may be otherwise expressly provided in this Agreement), during the Term and for [*] after the expiration or termination of this Agreement, SAFC shall obtain and maintain commercial general liability/product liability insurance with limits of not less than [*] per occurrence for general liability and product liability. With respect to all insurance coverage required under this Section 6.9, (i) SAFC shall, promptly upon Company's request, furnish Company with certificates of insurance evidencing such insurance and (ii) all policies shall include provisions for at least [*] prior written notice of cancellation. Company, upon request, shall be named as an additional insured under the policies of insurance required by this Section 6.9.

7. Regulatory Matters; Compliance with Laws

7.1 Regulation of Manufacturing Process. If SAFC is required by the FDA, EMA, or any other Regulatory Agency to modify the Facility or validate or re-validate Manufacturing Processes that will impact the Manufacturing of SGD-1006, SAFC shall notify Company and consult with Company regarding the required activities. SAFC shall be responsible for the costs of any such validation or re-validation that is required due to the non-compliance of the Facility with cGMPs, due to SAFC's breach of this Agreement or due to SAFC's negligence or wilful misconduct; otherwise any such costs shall be borne by Company.

7.2 Correspondence. SAFC will notify Company promptly, but no later than within [*], upon receipt of any correspondence from a Regulatory Agency, which relates to the SGD-1006, or any correspondence pertaining to or affecting the Manufacturing of SGD-1006, including, license status of SAFC, importation or exportation of SGD-1006, or SAFC's quality systems or procedures. In addition, SAFC will cooperate with Company to provide to the Regulatory Agencies all documents and information

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requested by such authority, including without limitation SAFC's protocols, standard operating procedures and other written processes and procedures, equipment specifications, and licenses and drug master files, and shall submit to all inquiries, audits and inspections by the Regulatory Agencies. Company acknowledges that it may be permitted to cross-reference rather than have copies of certain proprietary documents of SAFC which are required for submission to regulatory authorities with respect to the Finished Product.

7.3 Compliance with Laws; Authorizations. In performing this Agreement, each Party shall (i) comply with all Applicable Laws and (ii) obtain all releases, licenses, permits or other authorization required by any Regulatory Agency.

8. Confidentiality; Intellectual Property License

8.1 Confidentiality Obligations of SAFC. In the course of the performance of this Agreement, Company may, from time to time, disclose Confidential Information of Company to SAFC or its Affiliates. Except as expressly permitted otherwise by the terms of this Agreement, SAFC shall: (i) maintain in confidence and not disclose the Confidential Information of Company to any third party, except on a need-to-know basis to SAFC's (or its Affiliates') employees and agents to the extent such disclosure is reasonably necessary in connection with SAFC's (or its Affiliates') activities as expressly authorized by this Agreement and upon obligations of confidentiality similar to those set forth herein; and (ii) not use or grant the use of the Confidential Information of Company for any purpose other than the performance of SAFC's obligations hereunder.

8.2 Confidentiality Obligations of Company. In the course of the performance of this Agreement, SAFC may, from time to time, disclose Confidential Information of SAFC to Company or its Affiliates. Except as expressly permitted otherwise by the terms of this Agreement, Company shall: (i) maintain in confidence and not disclose the Confidential Information of SAFC to any third party, except on a need-to-know basis to Company's (or its Affiliates') employees and agents to the extent such disclosure is reasonably necessary in connection with Company's (or its Affiliates') activities as expressly authorized by this Agreement and upon obligations of confidentiality similar to those set forth herein; and (ii) not use or grant the use of the Confidential Information of SAFC for any purpose other than the performance of Company's obligations hereunder.

8.3 Exceptions. The provisions of Sections 8.1 and 8.2 above shall not apply to any Confidential Information of the disclosing Party that can be shown by competent evidence by the receiving Party:

(a) To have been known to or in the possession of the receiving Party without any separate obligation of confidentiality before the date of its actual receipt from the disclosing Party;

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(b) To be or to have become readily available to the public other than through any act or omission of any Party in breach of any confidentiality obligations owed to the disclosing Party;

(c) To have been disclosed to the receiving Party, other than under an obligation of confidentiality, by a third party which is not known to the receiving Party to have had an obligation to the disclosing Party not to disclose such information to others; or

(d) To have been subsequently independently developed by the receiving Party without use of or reference or access to the disclosing Party's Confidential Information.

8.4 Ownership in Intellectual Property. Subject to the following paragraph, the rights of ownership in Intellectual Property, including any patent or patent application claiming such Intellectual Property, are retained by the Party that employs or otherwise engages the inventor, with inventorship being determined under U.S. patent law and with the rights in ownership being determined under this Agreement and in accordance with U.S. patent law. Accordingly, subject to the following paragraph, SAFC shall own Intellectual Property, made solely by employees or agents of SAFC, Company shall own Intellectual Property made solely by employees or agents of Company. The Party owning the Intellectual Property shall be responsible for all administration, filing and expenses related to the Intellectual Property unless such Intellectual Property is otherwise assigned under the provisions of this Agreement.

Notwithstanding the foregoing, with respect to any Intellectual Property or other ideas, innovations or inventions (whether or not patentable) developed by SAFC or Company acting alone or in conjunction with each other or third parties in activities conducted under the provisions of this Agreement and during the Term of this Agreement and relating: (i) to the [*], (ii) or to the [*] or the specific [*], including the [*], but not methods or processes of general manufacturing applicability or (iii) to and requiring use of Company Confidential Information, its know-how or patent rights (collectively, "Company Inventions"), Company shall own all proprietary rights to Company Inventions and such Intellectual Property or such ideas, innovations and inventions, and may obtain patent, copyright, and/or other proprietary protection relating to such ideas, innovations and inventions. SAFC hereby assigns and shall assign to Company all of SAFC's right, title and interest in and to Company Inventions.

