SeattleGenetics®

2019 ANNUAL REPORT

# TRANSFORMATIVE Moments

# TRANSFORMATIVE Medicines

Cancer isn't a single disease, and people with cancer need safe and effective therapies that target their specific disease biology. Seattle Genetics is building a diversified commercial portfolio and advancing a robust development pipeline of programs that are based on innovative science and rigorous clinical evidence that address diverse cancer indications.

## ON THE COVER

Sandy, a mother and grandmother, was diagnosed with urothelial cancer. After multiple rounds and types of treatment failed, her oncologist gave her two options: hospice or participating in a clinical trial. She chose to enroll in a PADCEV clinical trial and responded to treatment. Today she has resumed many of her favorite activities and is thinking about traveling and playing tennis again.

Michael was training to be a firefighter and had been married three months before he discovered he had Hodgkin lymphoma. Michael received treatment with ADCETRIS and is now doing well, enjoying hiking as well as other outdoor activities.

## DEAR SHAREHOLDERS,

2019 was a transformational year for Seattle Genetics as we launched our second drug and realized our goal of becoming a multi-product company. The FDA approved PADCEV™ for certain types of metastatic urothelial (bladder) cancer in December, expanding our commercial portfolio into solid tumors and positioning us to bring another meaningful new medicine to cancer patients. Tucatinib, for metastatic breast cancer, is on the horizon in 2020 as a potential third drug approval based on remarkable clinical data reported in 2019. These accomplishments are in addition to progress with ADCETRIS, which is a growing franchise globally that is approved in more than 70 countries and has been used in the treatment of more than 60,000 patients with lymphoma worldwide. Behind these three agents, we are advancing a robust pipeline of proprietary programs that we believe have the potential to give more patients transformative moments in their cancer care.

PADCEV is now approved in the United States for patients with locally advanced or metastatic urothelial cancer who have previously received both a PD-1 or PD-L1 inhibitor and a platinum-containing chemotherapy. This is an area of high unmet medical need and PADCEV is the first drug approved in this setting. Clinical data presented in 2019, which supported FDA accelerated approval, demonstrated that PADCEV could change the treatment paradigm for these patients. Seattle Genetics and our partner Astellas are jointly selling PADCEV in the United States, and we are pleased by our progress in the early stage of product launch.

We believe that PADCEV has substantial clinical and commercial potential across the spectrum of bladder cancer. Under our collaboration with Astellas, we plan to build upon the initial approval of PADCEV in advanced urothelial cancer by evaluating earlier lines of metastatic disease as well as non-metastatic bladder cancer. We have completed enrollment in a randomized phase 3 trial (EV-301) in advanced metastatic urothelial cancer that is intended to serve as a confirmatory trial in the United States and support global applications for approval. We have also initiated, in collaboration with Astellas and Merck, a global randomized phase 3 trial (EV-302) studying the combination of PADCEV with Merck's PD-1 inhibitor Keytruda®, either with or without chemotherapy, for treatment of first-line metastatic urothelial cancer. Encouraging phase 1 data from the combination of PADCEV and Keytruda in this setting led to FDA Breakthrough Therapy designation and reinforce further exploration of this chemotherapy-free option. Our efforts in non-metastatic bladder cancer are beginning with an ongoing clinical trial of PADCEV in muscle-invasive disease. Despite treatment including surgical removal of the bladder, there is a high risk of recurrence with metastatic disease for these patients. We also plan to explore non-muscle invasive bladder cancer. Beyond urothelial cancer, we and Astellas recently initiated a trial in other solid tumors to identify other potential therapeutic applications for PADCEV.

In 2019, we reported strong results from HER2CLIMB, a pivotal randomized trial evaluating tucatinib in combination with trastuzumab and capecitabine in patients with locally advanced or metastatic HER2-positive breast cancer. Nearly 50 percent of those enrolled had brain metastases, a negative prognostic factor. The results demonstrated that the tucatinib-containing arm achieved a statistically significant and clinically meaningful improvement across

**PADCEV**
**U.S. Approval and Launch**

Seattle Genetics became a multi-product oncology company in 2019. PADCEV is the first drug approved in its treatment setting and meets a significant unmet need for patients with metastatic urothelial cancer. Ongoing clinical trials have the opportunity to further expand its use.

the primary and all secondary endpoints, including improvement in progression-free and overall survival, compared to the control arm. Notably, the combination was generally well tolerated with a manageable safety profile. HER2CLIMB data were published in the *New England Journal of Medicine* and supported FDA Breakthrough Therapy designation. The positive results of the HER2CLIMB trial validate our belief in the potential of tucatinib as a best-in-class oral HER2 tyrosine kinase inhibitor that improves outcomes for patients.

We submitted a New Drug Application (NDA) for tucatinib to the FDA in December 2019, and in February 2020 the FDA set a PDUFA target action date of August 20, 2020. The application was submitted under the FDA's Real-Time Oncology Review Pilot Program and the NDA is being reviewed under Project Orbis, an initiative of the FDA Oncology Center of Excellence that provides a framework for concurrent submission and review of oncology drugs among the United States, Canada, Switzerland, Singapore and Australia. In addition, January 2020 saw both the submission of the tucatinib Marketing Authorization Application (MAA) and its validation by the European Medicines Agency. With that in mind, we are in the process of expanding our European capabilities and adding leadership in key countries.

Our tucatinib development program encompasses a number of ongoing and planned clinical trials. This includes a phase 3 trial called HER2CLIMB-02 in first- and second-line metastatic HER2-positive breast cancer and a trial of tucatinib in neoadjuvant breast cancer. We also believe tucatinib may have application in other HER2-positive cancers, such as colorectal cancer, and are conducting a phase 2 trial designed to support potential accelerated approval in the metastatic setting. We are planning trials in other HER2-positive solid tumors as part of our goal to broadly bring tucatinib to patients in need.

In addition to PADCEV and tucatinib, we continue to achieve significant milestones in the commercialization and further clinical development of ADCETRIS. In 2019, we achieved record ADCETRIS revenues in the United States and Canada of $628 million, up 32 percent over 2018. Taken together with sales of ADCETRIS by our partner Takeda in its territory, global sales exceeded $1 billion in 2019, underscoring the importance of ADCETRIS to physicians and patients around the world. A primary driver of this growth is use of ADCETRIS in combination with chemotherapy for newly diagnosed Hodgkin lymphoma and peripheral T-cell lymphomas (PTCL). In December 2019, we presented 4-year

**Diversifying our commercial portfolio and advancing broad development programs across our pipeline**

ADCETRIS® brentuximab vedotin | for injection

Fulfilling the promise for CD30-expressing lymphomas

PADCEV™ enfortumab vedotin-ejfv Injection for IV infusion 20 mg & 30 mg vials

First-in-class antibody-drug conjugate (ADC) for urothelial cancer

## Tucatinib

Potential best-in-class tyrosine kinase inhibitor for metastatic HER2-positive breast cancer

## Deep pipeline

Includes tisotumab vedotin and other novel ADC and immuno-oncology agents

progression-free survival data from the ECHELON-1 trial in frontline Hodgkin lymphoma that showed sustained clinically meaningful benefit of ADCETRIS plus chemotherapy in this setting. We continue to explore other uses of ADCETRIS that may support label expansions and inform application in clinical practice. We are evaluating retreatment with ADCETRIS, use in patients who are unfit for combination chemotherapy, novel frontline Hodgkin lymphoma regimens and relapsed/refractory diffuse large B-cell lymphoma.

**Marketing Applications Under Review for Tucatinib**

Remarkable results from the HER2CLIMB clinical trial of tucatinib for patients with metastatic HER2-positive breast cancer supported FDA Breakthrough Therapy designation and were the basis for marketing applications in the U.S., E.U. and certain other countries globally. If approved, 2020 will be the year that we add a third commercial product to our portfolio.

As our commercial portfolio is becoming more diverse with products addressing hematological malignancies and solid tumors, we are also advancing a pipeline of programs across a range of cancer types. The most advanced of these is tisotumab vedotin, which we are developing in collaboration with Genmab. Our initial focus is in recurrent or metastatic cervical cancer, and we expect to report topline data from a pivotal phase 2 trial in this setting in the first half of 2020. We are also studying tisotumab vedotin in other solid tumors including ovarian and head and neck cancers.

Our commitment to transforming cancer care demands that we address the molecular biology of specific cancer types. Doing so requires advancing a variety of small molecule, antibody-based and immuno-oncology therapies that target specific mutations inside cancer cells, on their surfaces and in their surrounding microenvironments. Seattle Genetics' clinical-stage pipeline highlights our ability to identify and develop potentially differentiated new therapies across therapeutic classes. We intend to continue our investment in product candidates that we believe can be first-in-class or best-in-class, including antibody-drug conjugates and other targeted therapies. In addition to many early-stage assets already in clinical trials, we expect to advance four novel agents into the clinic in 2020 and another four in 2021. We are utilizing efficient clinical trial designs that are intended to inform clear, rapid and evidence-based development decisions. We look forward to keeping you updated on our progress with this deep pipeline of programs that we believe will be drivers of our future growth.

Over the past two years we have made rapid progress in advancing multiple therapies. The 2018 approval of ADCETRIS in frontline PTCL just 11 days after submission of a supplemental Biologics License Application, the 2019 approval of PADCEV only 26 months after the first patient was enrolled in the pivotal trial, the submission of six tucatinib marketing applications within three months of having pivotal data and the initiation of trials with multiple new agents in 2019 – each of these achievements reflects our deep sense of urgency, our research and development expertise and our commitment to advancing important new medicines. As this letter goes to print, the global impact of the COVID-19 pandemic is evolving. In this rapidly changing environment, our focus remains on the pursuit of transformative therapies that make a meaningful difference in cancer patients' lives.

**Clay B. Siegall, Ph.D.**
President, Chief Executive Officer and Chairman of the Board

# MOMENTS Matter

As we move into and through 2020, we remain committed to developing transformative medicines for people with cancer. We expect ADCETRIS to continue growing as a mainstay in the treatment of several types of lymphoma. The launch of PADCEV will give patients with certain types of metastatic urothelial cancer new options for treating their disease. The potential approval of tucatinib holds the promise of an innovative treatment for metastatic HER2-positive breast cancer. The continued advancement and expansion of our clinical programs for ADCETRIS, PADCEV, tucatinib and our pipeline programs will support the further evolution of Seattle Genetics from a leading innovator of cutting-edge ADC technology and other targeted therapies to a diversified, global oncology company. Underpinning this vision is our dedication to patients, commitment to excellence and the urgent need to make every moment matter.

SeattleGenetics®

2019 FORM 10-K

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# Form 10-K

**(Mark One)**

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

**For the fiscal year ended December 31, 2019**

**OR**

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

**For the transition period from _____to _____**
**Commission file number: 0-32405**

SeattleGenetics

# Seattle Genetics, 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 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 $7.5 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 53,192,037 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 172,259,645 shares of the registrant's Common Stock issued and outstanding as of February 3, 2020.

**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 2020 Annual Meeting of Stockholders.

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***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," "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.***

## PART I

### Item 1. Business

#### Overview

Seattle Genetics is a biotechnology company that develops and commercializes therapies targeting cancer. We are commercializing ADCETRIS®, or brentuximab vedotin, for the trbreatment of certain CD30-expressing lymphomas, and PADCEV™, or enfortumab vedotin-ejfv, for the treatment of certain metastatic urothelial 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.

ADCETRIS is commercially available in more than 70 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. ADCETRIS is approved by the U.S. Food and Drug Administration, or FDA, in six indications. In Hodgkin lymphoma, ADCETRIS is approved as monotherapy for patients whose disease has relapsed and as consolidation therapy following prior treatment, and in combination with chemotherapy for the treatment of patients with previously untreated disease. In T-cell lymphomas, ADCETRIS is approved as monotherapy for patients with relapsed or refractory systemic anaplastic large cell lymphoma, or sALCL, or certain types of cutaneous T-cell lymphoma, and in combination with chemotherapy for patients with previously untreated CD30-expressing peripheral T-cell lymphoma, or PTCL.

Beyond our current labeled indications, we are evaluating ADCETRIS in several clinical trials. These include a potentially registration-enabling trial evaluating treatment with ADCETRIS in Hodgkin lymphoma and PTCL patients who are unfit for combination chemotherapy, and a potentially registration-enabling trial evaluating retreatment with ADCETRIS in Hodgkin and T-cell lymphoma patients who progress after a prior response, including in the frontline setting. In addition, we are evaluating ADCETRIS in combination with nivolumab for Hodgkin and non-Hodgkin lymphoma under a clinical collaboration with Bristol-Myers Squibb Company, or BMS. Nivolumab is a programmed death-1, or PD-1, immune checkpoint inhibitor.

Our second marketed product 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 or in a locally advanced or metastatic setting. It is the first FDA approved treatment for these patients. PADCEV was approved under the FDA's Accelerated Approval Program based on tumor response rate. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials. A global, randomized phase 3 clinical trial, called EV-301, which is a required confirmatory trial, is ongoing and is also intended to support global registrations. We completed enrollment in the trial in January 2020.

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.

FDA approval of PADCEV was supported by data from a single-arm pivotal phase 2 clinical trial called EV-201. The trial enrolled 125 patients with locally advanced or metastatic urothelial cancer who received prior treatment with a PD-1 or PD-L1 inhibitor and a platinum-based chemotherapy. Positive results from the first cohort were presented at the American Society of Clinical Oncology, or ASCO, 2019 annual meeting and published in the *Journal of Clinical Oncology*. We are continuing enrollment in the EV-201 trial for the second cohort of patients who previously received a PD-1 or PD-L1 inhibitor, but who were not candidates for treatment with a platinum agent, which we believe could potentially serve as the basis for a second indication.