8.5 License. During the Term, Company hereby grants to SAFC a [*], [*] license under any Company Inventions, know-how, trade secrets, copyrights, designs, databases, discoveries, improvements and/or inventions (whether patentable or not) related to the SGD-1006 or the Manufacture of the SGD-1006 that are owned or controlled by Company and that are useful for SAFC's performance of its obligations under this Agreement, but only for such purposes and only to the extent useful for SAFC to perform its obligations under this Agreement. During the Term, SAFC hereby grants to Company a [*], [*] license under any SAFC Intellectual Property, know-how, trade

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secrets, copyrights, designs, databases, discoveries, improvements and/or inventions (whether patentable or not) related to the SGD-1006 or the Manufacture of the SGD-1006 that are owned or controlled by SAFC, but only for such purposes and only to the extent useful for Company to perform its obligations under this Agreement.

9. Term and Termination

9.1 Term. The initial period of this Agreement shall commence as of the Effective Date and shall continue in full force and effect until the [*] of the Commencement Date, unless earlier terminated as provided in Sections 9.2 and 9.3 below. Thereafter the Agreement shall be renewed automatically for additional [*], unless cancelled by one of the Parties upon at least [*] prior written notice. Such initial period and any renewal period shall be referred to herein as the "Term".

9.2 Termination. Notwithstanding the provisions of Section 9.1 above, the Parties may terminate this Agreement in the event of either of the following:

(a) Termination for Material Breach. Either Party may terminate this Agreement by written notice at a date set in the notice (allowing at least [*] for cure) in the event of a material breach of this Agreement by the other Party; provided that the breaching Party fails to cure such breach within [*] from the date of such notice.

(b) Insolvency. If either Party shall become insolvent or shall make or seek to make an arrangement with, or an assignment for the benefit of creditors, or if proceedings in voluntary or involuntary bankruptcy shall be instituted by, on behalf of or against such Party, or if a receiver or trustee of such Party's assets shall be appointed, or bankruptcy proceedings begin, the other Party may terminate this Agreement, as may be permitted by the applicable laws, with immediate effect.

9.3 Termination by Company. Notwithstanding the provisions of Section 9.1 above, Company may terminate this Agreement in the event of any of the following:

(a) Immediately in the event Company fails, for any reason, to receive regulatory approval from the U.S. Food and Drug Administration needed to sell and/or market the Finished Product.

(b) Upon [*] prior written notice to SAFC, in the event Company notifies SAFC of the failure of SGD-1006 to meet the SGD-1006 Requirements pursuant to Section 4.1 (including shortages) [*] or more times in any [*] period or in respect of two consecutive shipments.

(c) Pursuant to Section 2.6 (Changes to Specifications and Process), Section 6.2(h) (Debarment) and/or Section 11.17 (Force Majeure).

(d) For any reason upon [*] written notice by Company.

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9.4 Rights and Obligations Upon Termination.

(a) Return of Inventory and Confidential Information. In the event of any termination, SAFC shall return to Company: (i) all Company property (including but not limited to raw materials, equipment, samples, and data) at Company's expense, unless such termination shall have been as a result of a breach of this Agreement by SAFC in accordance with Section 9.2(a) or termination by Company in accordance with 9.3(b) or 9.3(c), in which case such property shall be returned at [*], except to the extent required to be retained by law or to comply with such Party's continuing obligations hereunder; and (ii) all Confidential Information of Company and shall make no further use of such Confidential Information without the prior written consent of Company.

(b) Payments. Termination of this Agreement shall not release either Party from the obligation to make payment of all amounts then or thereafter due and payable.

(c) Upon termination of this Agreement by SAFC pursuant to Section 9.2(a), Company shall [*] and all other outstanding inventory (meaning all raw materials that are specifically required and purchased by SAFC for the manufacture of the SGD-1006) to the extent that such items were reasonably acquired by SAFC to meet its obligations hereunder in a timely manner, [*].

(d) Technology Transfer. Upon Company's request and provided that the Agreement was not terminated by SAFC in accordance with Section 9.2(a) due to Company's breach, SAFC [*] will reasonably assist Company with the transfer of the Manufacturing Process and Specifications associated with the SGD-1006 to Company or its designee (in the event that the Agreement was terminated by SAFC in accordance with Section 9.2(a), Company shall have the option to have SAFC reasonably assist Company with the transfer of the Manufacturing Process and Specifications associated with the SGD-1006 to Company or its designee, [*]).

9.5 Surviving obligations. Termination or expiration of this Agreement shall not affect any accrued rights or obligations of either Party. The terms of Sections 2.7, 3.6, 4, 5.4, 5.5(c), 5.5(d), 5.5(e), 6.1, 6.2, 6.4 through 6.9, 7.2, 8.1 through 8.4, 9.4, 9.5, 10 and 11 of this Agreement shall survive termination of this Agreement.

10. Governing Law; Dispute Resolution

10.1 Governing Law. This Agreement shall be governed by, and interpreted and construed in accordance with, the laws of the State of [*], without regard to its conflict of law provisions. The U.N. Convention on International Sales of Goods shall not apply to this Agreement.

10.2 Good Faith Meeting. In the event of any dispute arising between the Parties concerning this Agreement, Company and SAFC agree that in the first place they shall meet for good faith discussions in an attempt to negotiate an amicable solution.

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10.3 Arbitration

(a) Any dispute arising between the Parties out of or in connection with this Agreement, or the interpretation, breach or enforcement thereof that cannot be amicably resolved pursuant to Section 10.2 above within [*] as from the first notice of such dispute shall be finally settled by arbitration as set forth in this Section 10.3.

(b) The arbitration shall be conducted in accordance with the Commercial Arbitration Rules of the American Arbitration Association in effect at the time of the arbitration to the extent that both Parties are domestic United States companies or in accordance with the International Arbitration Rules of the American Arbitration Association in effect at the time of the arbitration to the extent that one of the Parties is not a domestic United States company, except, in each instance, as such rules may be modified herein or by mutual agreement of the Parties.

(c) The seat of the arbitration shall be [*], and it shall be conducted in the English language.

(d) The arbitration shall be conducted by three arbitrators. The Party initiating arbitration ("Claimant") shall appoint an arbitrator in its request for arbitration ("Request"). The other Party ("Respondent") shall appoint an arbitrator within [*] of receipt of the Request and shall notify the Claimant of such appointment in writing. If within [*] of receipt of the Request by the Respondent, either Party has not appointed an arbitrator, then that arbitrator shall be appointed by the American Arbitration Association. The first two arbitrators appointed in accord with this provision shall appoint a third arbitrator within [*] after the Respondent has notified Claimant of the appointment of the Respondent's arbitrator or, in the event of a failure by a Party to appoint, within [*] after the American Arbitration Association has notified the Parties and any arbitrator already appointed of its appointment of an arbitrator on behalf of the Party failing to appoint. When the third arbitrator has accepted the appointment, the two arbitrators making the appointment shall promptly notify the Parties of the appointment. If the first two arbitrators appointed fail to appoint a third arbitrator or so to notify the Parties within the time period prescribed above, then the American Arbitration Association shall appoint the third arbitrator and shall promptly notify the Parties of the appointment. The third arbitrator shall act as Chair of the tribunal.

(e) The arbitral award shall be in writing, state the reasons for the award, and be final and binding on the Parties. The award may include an award of costs, including reasonable attorneys' fees and disbursements. Judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party or its assets.

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(f) Notwithstanding Section 10.1 hereof, the arbitration and this Section 10.3 shall be governed by Title 9 (Arbitration) of the United States Code.

(g) The Parties agree that the arbitration shall be kept confidential and that the existence of the proceeding and any element of it (including but not limited to any pleadings, briefs or other documents submitted or exchanged, any testimony or other oral submissions, and any awards) shall not be disclosed beyond the tribunal, the American Arbitration Association, the Parties, their counsel and any person necessary to the conduct of the proceeding, except as may be lawfully required in judicial proceedings relating to the arbitration or otherwise.

11. Miscellaneous

11.1 Conditional Effectiveness. The effectiveness of this Agreement is conditioned upon Company and SAFC duly executing and delivering the Quality Agreement.

11.2 Publicity. Any public announcement or similar publicity with respect to this Agreement will be issued, if at all, at such times and in such manner as shall be mutually agreed in writing by the Parties.

11.3 Use of Names. SAFC shall not use the name of Company or the names of their employees, or representatives or Affiliates in any advertising materials or in any publication without prior written consent of Company. Company shall not use the name of SAFC or the names of their employees, or representatives or Affiliates in any advertising materials or in any publication without prior written consent of SAFC. Notwithstanding the foregoing, Company shall be entitled to identify SAFC as the source of the SGD-1006 in any regulatory submission without SAFC's prior written consent.

11.4 Marks. Each Party reserves all rights to any name, trademark, service mark or logo ("Marks") it may have or hereafter acquire. Neither Party shall by this Agreement obtain any right, title or interest in or to any Marks of the other Party or its Affiliates. Accordingly, neither Party shall use any Marks confusingly similar to or likely to cause confusion with the Marks of the other or of any other person or entity. Each use by a Party of any Marks of the other Party, whether in advertising or marketing materials, websites, company announcements or offering circulars, informational materials, public events, or otherwise, shall be subject to the prior written approval of the other Party.

11.5 Limitation of Liability.

(a) NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (SUCH AS LOST PROFITS) OR ANY SPECIAL OR PUNITIVE DAMAGES ARISING OUT OF THE PERFORMANCE OF THIS AGREEMENT, WHETHER BASED ON CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE AND REGARDLESS OF WHETHER ANY PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

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(b) EXCEPT AS SET FORTH IN SECTION 6.6 OR IN CASES OF SAFC'S [*], THE MAXIMUM LIABILITY OF SAFC UNDER THIS AGREEMENT FOR ALL CLAIMS, WHETHER IN CONNECTION WITH A WARRANTY CLAIM, AN INDEMNITY CLAIM, A COMBINATION THEREOF, OR OTHERWISE AND WHETHER ARISING UNDER CONTRACT, WARRANTY, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, PRODUCT LIABILITY, A COMBINATION THEREOF, OR ANY OTHER THEORY OF LIABILITY OR INDEMNIFICATION SHALL NOT EXCEED, AN AMOUNT EQUAL TO [*] UNDER THE PROVISIONS OF THIS AGREEMENT [*]. The foregoing limitations in Section 11.5(a) and (b) above shall survive notwithstanding any failure of essential purpose of a limited remedy.