PADCEV is also being investigated in frontline metastatic urothelial cancer and earlier stages of bladder cancer. We and Astellas are conducting a phase 1/2 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 and/or chemotherapy. The trial is evaluating safety, tolerability and activity in locally advanced and first- and second-line metastatic urothelial cancer, and was recently expanded to include muscle invasive bladder cancer. In September 2019, initial 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 European Society for Medical Oncology, or ESMO, 2019 Congress, that demonstrated a confirmed objective response rate, or ORR, of 71 percent and met safety outcome measures.

Positive initial data from the EV-103 trial support a recently initiated global, registrational phase 3 trial, called EV-302, in frontline metastatic urothelial cancer that is being conducted under a clinical collaboration agreement between us, Astellas and Merck. Under the terms of the agreement, we, Astellas and Merck are jointly funding EV-302. The trial was initiated in January 2020 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 with or without chemotherapy versus chemotherapy alone in patients with previously untreated locally advanced or metastatic urothelial cancer. The trial is expected to enroll 1,095 patients and the dual primary endpoints are progression-free survival, or PFS, and overall survival, or OS.

In addition in January 2020, we and Astellas 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.

The most advanced program in our clinical pipeline is tucatinib, an oral, small molecule tyrosine kinase inhibitor, or TKI, that is highly selective for HER2, a growth factor receptor overexpressed in many cancers. Positive results from the tucatinib HER2CLIMB-01 pivotal trial were presented in December 2019 at the 2019 San Antonio Breast Cancer Symposium and simultaneously published in the *New England Journal of Medicine*. HER2CLIMB-01 is a randomized pivotal clinical trial comparing tucatinib added to trastuzumab and capecitabine versus trastuzumab and capecitabine alone in patients with locally advanced or metastatic HER2-positive breast cancer who were previously treated with trastuzumab, pertuzumab and ado-trastuzumab emtansine, or T-DM1.

Based on the HER2CLIMB-01 results, in December 2019, tucatinib was granted Breakthrough Therapy designation by the FDA in combination with trastuzumab and capecitabine for treatment of patients with locally advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have been treated with trastuzumab, pertuzumab and T-DM1. Also in December 2019, we submitted a New Drug Application, or NDA, to the FDA under Oncology Center of Excellence's, or OCE's, Real Time Oncology Review, or RTOR, pilot program. We are also participating in the Project Orbis initiative of the FDA OCE which provides a framework for concurrent submission and review of oncology products among international partners. Countries currently included in this initiative are Australia, Canada, Singapore, Switzerland and the U.S. In addition to the U.S., applications for approval were submitted to the other participating countries. In January 2020, we submitted a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, and the submission was validated, which confirms it is sufficiently complete to begin the formal review process.

We intend to conduct a broad clinical development program of tucatinib 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, of tucatinib versus placebo, 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 also conducting a phase 2 trial, called MOUNTAINEER, evaluating tucatinib 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 have expanded enrollment in the trial so that it could potentially support an application for accelerated approval in the U.S.

In collaboration with Genmab A/S, or Genmab, we are developing tisotumab vedotin, which is an ADC targeting tissue factor. We and Genmab are conducting a pivotal phase 2 trial, called the innovaTV 204 trial, evaluating single-agent tisotumab vedotin for patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment. The trial is intended to support a potential regulatory submission under the FDA's accelerated approval pathway. In March 2019, we completed enrollment in the innovaTV 204 trial and we anticipate reporting topline data from the trial in the first half of 2020. We are also conducting a phase 2 clinical trial called innovaTV 207 for patients with relapsed, locally advanced or metastatic solid tumors which is intended to inform future development plans. In addition, we are conducting a phase 2 clinical trial, called innovaTV 208, for patients with platinum-resistant ovarian cancer.

We are developing ladiratuzumab vedotin, 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.

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 have advanced several product candidates into clinical development in 2019 and we plan to submit several investigational new drug applications, or INDs, to the FDA in 2020.

We have active license agreements for our ADC technology with a number of biotechnology and pharmaceutical companies, including AbbVie Biotechnology Ltd., or AbbVie; Genentech, Inc., a member of the Roche Group, or Genentech; GlaxoSmithKline LLC, or GSK; and Progenics Pharmaceuticals Inc, as well as collaboration agreements with Astellas and Genmab. Genentech and GSK have ADCs using our technology in late-stage clinical trials. In June 2019, Genentech received accelerated approval from the FDA and, in January 2020, received conditional marketing authorization from the European Commission for Polivy® (polatuzumab vedotin-piic), an ADC that uses our technology, to treat patients with relapsed or refractory diffuse large B-cell lymphoma. Under our ADC license agreement with Genentech, the accelerated approval of Polivy triggered a milestone payment to us and we also receive royalties on net sales of Polivy worldwide. In January 2020, the FDA granted priority review for GSK's Biologics License Application, or BLA, and in February 2020 the EMA validated GSK's MAA for belantamab mafodotin, an additional ADC that uses our technology, for the treatment of patients with relapsed or refractory multiple myeloma, whose prior therapy included an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody. Additionally, GSK initiated a phase 3 clinical trial of belantamab mafodotin in the fourth quarter of 2019.

**Our Strategy**

Our strategy is to become a global oncology company developing and marketing targeted therapies for cancer. Key elements of our strategy are to:

- *Successfully Execute Our ADCETRIS Commercial Plan.* We continue to focus our efforts on commercializing ADCETRIS in the United States and Canada, particularly its use for previously untreated Hodgkin lymphoma and CD30-expressing PTCL, through the coordinated efforts of our sales, marketing, reimbursement and market planning groups. Beyond the frontline setting in the U.S. and Canada, ADCETRIS is approved by the FDA for four additional indications in other settings for the treatment of Hodgkin lymphoma and T-cell lymphomas. In addition, we are continuing to support Takeda's efforts to obtain regulatory approvals and conduct commercial launches in additional countries worldwide.
- *Expand the Therapeutic Potential of ADCETRIS.* We believe ADCETRIS may have additional applications in the treatment of Hodgkin lymphoma and other types of CD30-expressing lymphomas. Clinical trials are being conducted by us, including ones that are potentially registration-enabling, as well as by our collaborators and by investigators in different CD30-expressing indications. They include novel combinations of ADCETRIS plus other anticancer agents and in other areas of medical and scientific interest. Several clinical trials are evaluating ADCETRIS in combination with nivolumab, a PD-1 inhibitor, in various lymphoma settings.
- *Successfully Commercialize PADCEV in the U.S. and Seek Approval in Other Territories Globally.* We and our partner Astellas are focused on commercializing PADCEV in the U.S. following accelerated approval by the FDA in December 2019. We have established an experienced commercial team that is providing information to patients and physicians as to the efficacy and safety of PADCEV for the treatment of patients with previously treated metastatic urothelial cancer. We are also advancing a global, randomized phase 3 clinical trial, EV-301, that is intended to support global regulatory applications for potential approvals.
- *Expand the Therapeutic Potential of PADCEV.* We are conducting trials evaluating PADCEV both as a single agent and in combination with other anticancer agents in different settings of urothelial cancer. We have initiated a registration-enabling phase 3 trial of PADCEV in combination with pembrolizumab for previously untreated metastatic urothelial cancer based on positive results from the EV-103 trial. Additionally, we are investigating PADCEV in a phase 1/2 trial for treatment of muscle-invasive bladder cancer, an earlier non-metastatic stage of the disease, as well as in other solid tumors.
- *Seek Approval and Commercialize Tucatinib in the U.S., Europe and Other Territories Globally.* Our efforts are focused on advancing applications for approval submitted to the FDA in December 2019 and the EMA in January 2020 for patients with previously treated HER2-positive metastatic breast cancer. Our strategy is to commercialize tucatinib in the U.S., Europe and additional countries globally.
- *Expand the Therapeutic Potential of Tucatinib in Earlier Lines of HER2-Positive Metastatic Breast Cancer and Other HER2-Positive Cancers.* We are advancing a registration-enabling phase 3 trial of tucatinib in combination with T-DM1 in previously treated HER2-positive metastatic breast cancer that would potentially support use in earlier lines of therapy. In addition, we are conducting a phase 2 trial in HER2-positive metastatic colorectal cancer.
- *Advance Our Clinical Pipeline of Oncology Drugs*. We are deploying our clinical, development, regulatory and manufacturing expertise with the goal of advancing our product candidates. Our key efforts in this regard include:
    - *Advance Tisotumab Vedotin including in a Pivotal Trial for Cervical Cancer.* We and Genmab are conducting a pivotal phase 2 trial for patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment. In addition, as part of our strategy to broadly investigate tisotumab vedotin for cancer we and Genmab are conducting clinical trials for patients in other solid tumors that are intended to inform future development plans.

- *Continue to Develop Our Other Pipeline Programs.* We believe that it is important to maintain a diverse pipeline of product candidates to sustain our future growth. To accomplish this, we are continuing to advance the development of our other clinical product candidates as well as other preclinical and research-stage programs that employ our proprietary technologies. We are evaluating our programs as monotherapy, and in some cases in combination with other anticancer agents such as checkpoint inhibitors, to broadly assess the potential of our pipeline as part of existing and emerging therapeutic regimens.

- *Support Growth of Our Pipeline through Internal Research Efforts, and Enter Into Strategic Transactions and Collaborations.* We have internal research programs 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 for our ADC technology. In addition, we supplement these internal efforts through ongoing initiatives to identify product candidates, products and technologies to acquire or in-license from biotechnology and pharmaceutical companies and academic institutions. We have also entered into collaborations to broaden and accelerate clinical trial development and potential commercialization of our product candidates. Collaborations may be entered into in order to supplement our own internal expertise in key areas such as manufacturing, regulatory affairs and clinical development, or provide us with access to our collaborators' marketing, sales and distribution capabilities in specific territories.

- *Continue to Expand Globally.* We have established operations in Zug, Switzerland and in Amsterdam, the Netherlands to support our operations within Europe. We acquired global rights to tucatinib in 2018, and we plan to continue to develop our European presence in support of our commercialization of tucatinib in Europe. We plan to expand globally in stages and are evaluating different alternatives for tucatinib commercialization in regions outside of the United States, Canada and Western Europe including potential distributorships, partnering and out-license arrangements.

- *Continue to Leverage Our Industry-Leading ADC Technology.* We have developed proprietary ADC technology designed to empower monoclonal antibodies. We are currently developing multiple product candidates that employ our ADC technology and we have also licensed this technology to biotechnology and pharmaceutical companies to generate collaboration revenues and funding, as well as potential milestones and potential future royalties. Presently, we have active ADC license agreements with AbbVie, Genentech, GSK, and Progenics, as well as collaboration agreements with Astellas and Genmab. ADC collaboration and license agreements have generated over $425 million as of December 31, 2019, primarily in the form of upfront and milestone payments. In June 2019, Genentech received approval for Polivy from the FDA and, in January 2020, from the European Commission. In January 2020, the FDA granted priority review for GSK's Biologics License Application, or BLA, and in February 2020 the EMA validated GSK's MAA for belantamab mafodotin for the treatment of patients with relapsed or refractory multiple myeloma, whose prior therapy included an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody.

**Marketed Products**

We are currently commercializing ADCETRIS for patients with certain CD30-expressing lymphomas and PADCEV for patients with previously treated metastatic urothelial cancer.

***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. We are collaborating with Takeda on the global development and commercialization of ADCETRIS. Under this collaboration, we have rights to commercialize ADCETRIS in the United States and Canada. Takeda has exclusive rights to commercialize ADCETRIS in the rest of the world. ADCETRIS has received regulatory approvals in the United States and Canada as follows:

| Indication[1] | Approvals |
|---|---|
| ***ADCETRIS approvals in classical Hodgkin lymphoma (cHL)*** | |
| Previously untreated Stage III/IV cHL in combination with doxorubicin, vinblastine and dacarbazine | U.S.<br>Canada |
| cHL at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation | U.S.<br>Canada |
| 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 | U.S.<br>Canada |
| ***ADCETRIS approvals in 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 | U.S.<br>Canada |
| sALCL after failure of at least one prior multi-agent chemotherapy regimen | U.S.<br>Canada[2] |
| Primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy | U.S.<br>Canada |

1. *ADCETRIS is only indicated for adults.*
2. *Approval with conditions.*

Takeda has received regulatory approval 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 the rest of the world, and is pursuing additional regulatory approvals. ADCETRIS is commercially available in more than 70 countries worldwide.

*Market Opportunities*

According to the American Cancer Society, approximately 8,500 cases of Hodgkin lymphoma are expected to be diagnosed in the United States during 2020, and an estimated 1,000 people are expected to die of the disease. Approximately 4,000 patients are diagnosed annually in the United States with a type of CD30-expressing PTCL, including sALCL. The standard of care frontline therapy for patients with Hodgkin lymphoma and PTCL has seen limited improvement over the last few decades. Additionally, these 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. An estimated 1,000 people annually have CD30-expressing mycosis fungoides or primary cutaneous ALCL requiring systemic therapy.

***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 or in a locally advanced or metastatic setting. It is the first FDA approved treatment for these patients. PADCEV is approved under the FDA's Accelerated Approval Program based on tumor response rate. The FDA's Accelerated Approval Program allows approval of a medicine based on a surrogate endpoint, such as tumor response rate, if the medicine fills an unmet medical need for a serious condition. A global, randomized phase 3 clinical trial, EV-301, which is a required confirmatory trial, completed enrollment in January 2020 and is also intended to support global registrations.