11.6 Assignment; Successors; Subcontractors; Third-Party Beneficiaries.

(a) Neither Party may assign or otherwise transfer any of its rights or obligations under this Agreement without the prior written consent of the other Party, which will not be unreasonably withheld, except that subject to compliance with Section 2.6 regarding process and/or facility change(s), either Party may assign, in whole or in part, without such consent any of its rights or obligations under this Agreement (i) to any Affiliate of such Party, provided that any such assignment to an Affiliate shall not relieve such Party as the primary obligor hereunder, or (ii) in connection with the merger, consolidation or sale of the stock or substantially all of the assets of the such Party's business responsible for the performance of this Agreement.

(b) Subject to the preceding subsection (a), this Agreement will apply to, be binding in all respects upon, and inure to the benefit of the successors and permitted assigns of the Parties.

(c) SAFC shall not utilize a third party to manufacture any portion or all of the SGD-1006 without first obtaining Company' written consent, which consent shall not be unreasonably withheld, conditioned or delayed. In the event that SAFC is authorized to utilize a third party in the manufacture of SGD-1006, such third party shall be approved by SAFC's and Company' Quality Assurance departments. Any third party contract entered into by SAFC and that third party shall contain a provision that allows Company to audit such third party's facilities. SAFC agrees that it shall remain liable for the performance of SAFC's obligations hereunder in the event that SAFC is authorized to use a third party to perform SAFC's obligations on its behalf. It shall be deemed reasonable for Company to withhold consent to SAFC's utilization of a third party to manufacture any portion of the SGD-1006 in the event that such utilization would have a substantial likelihood of (a) impairing or jeopardizing any pending or actual regulatory approval for the manufacture of the SGD-1006, (b) adversely affecting the regulatory status of the SGD-1006 or (c) materially delaying delivery schedules, increasing the pricing or adversely affecting the quality of the SGD-1006.

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(d) Nothing expressed or referred to in this Agreement will be construed to give any person other than the Parties any legal or equitable right, remedy or claim under or with respect to this Agreement or any provision of this Agreement. This Agreement and all of its provisions and conditions are for the sole and exclusive benefit of the Parties to this Agreement and their successors and assigns.

11.7 Transactions Outside Scope of Agreement. Other than as expressly provided for otherwise in this Agreement, this Agreement shall in no way limit or restrict the ability of either Party or any Affiliate of such Party to offer its products or services to any other person.

11.8 No Transfer of Rights. No transfer, grant or license of rights under any patent or copyright or to any proprietary information or trade secret is made or is to be implied by this Agreement except as may be expressly stated otherwise herein.

11.9 Independent Contractors. The Parties undertake to carry out this Agreement as independent contractors. No franchise, partnership, joint venture or relationship of principal and agent is intended by this Agreement. Neither Party is authorized, in the name of or on behalf of the other Party, to incur any obligation, receive any benefit or right or otherwise bind the other Party. All employees, agents, representatives and contractors of a Party are solely those of such Party and no acts thereof will be binding upon the other Party.

11.10 Waiver. The failure or the delay of any Party hereto to enforce at any time any provision of this Agreement shall not be construed to be a waiver of such provision or of the right of such Party thereafter to enforce such provision. No waiver of any breach of this Agreement shall be held to constitute a waiver of any other or subsequent breach of this Agreement.

11.11 Severability. Should any provision of this Agreement become void or be cancelled, then the other provisions shall remain in full force and effect. If a provision of this Agreement should be void or should be declared void, then the Parties will attempt to replace it by another valid provision or will leave the provision unreplaced by mutual consent. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

11.12 Appendices. All appendices attached hereto are hereby incorporated in and made a part of this Agreement as if fully set forth herein.

11.13 Entire Agreement. This Agreement, including all appendices hereto, contains the final, complete and exclusive agreement of the Parties relative to the subject matter hereof and supersedes all prior and contemporaneous understandings and agreements relating to its subject matter.

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11.14 Amendment. This Agreement shall not be deemed or construed to be modified, amended, rescinded, cancelled or waived, in whole or in part, except by written amendment signed by the Parties hereto.

11.15 Notices. All notices, consents, waivers and other communications under this Agreement must be in writing and will be deemed to have been duly given when (i) delivered by hand (with written confirmation of receipt), (ii) sent by facsimile (with written confirmation of transmission), (iii) when received by the addressee if sent by registered or certified mail (return receipt requested) or if sent by an internationally recognized overnight delivery service, in each case to the appropriate addresses and facsimile numbers set forth below (or to such other addresses and facsimile numbers as a Party may designate by notice to the other Party):

If to Company: Seattle Genetics, Inc.
21823 - 30th Drive S.E.
Bothell, WA 98021
Attention: President & CEO
Facsimile No.: (425) 527-4001

With a copy to: Seattle Genetics, Inc.
21823 - 30th Drive S.E.
Bothell, WA 98021
Attention: General Counsel
Facsimile No.: (425) 527-4001

If to SAFC: [*]
[*]
[*]
Facsimile No.:[*]

With a copy to: SAFC
[*]
[*]
Attention: Legal Department
Facsimile No.: [*]

With a copy to: [*]
[*]
[*]
Attention: [*] Facsimile
No.: [*]

11.16 Section Headings; Construction. The headings of Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation. Unless otherwise expressly provided, the word "including" does not limit the preceding words or terms.

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11.17 Force Majeure. Any events that cannot be prevented by either one of the Parties, such as fire, flood, war, strike, civil unrest, terrorism, natural catastrophes, government acts and regulations, and other cases of force majeure beyond a Party's control, will free the affected Party for the duration of the event from its obligations under this Agreement. As soon as there is an indication of an event of force majeure, the Party affected by it will advise the other Party immediately or as soon as practical of the effect of such event on this Agreement and about the measures to be taken to mitigate such effect. The Parties are obligated to mitigate damages and to resume the fulfilment of the contractual obligations as quickly as possible. Notwithstanding anything to the contrary, Company may cancel without penalty (and shall have no obligation to pay any amounts attributable to the Compliance Level or firm Purchase Orders applicable to any period following the date of the force majeure event) (a) any and all Purchase Orders in the event SAFC is unable to fulfil an outstanding purchase order within [*] of its scheduled delivery date due to a force majeure event and/or (b) this Agreement if the force majeure event affects SAFC's ability to perform pursuant to this Agreement for more than an aggregate of [*] in any [*]or any consecutive period of [*]. Provided that this Agreement has not been terminated in accordance with 11.17(b) hereof, upon cessation of such force majeure event, the affected Party shall promptly resume performance on all Purchase Orders which have not been terminated.

11.18 Expenses. Except as otherwise expressly provided in this Agreement, in the appendices hereto or in any agreement or other document expressly referenced herein and forming a part hereof, including the Quality Agreement, each Party to this Agreement will bear its respective expenses incurred in connection the performance of its obligations hereunder. In the event of termination of this Agreement, the obligation of each Party to pay its own expenses will be subject to any rights of a Party arising from a breach of this Agreement by the other.

11.19 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement.

11.20 Governing Language. The validity, interpretation, construction and performance of this Agreement shall be in accordance with the English language. If this Agreement is translated into another language and there is a conflict between the non-English version and the English version, then the English version shall control.

IN WITNESS WHEREOF, the Parties intending to be bound by the terms and conditions hereof have caused this Agreement to be signed effective as of the Effective Date by their duly authorized representatives.

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SAFC, an operating division of Sigma-Aldrich, Inc.	Seattle Genetics, Inc.
By: /s/ Gilles Cottier	By: /s/ Clay B. Siegall
Name: Gilles Cottier	Name: Clay B. Siegall, Ph.D.
Title: President, SAFC	Title: President & CEO



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APPENDIX 1

QUALITY AGREEMENT

[*]

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APPENDIX 2

SPECIFICATIONS

[*]

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APPENDIX 3

PRICING

[*]

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SAFC℠ Inspiring Science

Amendment to SGD-1006
Commercial Supply Agreement executed on 1 December 2010.
[*] Manufacturing Controls Price Increase

27 August 2013

Vaughn Himes
VP, Manufacturing
21823- 30th Drive S.E.
Bothell, WA 98021

Dear Vaughn:

Based on the recent Safebridge assessment of SGD-1006 and SGD-1010 occupation exposure level (OEL), a [*] classification has been applied to these molecules. This change in classification will require additional manufacturing containment and precautions for these [*].

This letter serves to amend the SGD-1006 pricing outlined in the supply agreement executed on 1 December 2010. The purpose of this costing revision is to capture the additional time and materials required to manufacture SGD-1006 [*].

[*] implementation will require extended suite time, additional materials, and FTEs. It is estimated that the implementation will result in a cost increase of [*]. Based on this assessment Seattle Genetics have agreed to increase payment for the [*]. The revised price per gram is outlined in the table below:

Revised SGD-1006 Pricing Schedule:

SG6 Quantity (g)	Current Price ($)/g	Batch Cost Increase	Revised Cost/g
[*]	[*]	[*]	[*]

[*]

SAFC™ Inspiring Science

IN WITNESS WHEREOF, the parties have executed this Amendment, effective as of the Amendment Effective Date.

Agreed and Accepted:

SAFC, Inc.		Seattle Genetics, Inc.	
By:	/s/ Gills Cotter	By:	/s/ Clay B. Siegall
Name:	Gills Cotter	Name:	Clay B. Siegall
Title:	President	Title:	President and CEO
Date:	December 15, 2014	Date:	January 20, 2014

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3050 Spruce Street
St. Louis, MO 63103
Tel (800) 448-0471
Fax (314) 286-7817
www.safcglobal.net

Second Amendment to SGD-1006
Commercial Supply Agreement executed on 1 December 2010 and
First Amendment to Commercial Supply Agreement executed on
20 January 2014 (the "First Amendment")(the Commercial Supply
Agreement together with the First Amendment, the "Supply Agreement")

19 September 2016
Vaughn Himes
21823 30th Drive S.E.
Bothell, WA 98021

Dear Vaughn

This letter agreement (the "Second Amendment") confirms the Parties' agreement to amend the Supply Agreement to change the price per gram/per Batch (the "Price") for SGD 1006 set forth in Appendix C to the Supply Agreement. The purpose of the pricing revision is to a) capture the cost of the [*] used in the manufacture of SGD-1006, b) capture the operational efficiencies gained during the manufacturing of the [*] c) capture the increased labor and overhead costs in the [*] , and d) capture the [*] inventory remaining from production [*] . Beginning as of January 1, 2017, certain [*] , as listed in the second table below, that were previously provided [*] in accordance with cGMP, Applicable Laws and the Quality Agreement, and the [*] . Through 2016, these [*] had been provided by or purchased separately by [*] . In addition, effective as of January 1, 2017, any [*] from each batch production will now be owned by [*] .

The table below compares the current price per gram under the First Amendment with the Price per gram effective as of the Effective Date of this Second Amendment.