The primary basis for the BLA submission to the FDA was the positive EV-201 pivotal trial results of PADCEV. EV-201 is a phase 2 multi-center trial that enrolled 125 patients with locally advanced or metastatic urothelial cancer who received prior treatment with a PD-1 or PD-L1 inhibitor and a platinum-based chemotherapy. In the trial, the primary endpoint of confirmed ORR was 44 percent per blinded independent central review (55/125; 95 percent Confidence Interval, or CI,: 35.1, 53.2). Among patients treated with the single agent PADCEV, 12 percent (15/125) experienced a complete response, meaning no cancer could be detected at the time of assessment, and 32 percent (40/125) experienced a partial response, meaning a decrease in tumor size or extent of cancer in the body. The median duration of response, or DoR, a secondary endpoint, was 7.6 months (95 percent CI: 6.3, not estimable). The most common serious adverse reactions (≥3 percent) were urinary tract infection (6 percent), cellulitis (5 percent), febrile neutropenia (4 percent), diarrhea (4 percent), sepsis (3 percent), acute kidney injury (3 percent), dyspnea (3 percent), and rash (3 percent). The most common adverse reaction leading to discontinuation was peripheral neuropathy (6 percent). The most common adverse reactions (≥20 percent) were fatigue (56 percent), peripheral neuropathy (56 percent), decreased appetite (52 percent), rash (52 percent), alopecia (50 percent), nausea (45 percent), dysgeusia (42 percent), diarrhea (42 percent), dry eye (40 percent), pruritus (26 percent) and dry skin (26 percent). The most common Grade ≥3 adverse reactions (≥5 percent) were rash (13 percent), diarrhea (6 percent) and fatigue (6 percent).

*Market Opportunities*

Approximately 154,000 people in the United States will present annually with the need for treatment for newly diagnosed or recurrent bladder cancer. This includes approximately 20,000 with metastatic disease, 28,000 with muscle invasive disease and 106,000 with non-muscle invasive disease. 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 and in muscle invasive bladder cancer. In addition, we are working on a development strategy in non-muscle invasive bladder cancer.

## Our Clinical Development Pipeline

The following table summarizes the clinical development status of ADCETRIS, PADCEV and our lead product candidates:

| Name of Product or Product Candidate | Therapeutic Area | Monotherapy/ Combination | Development Status |
|---|---|---|---|
| **ADCETRIS (brentuximab vedotin)** | Frontline Hodgkin lymphoma | In combination with nivolumab, doxorubicin and dacarbazine[1] | Phase 2 |
| | Frontline Hodgkin lymphoma or PTCL that is unfit for chemotherapy | Monotherapy | Phase 2 |
| | Relapsed Hodgkin lymphoma or PTCL; retreatment with ADCETRIS | Monotherapy | Phase 2 |
| | Relapsed Hodgkin lymphoma (pediatrics) | Combination with nivolumab[1] | Phase 2 (CheckMate 744) |
| **PADCEV (enfortumab vedotin-ejfv)[2]** | Metastatic urothelial cancer previously treated with a PD-1 or PD-L1 inhibitor and is platinum naive or cisplatin ineligible | Monotherapy | Pivotal Phase 2 (EV-201 cohort 2) |
| | Metastatic urothelial cancer previously treated with platinum chemotherapy and a PD-1 or PD-L1 inhibitor | | Phase 3 (EV-301) |
| | Frontline metastatic urothelial cancer | In combination with pembrolizumab with or without platinum agents | Phase 3 (EV-302) |
| | Frontline metastatic urothelial cancer or muscle invasive bladder cancer | In combination with platinum agents and/or pembrolizumab | Phase 1/2 (EV-103) |
| | Metastatic solid tumors including non-small cell lung cancer, head and neck, gastric/esophageal and breast cancer | Monotherapy | Phase 2 (EV-202) |
| **Tucatinib** | HER2+ metastatic breast cancer previously treated with HER2-targeted agents, including patients with brain metastases | In combination with capecitabine and trastuzumab | Pivotal Phase 2 (HER2CLIMB-01) |
| | HER2+ metastatic breast cancer previously treated with a taxane and trastuzumab, including patients with brain metastases | In combination with ado-trastuzumab (T-DM1) | Phase 3 (HER2CLIMB-02) |
| | HER2+ metastatic colorectal cancer | In combination with trastuzumab | Phase 2 (MOUNTAINEER) |
| **Tisotumab Vedotin[3]** | Recurrent/metastatic cervical cancer | Monotherapy | Pivotal Phase 2 (innovaTV 204) |
| | First- and -second-line metastatic cervical cancer | In combination with other cancer agents | Phase 1/2 (innovaTV 205) |
| | Relapsed, locally advanced or metastatic solid tumors | Monotherapy | Phase 2 (innovaTV 207) |
| | Platinum-resistant ovarian cancer | Monotherapy | Phase 2 (innovaTV 208) |

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*

## Development Status

### ADCETRIS (brentuximab vedotin)

Beyond our current labeled indications, we are evaluating ADCETRIS monotherapy and in combination with other agents in ongoing 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. Several investigator-sponsored trials are currently evaluating ADCETRIS with immuno-oncology compounds in Hodgkin lymphoma, and we expect that additional investigator-sponsored trials might evaluate ADCETRIS in novel combination regimens.

Recent clinical data and analyses from select trials of ADCETRIS were presented at the 61st American Society of Hematology annual meeting in December 2019 including:

- *Four-Year Update of the phase 3 ECHELON-1 Trial.* As previously reported, the 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. A four-year post-hoc exploratory analysis was conducted to examine PFS outcomes per investigator assessment in the intent-to-treat population of 1,334 patients. The four-year PFS rate for patients in the ADCETRIS plus AVD arm was 81.7 percent compared to 75.1 percent in the ABVD arm, a difference of 6.6 percent (hazard ratio, or HR, =0.69; 95 percent CI: 0.542, 0.881; p=0.003). This represents a 31 percent reduction in the risk of progression or death. Median follow-up time was 48.4 months. As previously reported for the primary analysis, on the ADCETRIS plus AVD arm, peripheral neuropathy events were observed in 67 percent of patients compared to 43 percent in the ABVD arm. The four-year update shows that among patients with peripheral neuropathy, 83 percent in the ADCETRIS plus AVD arm and 84 percent in the ABVD arm reported complete resolution or improvement at last follow-up.
- *Phase 2 Study of Frontline ADCETRIS Plus Nivolumab in Patients with Hodgkin Lymphoma Aged ≥ 60 Years.* Data were presented from an updated analysis of the phase 2 clinical trial evaluating ADCETRIS in combination with nivolumab as frontline therapy for Hodgkin lymphoma patients aged 60 years and older. Data were reported from 21 patients, and the median age was 72 years. The majority of patients (76 percent) had stage III/IV disease at the time of diagnosis. Of 19 response-evaluable patients, 18 patients (95 percent) had an objective response, including 13 patients (68 percent) with a complete response and five patients (26 percent) with a partial response. All response-evaluable patients experienced tumor reduction (complete response + partial response + stable disease) following treatment with ADCETRIS in combination with nivolumab. Median duration of response was not yet reached after median follow-up of 6.8 months and the maximum duration of response was 22 months and ongoing (95 percent CI: 7.06, not estimable). The most common treatment-related adverse events of any grade occurring in at least 20 percent of patients were fatigue, diarrhea, pyrexia, infusion related reaction, peripheral motor neuropathy, peripheral sensory neuropathy and increase in lipase. One treatment-related serious adverse event was pyrexia.

**PADCEV (enfortumab vedotin-efjv)**

PADCEV is an ADC composed of an anti-Nectin-4 monoclonal antibody linked to a potent auristatin compound using our proprietary ADC technology. Nectin-4 is a novel target expressed in multiple cancers including urothelial cancers, such as bladder cancer, as well as ovarian and lung cancers. We are developing PADCEV as a potential treatment for solid tumors under our collaboration with Astellas.

We and Astellas are conducting a pivotal, single-arm phase 2 clinical trial, called EV-201, of single-agent PADCEV for locally advanced or metastatic urothelial cancer patients who have been previously treated with PD-1 or PD-L1 inhibitor therapy. Results from the first cohort of patients who previously received both platinum chemotherapy and a PD-1 or PD-L1 inhibitor were submitted to the FDA in July 2019 for accelerated approval which was subsequently granted in December 2019. We are continuing enrollment in a second cohort of patients who previously received a PD-1 or PD-L1 inhibitor but who were not candidates for treatment with a platinum agent, which we believe could potentially serve as the basis for a second indication.

We and Astellas are also conducting a phase 1/2 trial, called EV-103, that is a multi-cohort, open-label trial of PADCEV alone or in combination with the immune therapy pembrolizumab and/or chemotherapy. The trial is evaluating safety, tolerability and activity in locally advanced and first- and second-line metastatic urothelial cancer, and was recently expanded to include muscle invasive bladder cancer. In September 2019, initial results from the trial were presented at the ESMO 2019 Congress. Forty-five patients were evaluated for safety with the combination of PADCEV and pembrolizumab in previously untreated patients with locally advanced or metastatic urothelial cancer who were ineligible for treatment with cisplatin-based chemotherapy. The trial met outcomes for safety and the data indicated that the combination of PADCEV plus pembrolizumab shrank tumors in the majority of patients, resulting in a confirmed ORR of 71 percent (95 percent CI: 55.7, 83.6). The complete response rate was 13 percent. Fifty-eight percent of patients had a partial response and 22 percent had stable disease. Ninety-one percent of responses were observed at the first assessment. The duration of response range was from one to 10.5 months and ongoing. Fifty-one percent of patients had an adverse event greater than or equal to Grade 3. Among these events, an increase in lipase was the most frequent (13 percent). Four patients (9 percent) discontinued treatment due to treatment-related adverse events, most commonly peripheral sensory neuropathy. There was one death deemed to be treatment-related by the investigator attributed to multiple organ dysfunction syndrome.

Positive initial data from the EV-103 trial support a recently initiated global, registrational phase 3 trial, called EV-302, in frontline metastatic urothelial cancer that is being conducted under a clinical collaboration agreement between us, Astellas and Merck. Under the terms of the agreement, the three companies are jointly funding EV-302. The trial was initiated in January 2020 and is being led by Seattle Genetics. EV-302 is an open-label, randomized phase 3 clinical trial evaluating the combination of PADCEV and pembrolizumab with or without chemotherapy versus chemotherapy alone in patients with previously untreated locally advanced or metastatic urothelial cancer. The trial is expected to enroll 1,095 patients and the dual primary endpoints are PFS and OS.

We and Astellas have also initiated a phase 2 clinical trial, EV-202, to evaluate PADCEV monotherapy in solid tumors that have high-level of Nectin-4 expression that include non-small cell lung, head and neck, gastric/esophageal and breast cancers.

**Tucatinib**

Tucatinib is an investigational oral, small molecule TKI that is highly selective for HER2, a growth factor receptor overexpressed in many cancers, including breast, colorectal esophageal, gastric, lung and ovarian cancers. Preclinical data indicate that tucatinib is highly selective for HER2 without significant inhibition of epidermal growth factor receptor, or EGFR. Inhibition of EGFR has been associated with significant toxicities, including skin rash and diarrhea. 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.

Tucatinib was evaluated in the HER2CLIMB-01 clinical trial which was a multinational randomized (2:1), double-blind, placebo-controlled, active comparator, pivotal clinical trial comparing tucatinib in combination with trastuzumab and capecitabine compared with trastuzumab and capecitabine alone in patients with locally advanced or metastatic HER2-positive breast cancer who were previously treated with trastuzumab, pertuzumab and T-DM1. The primary endpoint was PFS per Response Evaluation Criteria in Solid Tumors, or RECIST, v1.1 as determined by blinded independent central review in the first 480 patients enrolled in the trial. HER2CLIMB-01 enrolled a total of 612 patients to support the analyses of key secondary endpoints, including overall survival as well as PFS in patients with brain metastases at baseline. Forty-seven percent of the patients enrolled in the trial had brain metastases at the time of enrollment.

In October 2019, we announced positive topline results from the HER2CLIMB-01 trial and in December 2019 additional details were presented at the 2019 San Antonio Breast Cancer Symposium and published in the *New England Journal of Medicine*. The trial met the primary endpoint of PFS, demonstrating that the addition of tucatinib was superior to trastuzumab and capecitabine alone, with a 46 percent reduction in the risk of disease progression or death (HR=0.54; 95 percent CI: 0.42, 0.71; $p<0.00001$). Estimated PFS at one year was 33 percent (95 percent CI: 27, 40) in the tucatinib arm, compared to 12 percent (95 percent CI: 6, 21) in the trastuzumab and capecitabine arm (control arm). Median PFS was 7.8 months (95 percent CI: 7.5, 9.6) in the tucatinib arm, compared to 5.6 months (95 percent CI: 4.2, 7.1) in the control arm.