SGD-1006 - 300 gm batch	Price per gm
First Amendment to Commercial Supply Agreement executed on 20 January 2014	[*]
Second Amendment to Commercial Supply Agreement	[*]

The table below itemizes the components of the amended Price.

[*]

In addition to the [*] in this Second Amendment, SAFC and Seattle Genetics agree to perform an analysis of the [*] prior to discussing any change to the Price for 2018 to further [*] .

The Price as set forth in this Second Amendment shall be effective as of the first date of Manufacture of the [*] .

Terms capitalized, but not defined, herein shall have the meaning ascribed to them in the Supply Agreement. This Second Amendment shall be effective as of the date of the last signature below (the "Effective Date"). Except as set forth in this Second Amendment, all of the terms and conditions of the Supply Agreement remain in full force and effect.

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SAFC™ Inspiring Science

IN WITNESS WHEREOF, the parties have executed this Second amendment by their duly authorized representatives, effective as of the Effective Date.

Agreed and accepted:

SAFC, INC		SEATTLE GENETICS, INC.	
By	/s/ Mike Smith	By	/s/ Vaughn B. Himes
Name	Mike Smith	Name	Vaughn B. Himes
Title	Site Director	Title	EVP
Date	November 22, 2016	Date	December 2, 2016

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SIXTH AMENDMENT
TO DEVELOPMENT AND SUPPLY AGREEMENT

Effective as of date of the last signature below, Abbott Laboratories, an Illinois corporation having a principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064-3500 ("Abbott"), and Seattle Genetics, Inc., a Delaware corporation having a principal place of business at 21823 – 30th Drive Southeast in Bothell, Washington 98021 ("Seattle Genetics") (individually the "Party" or collectively the "Parties") agree to the following terms and conditions ("Sixth Amendment") as set forth below.

WHEREAS, the Parties entered into a Development and Supply Agreement with an Effective Date of February 23, 2004 for the manufacture of a chimeric anti-CD30 AC10 monoclonal antibody known as cAC10 Bulk Drug Substance (the "Original Agreement"), which also constitutes the antibody component of SGN-35 and the Parties subsequently entered into five amendments to the Original agreement (the "First Amendment", "Second Amendment", "Third Amendment", "Fourth Amendment" and "Fifth Amendment", respectively. Collectively the Original Agreement, the First Amendment, the Second Amendment, the Third Amendment, the Fourth Amendment and the Fifth Amendment are hereinafter referred to as the "Agreement"); and

WHEREAS, the Parties desire to further amend the Agreement as herein provided as of the date hereof.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained here and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. Incorporation of the Agreement. All capitalized terms which are used but not otherwise defined herein shall have the same meanings as set forth in the Agreement, and the Agreement, to the extent not inconsistent with this Sixth Amendment, is incorporated herein by this reference as though the same was set forth in its entirety. To the extent any terms and provisions of the Agreement are inconsistent with the amendments set forth in Paragraphs 2 and 3 below, such terms and provisions shall be deemed superseded hereby. Except as specifically set forth herein, the Agreement shall remain in full force and effect and its provisions shall be binding on the parties.

2. Process Development Work. The Parties agree that Abbott shall perform the activities set forth in Stage 6a of Attachment 1 hereto pursuant to the terms and conditions of the Agreement.

3. Payment Schedule. As compensation for the activities to be performed by Abbott pursuant to Attachment 1 hereto, Seattle Genetics shall pay to Abbott the price established for each project stage on the dates set forth in Attachment 2. Billings associated with this Sixth Amendment may be combined on the same invoice with other, regular Payment Schedule charges.

4. Project References. All references to the Project set forth in the Agreement, with the exception of the Payment Schedule and Facility Reservation Fee for the Project, shall also be deemed to apply to the activities performed by Abbott, pursuant to this Sixth Amendment.

6. Effectuation. The amendment to the Agreement contemplated by this Sixth Amendment shall be deemed effective as of the last date written below upon the full execution of this Sixth

Amendment and without any further action required by the parties hereto. There are no conditions precedent or subsequent to the effectiveness of this Sixth Amendment. All terms and conditions set forth in Agreement that are not amended hereby shall remain in full force and effect. Any term of this Sixth Amendment may be amended with the written consent of both parties. From the date hereof, any reference to the Agreement shall be deemed to refer to the Agreement as amended by this Sixth Amendment.

7. Counterparts. This Sixth Amendment may be executed in two or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument. One or more counterparts of this Sixth Amendment may be delivered by facsimile, with the intention that delivery by such means shall have the same effect as delivery of an original counterpart thereof.

8. Entire Agreement. This Sixth Amendment and exhibits hereto are the product of both of the parties hereto, and together with the Agreement and exhibits thereto constitute the entire agreement between such parties pertaining to the subject matter hereof, and merge all prior negotiations and drafts of the parties with regard to the transactions contemplated herein.

IN WITNESS WHEREOF, the parties have executed this Second Amendment as of the dates set forth below.

ABBOTT LABORATORIES		SEATTLE GENETICS, INC.	
By:	/s/ Keith Kentala	By:	/s/ Clay B. Siegall
Name:	Keith Kentala	Name:	Clay B. Siegall
Title:	General Manager, Commercial Operations	Title:	President & CEO
Date:	11/18/2010	Date:	11/8/2010

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED

ATTACHMENT 1

PROJECT SCOPE

[*]

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED

ATTACHMENT 2

PAYMENT SCHEDULE

[*]

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED

SEAGEN

Senior Executive Annual Bonus Plan

This Senior Executive Annual Bonus Plan (the "Plan") is intended to enhance stockholder value by promoting a connection between the performance of Seagen Inc. (the "Company") and the compensation of senior executives of the Company, and to promote retention of participating senior executives.

1. Executives employed by the Company and its direct or indirect subsidiaries ("Affiliates") at the Vice President level and above ("Participants") are eligible to receive annual bonuses for each calendar year (each, a "Plan Year") according to this Plan. The Plan will be administered by the Compensation Committee of the Board of Directors of the Company (the "Committee"). The Committee shall have all powers and discretion necessary to administer the Plan including any adjustments, amendments and modifications to the Plan or its application to all or any participants, and to control its operation, and may delegate responsibilities to Company officers as it deems appropriate. Participants are eligible to receive bonuses for each Plan Year based on their individual performance and the Company's performance during such Plan Year. A Participant who does not demonstrate a minimum level of individual performance (50% or higher) during any Plan Year, however, will not be eligible for any portion of his or her bonus for such Plan Year.

2. For each Plan Year, Company performance shall be determined by the Committee based on the Company's ability to meet or exceed Company goals for such Plan Year, as set forth by the Board of Directors of the Company or the Committee, which may include without limitation such factors as: sales or commercial goals; research, development and clinical activities, milestones and go/no go decisions; hiring, retention, development of plans and other operational goals; strategic alliances and acquisitions; licensing or partnering transactions; international expansion goals, government affairs and public policy goals; manufacturing and supply goals; quality goals; regulatory goals; expense and cost reduction goals; debt reduction; improvement in or attainment of working capital levels; financings; implementation or completion of projects or processes; and financial metrics, including stock price performance, profitability, cash flow or net income. For clarity, the Committee may determine in its sole discretion that the Company did not satisfactorily complete enough goals for the applicable Plan Year and in that case, the Committee may determine that no bonus shall be paid to Participants for such Plan Year. For each Plan Year, individual performance of the Participants who are senior executives on the Executive Committee and, if applicable, any other employee who is an "officer" within the meaning of Rule 16a-1(f) under the Exchange Act (each, an "Executive Officer"), shall be determined by the Committee upon review and recommendation to the Committee by the Head of Human Resources and the Chief Executive Officer, except for the Chief Executive Officer (whose bonus shall be based entirely on the Committee's determination of the Company's performance, as provided in Section 3). For each Plan Year, individual performance of Participants who are not Executive Officers ("Other Officers") will be reviewed and determined by the CEO. In the case of all executives other than the CEO, the determination of individual performance shall be based on the individual Participant's satisfactory completion of individual performance goals established for the applicable Plan Year and/or the individual Participant's contribution to the Company's success in achieving the Company goals for such Plan Year, and the application of guidelines established by the Committee.

3. The amount of a Participant's bonus for each Plan Year is based on a target percentage of such Participant's annual base pay as of the last day of such Plan Year. This target percentage shall be determined at the beginning of each Plan Year by the Committee in the case of Executive Officers or the CEO in the case of Other Officers. The Chief Executive Officer's final performance percentage for each Plan Year shall be based 100% on the Company's performance, as determined by the Committee in its sole discretion. For all Participants other than the Chief Executive Officer, the final performance percentage for each Plan Year shall be based 50% on the Company's performance and 50% on each Participant's individual performance. For example, for an applicable Plan Year, assuming the Company has met 130% of its goals, a Participant who is an Other Officer and has an individual performance percentage of 160% based on his or her exceptional performance, has a target percentage of 25% and has a base pay rate of $300,000 will receive a bonus of $108,750 for such Plan Year [(130% x 50% x $300,000 x 25%) + (160% x 50% x $300,000 x 25%) = $108,750]. For any Plan Year, the Company performance percentage and/or the individual performance percentage may exceed 100% in the event the Company or the individual Participant exceeds expected goals, provided that neither percentage may exceed 200%. Notwithstanding the foregoing, if a Participant's individual performance percentage is less than 100%, then regardless of the actual

Company performance percentage, in calculating such Participant's final bonus payout, the Company performance percentage shall be capped at the Participant's individual performance percentage. A Participant's bonus for any Plan Year may be paid in cash or stock or a combination of both at the discretion of the Committee. All determinations and decisions made by the Committee or the CEO as applicable shall be final, conclusive and binding on all persons and shall be given the maximum deference permitted by law.

4. To be eligible for a bonus for any Plan Year, a Participant must be on the Company's payroll prior to November 1 of such Plan Year and must be employed by the Company as of the date of payment of the bonus. A Participant hired after commencement of any Plan Year shall be eligible for a pro-rated bonus for such Plan Year. A Participant who, during any Plan Year, is promoted into a position with a higher bonus target will have a pro-rated bonus based on his or her time in each position during such Plan Year and the applicable individual performance targets for such positions for such Plan Year, but calculated based on the Participant's annual base pay as of the last day of such Plan Year.

5. A Participant who has taken an approved leave of absence pursuant to the Company's or an Affiliate's policies as applicable of longer than 90 calendar days during any Plan Year shall receive a pro-rated bonus for such Plan Year, calculated by excluding the number of days that exceed 90 calendar days during such Plan Year that he or she was on an approved leave of absence.

6. A Participant who is on an approved leave of absence on the date the bonus payment for any Plan Year is made will be eligible to receive a bonus for such Plan Year on the bonus payment date, provided that such bonus will be pro-rated as calculated above if he or she was on an approved leave of absence for longer than 90 calendar days during such Plan Year.