The trial also met all secondary endpoints at interim analysis. The tucatinib arm demonstrated an improvement in OS, with a 34 percent reduction in the risk of death (HR=0.66; 95 percent CI: 0.50, 0.88; $p=0.0048$) compared to trastuzumab and capecitabine alone. Estimated OS at two years was 45 percent (95 percent CI: 37, 53) in the tucatinib arm, compared to 27 percent (95 percent CI: 16, 39) in the control arm. Median OS was 21.9 months (95 percent CI: 18.3, 31.0) in the tucatinib arm, compared to 17.4 months (95 percent CI: 13.6, 19.9) in the control arm. For patients with brain metastases at baseline, the tucatinib arm also demonstrated superior PFS, with a 52 percent reduction in the risk of disease progression or death compared to those who received trastuzumab and capecitabine alone (HR=0.48; 95 percent CI: 0.34, 0.69; $p<0.00001$). The estimated PFS at one year was 25 percent (95 percent CI: 17, 34) with the tucatinib regimen, compared to zero percent in the control arm. Median PFS was 7.6 months (95 percent CI: 6.2, 9.5) in the tucatinib arm, compared to 5.4 months (95 percent CI: 4.1, 5.7) in the control arm. Additionally, the confirmed ORR in the patient population with measurable disease at baseline (511/612) was 40.6 percent (95 percent CI: 35.3, 46.0) in the tucatinib arm, compared with 22.8 percent (95 percent CI: 16.7, 29.8) for trastuzumab and capecitabine alone ($p=0.0008$).

Tucatinib in combination with trastuzumab and capecitabine was generally well tolerated with a manageable safety profile. The most common adverse events occurring in more than 20 percent of patients in the tucatinib arm vs. the control arm included: diarrhea (80.9 vs. 53.3 percent), palmar-plantar erythrodysaesthesia syndrome (PPE) (63.4 vs. 52.8 percent), nausea (58.4 vs. 43.7 percent), fatigue (45.0 vs. 43.1 percent) and vomiting (35.9 vs. 25.4 percent), which were primarily low grade. Discontinuation of tucatinib and placebo due to adverse events was 5.7 percent in the tucatinib arm and 3.0 percent in the control arm. Greater than or equal to Grade 3 diarrhea was seen in 12.9 percent of the patients in the tucatinib arm vs. 8.6 percent in the control arm. Antidiarrheal prophylaxis was not required per protocol. Antidiarrheals were used in less than half of all cycles where diarrhea was reported. In both treatment arms, when used, the duration of antidiarrheal treatment was short (median of 3 days/cycle). Greater than or equal to Grade 3 aspartate aminotransferase, or AST, was seen in 4.5 percent of the patients in the tucatinib arm vs. 0.5 percent in the control arm, and alanine aminotransferase, or ALT, elevation in 5.4 percent vs. 0.5 percent, respectively. Discontinuations due to liver transaminase elevations were infrequent in both arms (ALT: 1.0 vs. 0.5 percent; AST: 0.7 vs. 0.5 percent).

Based on the HER2CLIMB-01 results, we submitted an NDA to the FDA in December 2019 and in January 2020 submitted a MAA to the EMA. In the U.S., we are participating in the FDA OCE's RTOR pilot program. RTOR allows the FDA to review much of the data earlier, before the applicant formally submits the complete application so that by the time of the submission of the application, the agency’s review team is in a better position to conduct a more efficient review. We are also participating in the Project Orbis initiative of the FDA OCE, which provides a framework for concurrent submission and review of oncology products among international partners. Countries currently included in this initiative are Australia, Canada, Singapore, Switzerland and U.S.

In October 2019, we initiated a phase 3 randomized trial, called HER2CLIMB-02, of tucatinib versus placebo, 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. HER2CLIMB-02 was initiated based on positive results from a completed phase 1b trial. The trial is designed to enroll approximately 460 patients. The primary endpoint is PFS.

We are also conducting a phase 2 trial, called MOUNTAINEER, evaluating tucatinib 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 with an ORR of 52 percent. The median PFS was 8.1 months and the median OS was 18.7 months. The combination was generally well tolerated. We have expanded enrollment in the trial so it may support potential application for approval. The primary endpoint is confirmed ORR.

**Tisotumab Vedotin**

Tisotumab vedotin is an ADC composed of a human antibody that binds to tissue factor, or TF, linked to a potent auristatin compound using our proprietary ADC technology. TF is expressed on many solid tumors, including cervical, ovarian, prostate and bladder. We are developing tisotumab vedotin as a potential treatment for solid tumors under our collaboration with Genmab. This collaboration is discussed in more detail under “Corporate Collaborations” in this Item 1.

We and Genmab are conducting a pivotal phase 2 trial, called the innovaTV 204 trial, evaluating single-agent tisotumab vedotin for patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment. The trial is intended to support a potential regulatory submission under the FDA’s accelerated approval pathway. In March 2019, we completed enrollment in the innovaTV 204 trial and we anticipate reporting topline data from the trial in the first half of 2020. We are also conducting a phase 2 clinical trial called innovaTV 207 for patients with relapsed, locally advanced or metastatic solid tumors, which is intended to inform future development plans. In addition, we are conducting a phase 2 clinical trial called innovaTV 208 for patients with platinum-resistant ovarian cancer.

**Other Pipeline Activities**

We are developing ladiratuzumab vedotin, 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.

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 2019 and we plan to submit several IND applications to the FDA in 2020.

**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, which are designed to hold the cytotoxic agent to the monoclonal antibody until it binds to the cell surface receptor on the target cell and then to release the cytotoxic agent upon internalization within the target cell. 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 ladiratuzumab vedotin, 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 easier to scale 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. We believe that this may result in increased effector function and antitumor 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.

SEA-BCMA is a clinical-stage non-fucosylated BCMA-directed antibody developed using SEA technology that is designed to block proliferative tumor cell signaling, mediate antibody dependent cellular phagocytosis and induce enhanced cell lysis through antibody dependent cellular cytotoxicity. The cell surface protein BCMA is expressed on cells of several cancer types, including multiple myeloma and other B-cell malignancies. SEA-BCMA is currently in a phase 1 clinical trial for patients with relapsed or refractory multiple myeloma.

**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 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 agents, new ADC linkers, the identification of novel drug targets and monoclonal antibodies, and by 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.

*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 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, antibody masking technologies to enhance cancer specific binding, 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, 2019, we had achieved milestone payments totaling $157.5 million related to regulatory and commercial progress by Takeda. As of December 31, 2019, total future potential milestone payments to us under this collaboration could total $77.0 million. Of that amount, up to approximately $7.0 million relates to the achievement of development milestones, and up to $70.0 million relates to the achievement of regulatory milestones. 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. We rely on Astellas to supply PADCEV for commercial sales and for our clinical trials, and Astellas oversees the manufacturing supply chain 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 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 internal or through a third party.

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.

**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. We and Genmab will share all future costs and profits for development and commercialization of tisotumab vedotin on an equal basis.

We will be responsible for tisotumab vedotin commercialization activities in the U.S., Canada, and Mexico. Genmab will be responsible for commercialization activities in all other territories. We are currently in discussions with Genmab regarding the detailed terms on which we will work together to commercialize tisotumab vedotin under this agreement.

Either party may terminate the collaboration agreement if the other party becomes insolvent or materially breaches the 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.

**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. Under our ADC license agreement with Genentech, the accelerated approval of Polivy triggered a milestone payment to us and we also receive royalties on net sales of Polivy worldwide. In addition, Genentech and GSK have ADCs using our technology in late-stage clinical trials. The product candidates being developed under our other ADC license agreements are at various stages of clinical and preclinical development. Our ability to generate significant future revenues from our 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, at which point the milestone payments, royalties or other rights and benefits would become more substantial.

**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. 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 BioPharma, Inc. or 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 tucatinib. We will pay Array a portion of any non-royalty payments received from sublicensing tucatinib rights. Array is also entitled to receive a low double-digit royalty based on net sales of tucatinib by us and a single-digit royalty based on net sales of tucatinib 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 tucatinib within that country or 10 years after the first commercial sale of tucatinib 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. We have other non-exclusive licenses to other technology used in ADCETRIS that require us to pay a low single-digit royalty on net sales of ADCETRIS. 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, 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 and tisotumab vedotin, we seek to work closely with our development partners to coordinate patent efforts, including patent application filings, prosecution, term extension, defense and enforcement. As ADCETRIS, PADCEV and our 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 2020 and 2031.
- For PADCEV and our related ADC technology, we own, co-own or have licensed rights to twelve patents in the United States and Europe that will expire between 2022 and 2031. Of these patents, we own or co-own ten patents and have licensed rights to two patents.
- For tucatinib, we have licensed rights to eight 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 ten patents in the United States and Europe that will expire between 2022 and 2032. Of these patents, we own or co-own five patents and have licensed rights to five patents.
- For ladiratuzumab vedotin 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 2020 and 2032. Of these patents, we own or co-own seven patents and have licensed rights to two patents.

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 or PADCEV 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 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 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 agreements with collaborators require them to have a similar policy and agreements with their employees, consultants and advisors. 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.

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.

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. 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***

ADCETRIS and certain of our 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 FDA's Center for Drug Evaluation and Research and by 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 ADCETRIS, PADCEV or our 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.

***Regulation 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 such countries and approval of the regulators of such countries or economic areas before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval. We hold worldwide rights to develop and commercialize tucatinib, including in Europe. To commercialize tucatinib in Europe, we will need to comply with applicable European regulations.

*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 member states. Under this system, an applicant must obtain approval from the competent national 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 has issued a favorable opinion. The clinical trial application, or CTA, 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 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 expected that the new Clinical Trials Regulation (EU) No 536/2014 will come into effect sometime after 2020 with a three-year transition period. 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 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 order to be able to market our products outside of the U.S., we must obtain approval from the national competent regulatory authority. The approval requirements and process for each country can vary, and the time required to obtain approval may be longer or shorter than that required for FDA approval in the United States.

In the European Economic Area, which is comprised of the 27 member states of the EU plus the United Kingdom, Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a marketing authorization through either of the following procedures: centralized and decentralized. Under the centralized procedure, a single marketing authorization application is submitted to the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, which then makes a recommendation to the European Commission, or 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 decentralized procedure provides for mutual recognition of individual national approval decisions and is available for products that are not subject to the centralized procedure. Under the decentralized procedure, an identical dossier is submitted to the competent authorities of each of the member states in which the marketing authorization is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other member states (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national marketing authorization in all the member states (i.e., in the RMS and the Member States Concerned).

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. The 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 typically lasts 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, typically because 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 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 is usually 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.

*Manufacturing Regulation in Europe*

Various requirements apply to the manufacturing and placing on the EU market of medicinal products. 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.

*Post-approval Regulation in Europe*

In connection with potential regulatory approvals outside of the U.S., we expect to be subject to a variety of post-authorization regulations, including with respect to clinical studies, product manufacturing, advertising and promotion, distribution, and safety reporting.

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, 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***

Federal and state healthcare laws and regulations, including fraud and abuse and health information privacy and security laws and regulations, may also be 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, data privacy and security laws, as well as 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, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item, or service reimbursable, 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, claims for payment to 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 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.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, 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.

The federal Physician Payments Sunshine Act, created under PPACA and its implementing regulations, requires certain manufacturers of drugs, devices, biologicals 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, as defined by such law, 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. 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." 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 foreign countries and jurisdictions, including Canada and the European Union, 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 are 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, imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings 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 the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In the EU, 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 to the general public and may also impose limitations on promotional activities with health care professionals. There are data privacy and security laws, to which we are currently and/or may in the future, be subject. For example, European Union, or EU, member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, effective May 25, 2018, the collection and use of personal health data 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.

***Coverage and Reimbursement***

Sales of ADCETRIS, PADCEV 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 foreign governments 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 therapeutics 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, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

Many of the patients in the U.S. who seek treatment with ADCETRIS or PADCEV 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. In January 2017, the White House Office of Management and Budget withdrew the draft August 2015 Omnibus Guidance document that was issued by the Department of Health and Human Services Health Resources and Services Administration, or HRSA, that addressed a broad range of topics including, among other items, the definition of a patient's eligibility for 340B drug pricing. Federal budget decisions have and may result in reduced Medicare payment rates. Federal budget decisions have and may result in reduced Medicare payment rates. 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 and PADCEV 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 and PADCEV 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 ADCETRIS and PADCEV to these entities.

The requirements governing drug pricing vary widely from country to country. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. The European Union has adopted directives and other legislation governing labeling, advertising, distribution, supply, pharmacovigilance and marketing of pharmaceutical products. Such legislation provides mandatory standards throughout the EU and permits member states to supplement these standards with additional regulations. European governments also regulate pharmaceutical product prices through their control of national health care systems that fund a large part of the cost of such products to consumers. As a result, patients are unlikely to use a pharmaceutical product that is not reimbursed by the government. In many European countries, the government either regulates the pricing of a new product at launch or subsequent to launch through direct price controls or reference pricing. In recent years, many countries have also imposed new or additional cost containment measures on pharmaceutical products. Differences between national price regimes create price differentials within the EU that can lead to parallel trade in pharmaceutical products.

Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU member states, including countries representing major markets. The HTA process, which is governed by the national laws of these countries, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost and cost-effectiveness of individual medicinal products, as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal 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 EU member states were required to implement the provisions of the Directive into their national legislation by October 2013. 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 affects the pharmaceutical industry. PPACA aims to, among other things, expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to biopharmaceutical products, 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.

Many provisions of PPACA impact the biopharmaceutical industry, including that 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 and Congressional challenges to certain aspects of PPACA. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of PPACA. The Budget Resolution is not a law; however, it was widely viewed as the first step toward the passage of legislation that would repeal certain aspects of PPACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. While Congress has not passed repeal or replace 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 the 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. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace PPACA will impact PPACA and our business.

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 2029 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.