7. This Plan was originally adopted on January 1, 2017 and was amended on February 4, 2019 and February 9, 2021. Bonus payments for each Plan Year will be made by March 31st following the end of such Plan Year.

8. The Company shall provide a copy of this Plan to each Participant upon request and communicate to each Participant his or her target percentage for each Plan Year as determined by the Committee or the CEO, as applicable, at the beginning of such Plan Year.

9. This Plan supersedes all prior bonus plans or any written or verbal representations regarding the subject matter of this Plan and is the entire understanding between the Participant and the Company (and the Affiliate who employs the Participant, as applicable) regarding the subject matter of this Plan. The payment of any bonus under this Plan is fully discretionary. Participation in this Plan for any Plan Year or series of Plan Years does not and will not convey any entitlement whatsoever to participate in this Plan for any future Plan Year or in any future plans or to the same or similar future bonus payments. The Committee may at any time amend, suspend, or terminate this Plan, including amendment of the target percentages for each Participant and amendment so as to ensure that no amount paid or to be paid hereunder shall be subject to the provisions of Section 409(a)(1)(B) of the U.S. Internal Revenue Code of 1986, as amended (the "Code"). For the avoidance of doubt, it is intended that the Plan satisfy the exemption from the application of Section 409A of the Code and the Treasury Regulations and other guidance issued thereunder and any state law of similar effect provided under Section 1.409A-1(b)(4) of the Treasury Regulations, and the Plan shall be administered and interpreted to the greatest extent possible in compliance therewith.

10. The Company and its Affiliates shall withhold all applicable taxes from any bonus payment.

11. Nothing in this Plan shall interfere with or limit in any way the right of the Company or any Affiliate (as applicable) to terminate any Participant's employment or service at any time, with or without cause. Nothing in this Plan should be construed as an employment agreement or an entitlement to any Participant for any incentive payment hereunder.

12. This Plan and all awards shall be construed in accordance with and governed by the laws of the State of Washington, without regard to its conflict of law provisions. In the event of a conflict between the local law

applicable where a Participant is resident and the provisions of the Plan, the Company and its Affiliate(s) as applicable will apply the Plan so as to comply with applicable laws.

13. Payments under this Plan shall be unsecured, unfunded obligations of the Company. To the extent a Participant has any rights under this Plan, the Participant's rights shall be those of a general unsecured creditor of the Company.

14. Payments under this Plan shall be subject to recoupment, rescission, payback, cancelation or other action, in each case, in accordance with (i) any clawback policy adopted by the Company (whether such policy is adopted on or after the date of this Plan or required under applicable law), if applicable, and (ii) any such other clawback, recovery or recoupment provisions set forth in an individual written agreement between a Participant and the Company. No recovery of compensation under such a clawback policy shall be an event giving rise to a Participant's right to resign for "good reason" or "constructive termination" (or similar term) under any program of, or agreement with, the Company.

Exhibit 21.1

Subsidiaries of Seagen Inc.

Name	Jurisdiction of Incorporation
Biomira Management, Inc.	Delaware
Cascadian Therapeutics Luxembourg S.à r.l.	Luxembourg
Cascadian Therapeutics Inc.	Delaware
East Coast Ventures, Inc.	Delaware
Oncothyreon Canada Unlimited Liability Company	Canada
ProlX Pharmaceuticals Corporation	Delaware
Protocell Pharmaceuticals Corporation	Delaware
Seagen Australia Pty Limited	Australia
Seagen B.V.	Netherlands
Seagen Canada Inc.	Canada
Seagen Denmark ApS	Denmark
Seagen France SAS	France
Seagen Germany GmbH	Germany
Seagen International GmbH	Switzerland
SeaGen International Holdings, LLC	Delaware
SeaGen Ireland Limited	Ireland
Seagen Italy S.r.l.	Italy
Seagen Spain, S.L.	Spain
Seagen U.K. Ltd.	England and Wales
Seagen U.S. Inc.	Delaware
SeaGen US Holdings, LLC	Delaware
0811769 B.C. Unlimited Liability Company	Canada

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-240236, 333-232397, 333-226370, 333-212688, 333-204331, 333-197992, 333-188446, 333-176144, 333-168672, 333-148188, 333-56670) and Form S-3 (No. 333-251799) of Seagen Inc. of our report dated February 11, 2021 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/PricewaterhouseCoopers LLP
Seattle, Washington
February 11, 2021

Exhibit 31.1

CERTIFICATIONS

I, Clay B. Siegall, certify that:

1. I have reviewed this Annual Report on Form 10-K of Seagen 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(s) 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(s) 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.

By: /s/ Clay B. Siegall

Clay B. Siegall
Chief Executive Officer
(Principal Executive Officer)

Date: February 11, 2021

Exhibit 31.2

CERTIFICATIONS

I, Todd E. Simpson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Seagen 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(s) 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(s) 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.

By: /s/ Todd E. Simpson

Todd E. Simpson
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: February 11, 2021

Exhibit 32.1

SEAGEN INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Seagen Inc. (the "Company") on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Clay B. Siegall, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Clay B. Siegall
Clay B. Siegall
Chief Executive Officer
(Principal Executive Officer)

Date: February 11, 2021

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Seagen Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

SEAGEN INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Seagen Inc. (the "Company") on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Todd E. Simpson, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Todd E. Simpson

Todd E. Simpson
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: February 11, 2021

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Seagen Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.