Further, the Drug Supply Chain Security Act imposes on manufacturers of certain pharmaceutical products new obligations related to product tracking and tracing, among others. This legislation also requires covered manufacturers to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. Additionally, the Drug Supply Chain Security Act included provisions requiring that the transfer of information to subsequent product owners by manufacturers be done electronically. The Drug Supply Chain Security Act also requires covered manufacturers to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this legislation, covered manufacturers have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2020 contained further drug price control measures that could be enacted during the budget process or in other future legislation such as measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, on October 30, 2018, CMS issued an advance notice of proposed rulemaking with respect to the potential adaption of an international pricing index model that would be designed to reduce Medicare expenditures on certain Part B drugs to rates that are more closely aligned with the costs of such drugs in select comparator countries. In addition, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We cannot predict what healthcare reform initiatives may be adopted in the future. However, we anticipate that Congress, state legislatures, and third-party payors may continue to review and assess alternative healthcare delivery and payment systems and may in the future propose and adopt legislation or policy changes or implementations effecting additional fundamental changes in the healthcare delivery system. We also expect ongoing legislative and regulatory initiatives to increase pressure on drug pricing. We cannot assure you as to the ultimate content, timing, or effect of changes, nor is it possible at this time to estimate the impact of any such potential legislation; however, such changes or the ultimate impact of changes could negatively affect our revenue or sales of our products or any future approved products.

**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 (Opdivo®) and Merck's pembrolizumab (Keytruda®) are approved for the treatment of certain patients with relapsed or refractory classical Hodgkin lymphoma, and Celgene's romidepsin (Istodax®) and Spectrum Pharmaceuticals' pralatrexate (Folotyn®) and belinostat (Beleodaq®) are approved for relapsed or refractory sALCL among other T-cell lymphomas. Kyowa Kirin's mogamulizumab (Poteligeo®) 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. If this clinical trial demonstrates that pembrolizumab is more effective than ADCETRIS in that treatment setting, our sales of ADCETRIS would be negatively impacted. We are also aware of multiple investigational agents that are currently being studied, including Pfizer's avelumab, which, 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 pre-treated metastatic urothelial cancer include checkpoint inhibitor monotherapy, generic chemotherapy and, for patients with select fibroblast growth factor receptor genetic alterations, Janssen's erdafitinib (Balversa®). There are other investigational agents that, if approved, could be competitive with PADCEV, such as Immunomedics' sacituzumab govitecan. Treatment in front line metastatic urothelial cancer has traditionally been treated with chemotherapy alone but is evolving to include two recently approved 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 expected to report data in the near term.

With respect to tucatinib, there are multiple marketed products which target HER2, including the antibodies trastuzumab (Herceptin®) and pertuzumab (Perjeta®) and the antibody drug conjugate T-DM1 (Kadcyla®). In addition, lapatinib (Tykerb®) is an EGFR/HER2 oral kinase inhibitor for the treatment of metastatic breast cancer, and neratinib (Nerlynx®) is an irreversible pan-HER kinase inhibitor indicated for extended adjuvant use that is also being studied in a phase 3 trial in pre-treated HER2-positive metastatic breast cancer, for which positive data were reported in 2019. Daiichi Sankyo and AstraZeneca have fam-trastuzumab deruxtecan-nxki (Enhertu®) that was recently approved for patients who have received two or more prior anti-HER2-based regimens in the metastatic setting. Synthon has an antibody drug conjugate in a pivotal study in this patient population and MacroGenics has a HER2 targeted, Fc-optimized antibody, margetuximab, also in a pivotal study for which positive data were reported and a BLA was submitted in late 2019.

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, 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, Immunomedics, 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, ImmunoGen, Immunomedics, MedImmune, Mersana, Pfizer and Roche, 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 United States, 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 European Union, the European Commission 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, tucatinib, 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, tucatinib, 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, tucatinib, 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. The agreement generally provides for the supply by Millipore Sigma and the purchase by us of drug linker. 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***

We rely on Astellas to supply PADCEV for commercial sale and for our clinical trials, and Astellas oversees the manufacturing supply chain for 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 encounters challenges in negotiating commercially reasonable arrangements with these manufacturers.

***Product Candidates***

For the clinical supply of our product candidates, which include ADCs as well as antibodies and small molecules such as tucatinib, 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. We use the facility to support our clinical supply needs. However, for the foreseeable future, we expect to continue to rely on contract manufacturers and, in the case of tisotumab vedotin, our collaborators for much of the manufacturing to supply drug product for our clinical trials. With respect to tucatinib, we rely on third-party contract manufacturers to produce drug supply for our clinical trials and our potential future commercial supplies. We have limited prior experience as an organization manufacturing tucatinib and small molecule drug products generally, and have relatively new working relationships with many of the third party manufacturers involved in tucatinib manufacture. We may also need to put in place additional manufacturing arrangements or expand our current manufacturing arrangements with third party manufacturers to meet potential future commercial needs for tucatinib, 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. With respect to tisotumab vedotin, the manufacturing supply chain is overseen by Genmab, and we rely Genmab to supply sufficient supplies of drug product. For tisotumab vedotin, we believe that the existing supplies of drug product and Genmab's contract manufacturing relationships will be sufficient to accommodate ongoing and future clinical trials. However, we or Genmab may need to obtain additional manufacturing arrangements or increase manufacturing capability to meet potential future commercial needs with respect to tisotumab vedotin, which could require additional capital investment by us or cause us potential delays if Genmab encounters challenges in negotiating commercially reasonable arrangements with these manufacturers.

**Commercial Operations**

We have allocated commercial resources, including sales, marketing, supply chain management and reimbursement capabilities, to commercialize ADCETRIS in the U.S. and Canada, and PADCEV in the U.S. We believe the U.S. market for ADCETRIS and PADCEV in their approved indications, and Canadian market for ADCETRIS in its approved indications, are addressable with a targeted sales and marketing organization, and 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. We and Takeda have received marketing authorizations by regulatory authorities for ADCETRIS in more than 70 countries worldwide, and Takeda continues to pursue marketing authorizations in multiple other countries.

We sell ADCETRIS and PADCEV through a limited number of specialty distributors. Health care providers order ADCETRIS and PADCEV through these distributors. We receive orders from distributors and generally ship product directly to the health care provider. 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 revenue in 2019, 2018 and 2017.

**Employees**

As of December 31, 2019, we had 1,605 employees. Of these employees, 1,011 were engaged in or support research, development and clinical activities, 309 were in administrative and business related positions, and 285 were in sales and marketing. Each of our employees has signed confidentiality and inventions assignment agreements and none are covered by a collective bargaining agreement. We have never experienced employment-related work stoppages and consider our employee relations to be good.

**Corporate Information**

We were incorporated in Delaware on July 15, 1997. Our principal executive offices are located at 21823 30$^{th}$ Drive SE, Bothell, Washington 98021. Our telephone number is (425) 527-4000, and our website address is www.seattlegenetics.com. Seattle Genetics®, ADCETRIS® and PADCEV™ are our 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.seattlegenetics.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 Business*

***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 two marketed products are ADCETRIS®, or brentuximab vedotin and PADCEV™, or enfortumab vedotin-ejfv, which received accelerated approval in December 2019 by the U.S. Food and Drug Administration, or FDA. 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 and PADCEV 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 may be unable to effectively commercialize our products, including 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, for which the FDA approved ADCETRIS in combination with chemotherapy in March 2018 based on the results of the ECHELON-1 trial, or the frontline Hodgkin lymphoma indication, and the newly diagnosed, previously untreated systemic anaplastic large-cell lymphoma, or sALCL or other CD30-expressing peripheral T-cell lymphomas, or PTCL, including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified indication, for which the FDA approved ADCETRIS in combination with chemotherapy in November 2018 based on the results of the ECHELON-2 trial, or the frontline PTCL indication;
- we and our collaborators may not be able to obtain and maintain regulatory approvals to market our products for their currently approved indications or for any additional indications in our or our collaborators' respective territories, including any approvals for ADCETRIS in the ECHELON-2 treatment setting outside the U.S. and Canada or for PADCEV outside the U.S., 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., nivolumab and pembrolizumab) and other novel agents (e.g., mogamulizumab), or in PADCEV's approved indication, including antibody drug conjugates (e.g., sacituzumab govitecan) and other targeted agents (e.g., BALVERSA for patients with select FGFR alterations), 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 our commercial sales of ADCETRIS or PADCEV, respectively;

- there may be changes to the labels for our products, including the boxed warning in the ADCETRIS label, 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 ADCETRIS or PADCEV, including the post-approval confirmatory studies that our collaborator, Takeda Pharmaceutical Company Limited, or Takeda, is required to conduct as a condition to the conditional marketing authorization of ADCETRIS granted by the European Commission, or the EC, and the confirmatory post-marketing study that we and our collaborator, Astellas Pharma, Inc., or Astellas, are required to conduct as a condition to the accelerated approval of PADCEV by the FDA, or as a result of investigator-sponsored studies;
- 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 be adverse results or events reported in any of the clinical trials that we or our collaborators are conducting, or may conduct in the future, for our products;
- we and our collaborators may be unable to continue to effectively market, sell and distribute our products;
- in the case of PADCEV, our joint commercialization efforts in the U.S. with 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.

We have an agreement with Takeda to develop and commercialize ADCETRIS, under which we have commercial rights in the United States and its territories and Canada, and Takeda has commercial rights in the rest of the world. We also have agreements with Astellas to develop and commercialize PADCEV, under which we and Astellas jointly promote PADCEV in the U.S., we have commercialization rights in the other countries in North and South America, and Astellas has commercialization rights in the rest of the world. The success of these 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 or PADCEV, or to their marketing and distribution. Our ability to generate royalty revenues from ADCETRIS product sales by Takeda depends on Takeda’s ability to obtain regulatory approvals for ADCETRIS in Takeda's territory, and to achieve market acceptance of, and to otherwise effectively market, ADCETRIS for its approved indications in Takeda’s territory. 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, foreign sales could be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions or barriers and changes in tariffs, including as a result of the United Kingdom’s separation from the European Union, commonly referred to as Brexit, escalating global trade and political tensions, or otherwise.

While ADCETRIS product sales have grown over time, and our future plans assume that sales of ADCETRIS will increase, we expect lower sales growth for ADCETRIS in 2020 as compared to growth in 2019. We cannot assure you that ADCETRIS sales will continue to grow or that we can maintain sales of ADCETRIS at or near current levels. We

expect that our ability to 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 and PTCL indications, and the extent to which physicians make prescribing decisions with respect to ADCETRIS. Other important factors affecting ADCETRIS sales include the extent to which Takeda obtains further regulatory approvals of ADCETRIS in its territories, 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 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 ADCETRIS, increasing competition from competing therapies and the potential future approval of ADCETRIS in any additional indications. 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 launch, 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, 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 the successful completion of the required confirmatory post-marketing study that we and Astellas are subject to as a result of an accelerated approval by the FDA, 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 and potential competition from competing therapies. In addition, due to the lack of any historical sales data and these factors, PADCEV 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 of our product candidates and of 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 United States or foreign countries until we obtain marketing approvals from the FDA and foreign 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 the FDA and foreign regulatory authorities in order to market our current 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 tucatinib and tisotumab vedotin, and in seeking additional regulatory approvals for ADCETRIS and PADCEV. However, obtaining marketing approval is a lengthy, expensive and uncertain process, approval is never assured, and we have only limited experience in preparing and submitting the applications necessary to gain regulatory approvals. As an organization, we do not have any prior experience submitting an application to the FDA for a small molecule, such as tucatinib, or applying for regulatory approval 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 the potential commercial sale of tucatinib or of ADCETRIS or PADCEV 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 foreign regulatory authority or their respective advisors may disagree with our interpretations of this data. For example, we reported positive topline results from the pivotal clinical trial comparing tucatinib added to trastuzumab and capecitabine versus trastuzumab and capecitabine alone in patients with locally advanced or metastatic HER2-positive breast cancer who were previously treated with trastuzumab, pertuzumab and ado-trastuzumab emtansine, or T-DM1, which we refer to as the HER2CLIMB-01 trial. However, regulatory agencies may disagree with our interpretation of the data from the HER2CLIMB-01 trial and may otherwise determine not to accept for filing or approve the applications we submitted for tucatinib, including the New Drug Application, or NDA, we submitted to the FDA in December 2019 under the FDA's Oncology Center of Excellence's, or OCE's, Real Time Oncology Review, or RTOR, pilot program, submissions to other countries participating in the FDA OCE's Project Orbis initiative, and the Marketing Authorization Application, or MAA, we submitted to the European Medicines Agency, or EMA, in January 2020, in a timely manner or at all. Although the FDA granted Breakthrough Therapy designation to tucatinib in combination with trastuzumab and capecitabine, for treatment of patients with locally advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have been treated with trastuzumab, pertuzumab, and ado-trastuzumab emtansine, or T-DM1, and we submitted our tucatinib NDA under the RTOR pilot program, this Breakthrough Therapy designation and RTOR pilot program may not result in a faster review or approval process for tucatinib. Further, they do not increase the likelihood that the tucatinib NDA will be accepted for filing or approved or that tucatinib will otherwise receive any marketing approvals. We also cannot assure you that tucatinib or any of our other 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, including, with respect to tucatinib, our acquisition of Cascadian Therapeutics, Inc., or Cascadian, referred to as the Cascadian Acquisition. In addition, failure to obtain regulatory approval of tucatinib in Europe may negatively impact our plans to build a commercial infrastructure in Europe.

Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of ADCETRIS and PADCEV in any additional indications or territories, or of any future approved product. Regulatory agencies also may approve a product candidate 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 ADCETRIS or PADCEV 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 in additional indications. However, we and/or our collaborators may be unable to obtain any regulatory approvals for the commercial sale of ADCETRIS or PADCEV 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 current or future NDAs or BLAs, the commercialization of the affected product candidate, or of the affected product in any additional indications, could be delayed or impaired.

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 A/S, or Genmab, respectively, to effectively jointly launch and commercialize PADCEV and any potential future approved tisotumab vedotin products with us, our and our collaborators' ability to successfully comply with rigorous post-marketing requirements, including the successful completion of the required 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, our joint launch and commercialization of this product in the U.S. with Astellas is at an early stage and may not be successful. If we are unable to successfully launch and commercialize PADCEV jointly with Astellas in the U.S., our growth prospects and our prospects for profitability would be adversely affected. Likewise, although we have submitted certain applications for regulatory approval for tucatinib outside the U.S., 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 any approved tucatinib product. In addition, in many countries, the proposed pricing for a drug must be approved 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 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 could be delayed due to a variety of factors, including supply constraints, delays in arranging a commercial infrastructure or delays in negotiating pricing and reimbursement approvals. If we 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 tucatinib. In addition, if we 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 tucatinib in Europe and other regions could be negatively affected.

If we are unable to obtain and maintain necessary or desirable regulatory approvals for our products and product candidates, including for ADCETRIS, PADCEV and tucatinib, 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 Takeda is required to conduct as a condition of the marketing authorization of ADCETRIS by the EC and that we and Astellas are required to conduct in connection with the accelerated approval of PADCEV by the FDA in the U.S. 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. For example, there was an increased incidence of febrile neutropenia and peripheral neuropathy in the ADCETRIS plus doxorubicin, vinblastine and dacarbazine, or AVD, arm of the ECHELON-1 trial. The ADCETRIS prescribing information provides for use of prophylactic growth factors for Stage III or IV classical Hodgkin lymphoma patients receiving ADCETRIS plus AVD to mitigate events of neutropenia and febrile neutropenia, but despite this, these product safety concerns could limit prescribing of ADCETRIS for newly diagnosed patients with previously untreated Stage III and IV classical Hodgkin lymphoma and negatively impact sales of ADCETRIS or adversely affect ADCETRIS' acceptance in the market. There are no assurances that patients receiving ADCETRIS or PADCEV will not experience serious adverse events in the future, whether the serious adverse events are disclosed in the ADCETRIS or PADCEV prescribing information or are newly reported. Further, there are no assurances that patients receiving ADCETRIS or PADCEV with co-morbid diseases not previously studied, such as autoimmune diseases, will not experience new or different serious adverse events in the future.

Adverse events may negatively impact the sales of our products. We may be required to further 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, which could adversely affect the acceptance of our products in the market, make competition easier or make it more difficult or expensive for us to distribute our products. For example, the prescribing information for ADCETRIS has been revised over time to include warnings and precautions for hematologic toxicities, serious infections and opportunistic infections, increased toxicity in the presence of moderate or severe hepatic impairment, increased toxicity in the presence of severe renal impairment, hepatotoxicity, pulmonary toxicity, hyperglycemia and gastrointestinal complications, 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. Further, based on the identification of future adverse events, we may be required to further revise the prescribing information, including ADCETRIS' boxed warning, which could negatively impact sales of ADCETRIS or adversely affect ADCETRIS' acceptance in the market.

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 for any of our product candidates. We initiated the pivotal trials of tucatinib and tisotumab vedotin, in each case based on only limited clinical data. Data continues to be generated in these pivotal and other trials. Although we reported positive results from the pivotal HER2CLIMB-01 trial, there may still be important facts about the safety, efficacy, and risk versus benefit of tucatinib and each of our other product candidates that are not known to us at this time which may negatively impact our ability to develop and commercialize these product candidates. In response to prior safety events observed in our clinical trials of PADCEV and tisotumab vedotin, including 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 tucatinib or tisotumab vedotin or for PADCEV in any additional indications or territories, 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 ADCETRIS, PADCEV or the applicable product candidate. 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 or the inclusion of unfavorable information in our product labeling, and in turn delay or prevent us from commercializing ADCETRIS, PADCEV or the applicable 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 ADCETRIS, PADCEV or the particular product candidate, and could significantly harm our business, results of operations and prospects.

***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 and PADCEV 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. Unfavorable results from this post-marketing study or failure to complete this post-marketing study could result in the withdrawal of approval of PADCEV or 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 could entail significant expense and could negatively impact the potential commercialization of

PADCEV. In addition, the use of PADCEV may uncover additional adverse events that limit or prevent PADCEV's widespread use or that force us or Astellas to withdraw PADCEV from the market, and any problems with PADCEV or any violation of ongoing regulatory obligations could result in restrictions on PADCEV, including its withdrawal from the market.

ADCETRIS is approved for treating patients in the relapsed sALCL indication with conditions in Canada, and approved under conditional marketing authorization in relapsed Hodgkin lymphoma and sALCL in the European Union, in each case 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. For the European Union indications, Takeda is subject to certain post-approval requirements, including the requirement to conduct clinical trials to confirm clinical benefit. In Canada, the ECHELON-2 results may be sufficient to confirm the clinical benefit of ADCETRIS in relapsed sALCL. In the European Union, there are other post approval requirements to convert the conditional marketing authorization for ADCETRIS in relapsed Hodgkin lymphoma and relapsed sALCL into a standard marketing authorization. Takeda's failure to provide these additional clinical data from confirmatory studies could result in the EC withdrawing approval of ADCETRIS in the European Union for certain indications, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Takeda in the European Union and could adversely affect our results of operations. 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.

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

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

- issuance of Form FDA 483 notices or Warning Letters by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties;
- criminal prosecutions;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing clinical trials;
- total or partial suspension of manufacturing;
- delays in commercialization;

- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us;
- refusals to permit drugs to be imported into or exported from the United States;
- restrictions on operations, including costly new manufacturing requirements; and
- product recalls or seizures.

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

***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 are currently conducting multiple clinical trials for our products and product candidates and we plan to commence additional trials of our products and product candidates in the future. In this regard, we and Astellas are continuing enrollment in a single-arm pivotal phase-2 trial of PADCEV in patients with locally advanced or metastatic urothelial cancer, called the EV-201 trial, for the second cohort of patients who received prior treatment with a PD-1 or PD-L1 inhibitor and who were not candidates for treatment with a platinum agent, a global, randomized phase 3 clinical trial of PADCEV, called the EV-301 trial, for patients with metastatic urothelial cancer who previously received both platinum chemotherapy and a PD-1 or PD-L1 inhibitor, a phase 1/2, multi-cohort, open-label trial of PADCEV alone or in combination with the anti-PD-1 therapy pembrolizumab and/or chemotherapy, called the EV-103 trial, in locally advanced and first- and second-line metastatic urothelial cancer and muscle invasive bladder cancer and, under a collaboration with Merck, an open-label, randomized phase 3 trial, called the EV-302 trial, evaluating the combination of PADCEV and pembrolizumab with or without chemotherapy versus chemotherapy alone in patients with previously untreated locally advanced or metastatic urothelial cancer. Additionally, we are conducting a phase 3 randomized trial of tucatinib vs. placebo, in combination withT-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, which we refer to as HER2CLIMB-02, and a phase 2 trial evaluating tucatinib 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, which we call MOUNTAINEER. We are also conducting a pivotal phase 2 clinical trial of single-agent tisotumab vedotin with Genmab for patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment, which we refer to as the innovaTV 204 trial. Each of these trials was initiated based on only limited clinical data and we cannot be certain that the design of, or data collected from, these trials will be sufficient to support FDA or any foreign regulatory approvals. Furthermore, we do not have Special Protocol Assessment agreements with the FDA for any of these trials.

Each of our clinical trials requires the investment of substantial expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant 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.

Additionally, 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. 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, BMS, and other collaborators, which may delay the commencement or adversely affect the continuation or completion of these trials. From time to time, we have experienced enrollment-related delays in clinical trials and we will likely continue to experience similar delays in our current and future trials. We depend on medical institutions and clinical research organizations, or CROs, to conduct some of 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, we may be affected by increased costs, program delays or both, which may harm our business. In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign CROs, as well as expose us to risks associated with less experienced clinical investigators who are unknown to the FDA, different standards of medical care, and foreign currency transactions insofar as changes in the relative value of the U.S. dollar to the foreign currency where the trial is being conducted may impact our actual costs.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, foreign 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 foreign countries, and may require large numbers of test patients. We or our collaborators, the FDA, foreign 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 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 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 or the applicable product candidate may not appear to be more effective than current therapies;
- the quality or stability of ADCETRIS, PADCEV 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 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 CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and 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 CROs 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; or

- 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.

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 or to market ADCETRIS or PADCEV and/or expand ADCETRIS or PADCEV 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, even though we reported positive results from the HER2CLIMB-01 trial, regulatory agencies may disagree with our interpretation of the data from the HER2CLIMB-01 trial and may otherwise determine not to accept for filing or approve the applications for regulatory approval we submitted for tucatinib, including the NDA we submitted to the FDA in December 2019, submissions to other countries participating in the FDA OCE's Project Orbis initiative, and the MAA we submitted to the EMA in January 2020, in a timely manner or at all. Likewise, although we reported positive results in our ECHELON-2 trial, regulatory agencies outside of the U.S., 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. 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 or PADCEV, result in our failure to expand ADCETRIS or PADCEV into additional indications and territories, adversely affect our ability to market ADCETRIS or PADCEV, 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.

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

Our late-stage product candidates are tucatinib and tisotumab vedotin, each of which was advanced to pivotal trials based on only limited clinical data. Our earlier-stage clinical pipeline 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, to pursue, obtain and maintain regulatory approvals for, and to potentially commercialize tucatinib and tisotumab vedotin, if we are able to do so at all. Our other product candidates are in early or relatively early stages of development.

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. For example, with respect to tucatinib, we have incurred significant expenditures related to its development and potential launch, but there can be no assurances that the FDA, the other countries participating in the FDA OCE's Project Orbis initiative, or the EMA, will accept or approve our regulatory submissions for tucatinib or that tucatinib will otherwise receive any regulatory approvals, and we may therefore fail to receive any return on our investment in tucatinib or realize the anticipated benefits of the Cascadian Acquisition. Moreover, with the exception of the positive results we reported from the HER2CLIMB-01 trial, we have reported only limited data from earlier stage trials of our product candidates. 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, the encouraging or positive results from clinical trials of our product candidates in earlier stage trials may not be replicated in subsequent later-stage trials. In addition, we are developing 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 the product candidate 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 product candidates only to learn that a product candidate is not an effective treatment or is not superior to existing approved therapies, or has an unacceptable safety profile, which could prevent or significantly delay regulatory approval for such product candidate or could cause us to discontinue the development of such product candidate. Also, later-stage clinical trials could differ in significant ways from earlier stage clinical trials, which could cause the outcome of the later-stage trials to differ from earlier-stage clinical trials. Differences in earlier- and later-stage clinical trials may include changes to inclusion and exclusion criteria, efficacy endpoints and statistical design. In this regard, we initiated the EV-302 trial of PADCEV with Astellas, the HER2CLIMB-02 trial of tucatinib, and the innovaTV 204 trial of tisotumab vedotin with Genmab, in each case based on only limited clinical data, and we cannot be certain that the design of, or data collected from, these trials will be adequate to support FDA or any foreign regulatory approvals. Moreover, despite the positive results we and Astellas reported for the first cohort in the EV-201 trial and the positive initial data from the EV-103 trial, we cannot be certain that PADCEV will demonstrate sufficient efficacy in other trials, including in the EV-301 trial, the EV-302 trial, other cohorts of the EV-201 and EV-103 trials or any future trials. In this regard, despite the initial results we and Astellas reported from the EV-103 trial, PADCEV may not demonstrate sufficient efficacy in the EV-302 trial or in any other frontline setting, and PADCEV 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-01 trial, we cannot be certain that tucatinib will demonstrate sufficient efficacy in other trials, including the HER2CLIMB-02 trial, or will ever be approved for commercial sale. Tisotumab vedotin may likewise fail to demonstrate sufficient efficacy in pivotal trials despite the results observed in earlier-stage trials. In addition, there may still be important facts about the safety, efficacy, and risk versus benefit of PADCEV, tucatinib and tisotumab vedotin that are not known to us at this time which may negatively impact our ability to develop and commercialize PADCEV or these product candidates. 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. In addition, in response to prior safety events observed in our clinical trials of PADCEV and tisotumab vedotin, including 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, tucatinib 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, tucatinib and tisotumab vedotin. If we or our collaborators fail to produce positive results in our ongoing or planned clinical trials of PADCEV or any of our product candidates, the development timeline and regulatory approval and commercialization prospects for PADCEV and our product candidates, and, correspondingly, our business, financial condition, results of operations and growth prospects, 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 due to 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.

***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 will achieve and continue to have coverage available for our products and any product candidates that we commercialize and, if available, that the reimbursement rates will be adequate. If we are unable to obtain coverage and adequate levels of reimbursement for our current and any future approved products that we 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, if we are able to obtain any regulatory approval of tucatinib, for tucatinib based on their relative price and perceived benefits as compared to alternative treatment options or otherwise, which may materially harm our ability to successfully commercialize PADCEV and any approved tucatinib product. In addition, we are currently seeking regulatory approvals of tucatinib from the EMA and in the Project Orbis countries of Australia, Canada, Singapore and Switzerland. In many countries, the proposed pricing for a drug must be approved 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 from selling a product in a country where we have received regulatory approval. The launch of tucatinib in these markets could be delayed due to a variety of factors, including supply constraints, delays in arranging a commercial infrastructure or delays in negotiating pricing and reimbursement approvals. If we 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 tucatinib. In addition, if we 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 tucatinib 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 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. Further, in the United States, 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 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 presidential and Congressional focus on this issue create significant uncertainty regarding regulation of the healthcare industry and third-party coverage and reimbursement. If healthcare policies or reforms intended to curb healthcare costs are adopted 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 commercial opportunity may be limited and/or 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 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, as well as the acceptance and degree of adoption of our products and any future products by institutional pathways and institutional, local, and national guidelines such as the National Comprehensive Cancer Networks® Clinical Practice Guidelines in Oncology, or the NCCN Guidelines. 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.

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

In March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively PPACA, became law in the United States. PPACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. The provisions of PPACA of greatest importance to the pharmaceutical industry include increased Medicaid rebates, expanded Medicaid eligibility, extension of Public Health Service eligibility, annual fees payable by manufacturers and importers of branded prescription drugs, annual reporting of financial relationships with physicians and teaching hospitals, and a new Patient-Centered Outcomes Research Institute. Many of these provisions have had the effect of reducing the revenue generated by our sales of ADCETRIS and will have the effect of reducing any revenue generated by sales of PADCEV and any future commercial products we may have.

Certain provisions of the PPACA have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. For example, since January 20, 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provision of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017, includes 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." Additionally, the 2020 federal spending package permanently repealed, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device taxes, and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In December 2018, CMS published a new final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed. 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 the PPACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA and our business.

Further, on March 23, 2018, CMS finalized updates to the National Drug Rebate Agreement, or the Rebate Agreement, for the first time in 27 years, to incorporate legislative and regulatory changes that have occurred since the Rebate Agreement was first published. These updates align the Rebate Agreement with certain provisions of PPACA and contain additional changes incorporating CMS policies adopted over the years. In order to have our current and any future approved products covered under Medicaid, and Medicare Part B, we were required to enter into the revised Rebate Agreement with CMS. If we fail to comply with the terms of the revised Rebate Agreement, we will be unable to obtain, and maintain, Medicaid and Medicare Part B coverage and reimbursement, which could negatively affect our financial condition and results of operations.

We anticipate that the PPACA, as well as other healthcare reform measures that have been adopted, or may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the price that we receive for our current or any future approved products, which may harm our business. For example, increased discounts and rebates may be mandated by governmental entities, or requested by private insurers, or fee caps and pricing pressures could be enacted by industry organizations or state and federal governments, any of which could significantly affect the revenue generated by sales of our current or any future approved products. In addition, drug-pricing by pharmaceutical companies has come under increased scrutiny. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing by requiring drug companies to notify insurers, purchasers and government regulators of price increases and to provide an explanation as to the reasons for the increase, reduce the out-of-pocket costs to patients for prescription drugs, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2020 contained further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Moreover, in May 2018, the Trump administration released its "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," or the Blueprint. The Blueprint contains several potential regulatory actions and legislative recommendations aimed at lowering prescription drug prices, including measures to promote innovation and competition for biologics, changes to Medicare Part D to give plan sponsors more leverage when negotiating prices with manufacturers, and updating the Medicare drug-pricing dashboard to make price increases and generic competition more transparent. HHS has solicited feedback on some of these measures and, at the same, has implemented others under its existing authority. For example, on October 30, 2018, CMS issued an advance notice of proposed rulemaking with respect to the potential adaption of an international pricing index model that would be designed to reduce Medicare expenditures on certain Part B drugs to rates that are more closely aligned with the costs of such drugs in select comparator countries. In addition, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. The recommendations in the Blueprint, if enacted by Congress and the Department of Health and Human Services, or HHS, could lead to changes to Medicare Parts B and D, including the transition of certain drugs covered under Part B to Part D or the offering of alternative purchasing options under the Competitive Acquisition Program that currently applies to selected drugs and biologics covered under Part B. While many of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative, administrative and/or additional measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing, cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect further federal and state legislation and healthcare reforms to continue to be proposed to control increasing healthcare costs and to control the rising cost of prescription drugs. These proposals, if implemented, could limit the price for our current or any future approved products. Commercial opportunity could be negatively impacted by legislative action that controls pricing, mandates price negotiations, or increases government discounts and rebates.

Also, 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 addition, although ADCETRIS is approved in the European Union, Japan and other countries outside of the United States, government austerity measures or further healthcare reform measures and pricing pressures in other countries could adversely affect demand and pricing for ADCETRIS, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Takeda.

Other legislative changes have also 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 a 2% reduction in Medicare provider payments paid under Medicare Part B to physicians for physician-administered drugs, such as certain oncology drugs, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2029 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, legislation has been proposed to shorten the period of biologic data and market exclusivity granted by the FDA. If such legislation is enacted, we may face competition from biosimilars of our current or any future approved products earlier than otherwise would have occurred. Increased competition may negatively impact coverage and pricing of our products, which could negatively affect our financial condition or results of operations.

We also expect to experience pricing pressures in connection with the sale of our products due to certain managed healthcare initiatives. For example, the PPACA increased the mandated Medicaid rebate from 15.1% to 23.1% of Average Manufacturer Price, expanded the rebate to Medicaid managed care utilization and increased the types of entities eligible for the federal 340B drug discount program. As concerns continue to grow over the need for tighter oversight, there remains the possibility that the Heath Resources and Services Administration or another agency under the HHS will propose a similar regulation or that Congress will explore changes to the 340B program through legislation. For example, a bill was introduced in 2018 that would require hospitals to report their low-income utilization of the program. Further, the Centers for Medicare & Medicaid Services issued a final rule that would revise the Medicare hospital outpatient prospective payment system for calendar year 2019, including a new reimbursement methodology for drugs purchased under the 340B program for Medicare patients at the hospital setting and recently announced the same change for physician-based practices under 340B in 2019. In addition, HHS set January 1, 2019, as the effective date of the final rule setting forth the calculation of the ceiling price and application of civil monetary penalties. Pursuant to the final rule, after January 1, 2019, manufacturers must calculate 340B program ceiling prices on a quarterly basis. Moreover, manufacturers could be subject to a $5,000 penalty for each instance where they knowingly and intentionally overcharge a covered entity under the 340B program. A significant portion of purchases of our products are eligible for 340B drug pricing, and therefore an expansion of the 340B program or reduction in 340B pricing, whether in the form of the final rule or otherwise, would likely have a negative impact on our net sales of our products.

We cannot predict what healthcare reform initiatives may be adopted in the future. However, we anticipate that Congress, state legislatures, and third-party payors may continue to review and assess alternative healthcare delivery and payment systems and may in the future propose and adopt legislation or policy changes or implementations effecting additional fundamental changes in the healthcare delivery system. We also expect these initiatives to increase pressure on drug pricing. We cannot assure you as to the ultimate content, timing, or effect of changes, nor is it possible at this time to estimate the impact of any such potential legislation; however, such changes or the ultimate impact of changes could negatively affect our revenue or sales of our current and or potential future products.

***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 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.

***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 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 United States and Canada. In addition, we have entered into collaborations with Astellas for the development and commercialization of PADCEV and with Genmab for the development and commercialization of tisotumab 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 a clinical trial collaboration with BMS to evaluate the combination of nivolumab with ADCETRIS for the treatment of Hodgkin and non-Hodgkin lymphoma.

We also have antibody-drug conjugate, or ADC, license agreements with AbbVie Biotechnology Ltd., or AbbVie; Astellas; Genentech, Inc., a member of the Roche Group, or Genentech; Genmab; GlaxoSmithKline LLC, or GSK; and Progenics Pharmaceuticals Inc., or 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 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, such as our ADCETRIS collaboration with Takeda, our PADCEV collaboration with Astellas and our collaboration with Genmab, 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 commercialization plans and 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 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 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 be successful in their efforts to obtain regulatory approvals in a timely manner, or at all;
- our current and potential future collaborators and licensees may receive regulatory sanctions relating to other aspects of their business that could adversely affect the development, approval or commercialization of the applicable products or product candidates;
- 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 were to terminate the ADCETRIS collaboration, which it 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 United States and Canada. As a result of such termination, we may have to engage another collaborator to complete the ADCETRIS development process and to commercialize ADCETRIS outside the United States and Canada, or to complete the development process and undertake commercializing ADCETRIS outside the United States and Canada ourselves, either of which could significantly delay the continued development and commercialization of ADCETRIS and increase our costs. Similarly, both Astellas and Genmab have the right to opt out of their co-development obligations relating to PADCEV and tisotumab vedotin, respectively. If either Astellas or Genmab 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, 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 ADCETRIS, PADCEV or tisotumab vedotin, which are now being 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 United States, and we may lack the capital and resources necessary to market these products in certain regions outside the Unites States alone.

***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 (Opdivo®) and Merck's pembrolizumab (Keytruda®) are approved for the treatment of certain patients with relapsed or refractory classical Hodgkin lymphoma, and Celgene's romidepsin (Istodax®) and Spectrum Pharmaceuticals' pralatrexate (Folotyn®) and belinostat (Beleodaq®) are approved for relapsed or refractory sALCL among other T-cell lymphomas. Kyowa Kirin's mogamulizumab (Poteligeo®) 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 (Keytruda®) with ADCETRIS. If this clinical trial demonstrates that pembrolizumab is more effective than ADCETRIS in that treatment setting, our sales of ADCETRIS would be negatively impacted. We are also aware of multiple investigational agents that are currently being studied, including Pfizer's avelumab, which, 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 pre-treated metastatic urothelial cancer include checkpoint inhibitor monotherapy, generic chemotherapy or, for patients with select fibroblast growth factor receptor genetic alterations, Janssen's erdafitinib (Balversa®). There are other investigational agents that, if approved, could be competitive with PADCEV, such as Immunomedics' sacituzumab govitecan. Treatment in front line metastatic urothelial cancer has traditionally been treated with chemotherapy alone but is evolving to include two recently approved 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 expected to report data in the near term.

With respect to tucatinib, there are multiple marketed products which target HER2, including the antibodies trastuzumab (Herceptin®) and pertuzumab (Perjeta®) and the antibody drug conjugate T-DM1 (Kadcyla®). In addition, lapatinib (Tykerb®) is an EGFR/HER2 oral kinase inhibitor for the treatment of metastatic breast cancer, and neratinib (Nerlynx®) is an irreversible pan-HER kinase inhibitor indicated for extended adjuvant use that is also being studied in a phase 3 trial in pre-treated HER2-positive metastatic breast cancer, for which positive data was reported in 2019. Daiichi Sankyo and AstraZeneca have fam-trastuzumab deruxtecan-nxki (Enhertu®) that was recently approved for patients who have received two or more prior anti-HER2-based regimens in the metastatic setting. Synthon has an antibody drug conjugate in a pivotal study in this patient population and MacroGenics has a HER2 targeted, Fc-optimized antibody, margetuximab, also in a pivotal study for which positive data were reported and a BLA was submitted in late 2019.

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 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, Immunomedics, 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, ImmunoGen, Immunomedics, MedImmune, Mersana, Pfizer, and Roche, 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 United States, 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 European Union, 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, tucatinib, 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, tucatinib, 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, tucatinib, tisotumab vedotin or our other product candidates.

***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 and PADCEV'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 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, tucatinib, tisotumab vedotin and our other product candidates by us or our collaborators;
- changes in the prices of the Immunomedics, Inc., or Immunomedics, common stock that affect the valuation of the Immunomedics common stock that we hold; 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 will be difficult to predict from period to period. As a result, sales results or trends for PADCEV 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 tucatinib, 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 and our PADCEV collaboration with Astellas, 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.

Additionally, as of December 31, 2019, we held shares of Immunomedics common stock with a fair value of $163.3 million. We record changes in the fair value of our equity securities that we hold in net income or loss, which can lead to volatility of net income or loss to the extent that we continue to hold common stock or other equity securities. For example, in the year ended December 31, 2019, our net loss included a gain of $53.2 million associated with our holdings of Immunomedics common stock.

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 profitability for some time, if at all.***

We have incurred substantial net losses in each of our years of operation. 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 tucatinib, tisotumab vedotin and our other product candidates. We may also 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. Accordingly, we expect to continue to incur net losses in future periods and may not achieve profitability in the future 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.

***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 the potential launch and commercialization of tucatinib and any other future approved products may require expansion of our sales force and commercial organization, and we may need to commit significant additional funds, management and other resources to the growth of our commercial organization. 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 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 United States. 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 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. 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 qualified management personnel, 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.***

We are expanding our operations internationally. We have an expanding number of subsidiaries in foreign jurisdictions, including multiple subsidiaries in Europe, and we plan to build a commercial infrastructure in Europe and expand our commercial infrastructure in Canada. Consequently, we are, and will increasingly be, subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries 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 foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign 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 United States; 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 a 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 experience conducting operations outside of the United States 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 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.

In addition, since a significant proportion of the regulatory framework in the United Kingdom, or U.K., is derived from European Union directives and regulations, Brexit, which occurred on January 31, 2020, could materially change the regulatory regime applicable to our operations and those of our collaborators, including with respect to potential future marketing authorizations for ADCETRIS, PADCEV and our product candidates. Pursuant to the formal withdrawal arrangements agreed between the U.K. and the European Union, the U.K. will be subject to a transition period through December 31, 2020, or the Transition Period, during which European Union rules will continue to apply. Negotiations between the U.K. and the European Union are expected to continue in relation to the customs and trading relationship between the U.K. and the European Union following the expiry of the Transition Period. We or our collaborators may face new costs and challenges as result of Brexit, in particular following the Transition Period, that could have an adverse effect on our operations, including potential stresses and constraints on the capacity of service providers providing product release services in new locations outside of the U.K., potential challenges with releasing clinical product supplies into the U.K. and potential challenges or inefficiencies in obtaining approvals to commercialize our current or potential future products in the U.K., any of which could negatively impact our current and planned clinical trials and regulatory and commercial activities, and those of our collaborators, and increase our costs. It is also possible that Brexit will cause additional unanticipated negative impacts on our ability to supply clinical or commercial product, or on that of our collaborators, including Takeda and Astellas. Moreover, following the Transition Period, there is currently considerable uncertainty in relation to U.K. financial and banking markets as well as the pharmaceutical regulatory process in the U.K. In addition, the U.K. is likely to lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers and could make it more difficult for us and our collaborators to do business in the U.K., including to obtain and maintain regulatory approvals of products. In addition, currency exchange rates for the British Pound and the Euro with respect to each other and the U.S. dollar have already been affected by Brexit. Should this foreign exchange volatility continue, it could cause volatility in our quarterly financial results. In any event, we cannot predict to what extent these changes will impact our business or results of operations, or our or our collaborators' ability to continue to conduct operations in Europe or our ability to build and maintain a commercial infrastructure in Europe.

Moreover, the Trump administration has imposed tariffs on certain U.S. imports, and certain countries have responded with retaliatory tariffs on certain U.S. exports. We cannot predict what effects these and potential additional tariffs will have on our business, including in the context of escalating global trade and political tensions. However, such tariffs and other trade restrictions, whether resulting from Brexit or otherwise, could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our financial results.

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 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. 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 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. Moreover, there are a limited number of facilities in which ADCETRIS or PADCEV can be produced and any interruption of the operation of those facilities due to 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.

For the clinical supply of our product candidates, which include ADCs as well as antibodies and small molecules such as tucatinib, 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 tucatinib specifically, we have limited prior experience as an organization manufacturing tucatinib and small molecule drug products generally, and have relatively new working relationships with many of the third-party manufacturers involved in tucatinib 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. In this regard, in order to obtain regulatory approval of any product candidate, we or our supplier or suppliers for that product must obtain approval to manufacture and supply product, in some cases based on qualification data provided as part of a BLA, NDA or other application for regulatory approval, and the manufacturing facilities utilized to manufacture the 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 and/or result in delay in any approval decisions, including with respect to the tucatinib NDA, or our ability to obtain regulatory approval at all. In addition, with respect to tucatinib, we may need to put in place additional manufacturing arrangements or expand our current manufacturing arrangements with third-party manufacturers to meet future potential 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. 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 ability to launch and commercialize tucatinib in any markets where tucatinib obtains regulatory approval, if any, and could negatively impact our operating results and adversely affect our business.

With respect to tisotumab vedotin, we rely on drug product supply provided by Genmab and have little control over their supply chains or the contract manufacturers they utilize. For the foreseeable future, we expect to continue to rely on Genmab for manufacturing of clinical supplies of tisotumab vedotin. We or Genmab may need to obtain

additional manufacturing arrangements or increase manufacturing capability to meet potential future commercial needs, which could require additional capital investment by us or cause potential delays if we or Genmab encounter challenges in negotiating commercially reasonable arrangements with these manufacturers.

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 product on a timely basis or in accordance with applicable specifications and local requirements could negatively impact our ability to successfully launch and commercialize a newly-approved product, including PADCEV and, if tucatinib receives regulatory approval, tucatinib, and to generate sales of that product 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.

***We are using our own manufacturing facility to support our clinical-stage pipeline, and we could encounter challenges in operating this facility.***

We own a biologics manufacturing facility located in Bothell, Washington, which we acquired in 2017. We use this facility to support our clinical supply needs. Operating this facility requires us to comply with complex regulations and to continue to hire and retain experienced scientific, quality control, quality assurance and manufacturing personnel. We could encounter challenges in operating the manufacturing facility in compliance with cGMP, regulatory or other applicable requirements, resulting in potential negative consequences, including regulatory actions, which could undermine our ability to utilize this facility for our own manufacturing needs. Any of these risks, if actualized, could materially and adversely affect our business and financial position. In addition, despite the acquisition and operation of this facility, we nonetheless expect to continue to rely on corporate collaborators and contract manufacturing organizations to supply drug product and intermediates for commercial supply and our IND-enabling studies and clinical trials. Our continuing dependence on these manufacturers may impair the continued development and commercialization of our products and product candidates.

***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. For example, in March 2018, we made significant investment in tucatinib through the Cascadian Acquisition. The Cascadian Acquisition and 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, including tucatinib, 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, including in connection with the Cascadian Acquisition, 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.

***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 United States and Canada, our revenues still depend in part on Takeda's ability and willingness to market ADCETRIS outside of the United States and Canada. 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. Health care providers order ADCETRIS and PADCEV through these distributors. We receive orders from distributors and generally ship product directly to the health care provider. We do not promote our products to these distributors and they do not set or determine demand for our products; however, our ability to effectively commercialize our products will depend, in part, on the performance of these distributors. Although we believe we can find alternative distributors on relatively short notice, the loss of a major distributor could materially and adversely affect our results of operations and financial condition.

***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.***

Our operations may be directly or indirectly subject to various state and federal healthcare laws, including, without limitation, the federal Anti-Kickback Statute, federal civil and criminal false claims laws, the federal Health Insurance Portability and Accountability Act, or HIPAA, the federal Health Information Technology for Economic and Clinical Health Act, or HITECH, the federal civil monetary penalties statute, and the federal transparency requirements under the PPACA. These laws may impact, among other things, the sales, marketing and education programs for ADCETRIS or any future approved products.

The federal Anti-Kickback Statute prohibits persons and entities from 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 under a federal healthcare program such as the Medicare and Medicaid programs. 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 statute has been violated. Additionally, PPACA amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that would otherwise be lawful in businesses outside of the healthcare industry.

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. PPACA codified case law that provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Suits filed under the civil False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. Many pharmaceutical and other healthcare companies have recently been investigated or subject to lawsuits by whistleblowers and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper marketing or other activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, 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. Similar to the Anti-Kickback Statute, PPACA amended the intent requirement of the criminal healthcare fraud statutes such that a person or entity no longer needs to have actual knowledge of the statute or intent to violate it to have committed a violation.

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 with respect to the security and privacy of protected health information.

The federal 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 transparency requirements under PPACA, known as 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 to the CMS information related to payments and other transfers of value to physicians, as defined by such law, and teaching hospitals, and physician ownership and investment interests.

Many states and foreign jurisdictions have similar laws and regulations, such as anti-kickback, anti-bribery and corruption, false claims, privacy and data protection laws, to which we are currently and/or may in the future, be subject. For example, European Union, or EU, member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, effective May 25, 2018, the collection and use of personal health data 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. It is also possible that local data protection authorities may have different interpretations of the GDPR, leading to potential inconsistencies amongst various EU member states. Any failure or alleged failure (including as a result of deficiencies in our policies, procedures or measures relating to privacy, data protection, marketing or communications) by us 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 United States, the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018, which has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States, and we cannot determine the impact such new laws, regulations and standards may have on our business. Further, Brexit has created uncertainty with regard to data protection regulation in the U.K. In particular, 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. We may also be subject to state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or other reporting and registration requirements related to our business activities. Many of these state laws differ from each other in significant ways, thus complicating compliance efforts.

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 financial 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.

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, prohibits companies and individuals from engaging in specified activities to obtain or retain business or to influence a person working in an official capacity. Under the FCPA, it is illegal to pay, offer to pay, or authorize 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.

The number and complexity of both U.S. federal and state laws continue to increase. In addition to enforcement by governmental agencies, we also expect a continuation of the trend of private plaintiff lawsuits against pharmaceutical manufacturers under the whistleblower provisions of the civil False Claims Act and state equivalents or other laws and regulations such as securities laws and the evolution of new theories of liability under those laws and regulations. Government agencies will likely continue to intervene in such private whistleblower lawsuits and such intervention typically raises the company's cost significantly. For example, federal enforcement agencies have recently scrutinized product and patient assistance programs, including manufacturer reimbursement support services as well as relationships with specialty pharmacies. Several investigations have resulted in government enforcement authorities intervening in related whistleblower lawsuits and obtaining significant civil and criminal settlements.

In order to comply with these laws, we have implemented a compliance program to actively identify, prevent and mitigate risk through the implementation of compliance policies and systems and by promoting a culture of compliance. Although we take our obligation to maintain our compliance with these various laws and regulations seriously and our compliance program is designed to 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 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 civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, 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 foreign healthcare laws is costly and time-consuming for our management.

***Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal 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, SEC and other government agencies on which our operations may rely is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA 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.

***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 foreign 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 plan to build a commercial infrastructure in Europe. In this regard, we currently have multiple subsidiaries in foreign jurisdictions, including several subsidiaries in Europe, and plan in the future to have subsidiaries in additional jurisdictions. Our business activities outside of the United States 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 United States 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 foreign laws and regulations covering data privacy and the protection of health-related and other personal information. In this regard, EU member states and other foreign jurisdictions, 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.

***Any failures or setbacks in our ADC development program would negatively affect our business and financial position.***

ADCETRIS, PADCEV and our tisotumab vedotin and ladiratuzumab vedotin product candidates are all based on our 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, Astellas, Genentech, GSK, and Progenics, and our collaboration agreements with Takeda, Astellas, and Genmab. Certain of our ADC product candidates include additional proprietary technologies that have not yet been proven in late stage clinical development. 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 additional clinical holds on our trials of any of our other 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 internal 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 have been and may in the future be subject to litigation, including securities-related litigation, litigation pertaining to the conduct of our business, and litigation in connection with the Cascadian Acquisition and potential future strategic transactions. Such litigation could result in substantial damages and may divert management's time and attention from our business.***

In January 2017, a purported securities class action lawsuit was commenced in the United States District Court for the Western District of Washington, or the Court, naming as defendants us and certain of our officers. A related stockholder derivative lawsuit, or the Stockholder Derivative Action, was also filed in Washington Superior Court for the County of Snohomish, or the Snohomish County Superior Court, on March 29, 2017. While the class action lawsuit and the related Stockholder Derivative Action were subsequently dismissed, we may be the target of securities-related litigation in the future, both related and unrelated to the dismissed class action and Stockholder Derivative Action. Moreover, three purported stockholders of Cascadian filed a complaint seeking to inspect books and records in order to determine whether wrongdoing or mismanagement has taken place such that it would be appropriate to file claims for breach of fiduciary duty, and to investigate the independence and disinterestedness of the former Cascadian directors with respect to the Cascadian Acquisition. As a result of such complaint or otherwise, it is possible that additional lawsuits may be brought against us and/or Cascadian related to the Cascadian Acquisition.

We are also engaged in a dispute with Daiichi Sankyo regarding the ownership of certain technology used by Daiichi Sankyo in its metastatic breast cancer drug fam-trastuzumab deruxtecan-nxki (Enhertu®), among other product candidates. In addition, from time to time in the ordinary course of business we become involved in various 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 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, 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. In addition, the uncertainty associated with litigation could lead to increased volatility in our stock price.

***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 plans to build a commercial infrastructure in Europe and 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. For example, in connection with the Cascadian Acquisition, we sold 13,269,230 shares of our common stock in an underwritten public offering with the primary use of the net proceeds used to fund the Cascadian Acquisition. 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 or of any future approved products;
- the time and costs involved in obtaining regulatory approvals of our products in additional indications, if any, and potentially of tucatinib and/or 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 and revenue generated under our collaboration with Astellas;
- 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, as well as a rising interest rate environment, 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.

***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, 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, 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.

***If we are unable to enforce our intellectual property rights or if we fail to sustain and further build our 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 United States 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 United States 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.

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 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 United States 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.

***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 tucatinib. 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 United States 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 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 support our strategy to effectively commercialize PADCEV, to build a commercial infrastructure in Europe or to support the potential launch and commercialization of tucatinib and our other 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.

***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.

***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.

***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 and corporate records, communicate with staff and external parties and operate other critical functions. 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.

***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.

***The potential future impairment of in-process research and development and goodwill related to the Cascadian Acquisition may negatively affect our results of operations and financial position.***

As of December 31, 2019, we had recorded $574.7 million of in-process research and development and goodwill as a result of the Cascadian Acquisition. In-process research and development 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 in-process research and development 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, 2019, our closing stock price fluctuated between $56.37 and $121.62 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 and PADCEV product sales;
- announcements of FDA or foreign regulatory approval or non-approval of our products or any of our product candidates, including tucatinib, 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 or tucatinib or our other 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, especially our ADCETRIS collaboration with Takeda, our PADCEV collaboration with Astellas and our tisotumab vedotin collaboration with Genmab, or establishment of new collaborations or licensing arrangements;
- our failure to achieve the perceived benefits of our strategic transactions, including the Cascadian Acquisition, 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;
- 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. For example, negative publicity regarding drug pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the markets for biotechnology and pharmaceutical stocks. Likewise, as a result of Brexit and/or significant changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade and health care spending and delivery, including the possible invalidation, repeal and/or replacement of all or portions of PPACA or changes in tariffs and other trade restrictions stemming from Trump administration and foreign government policies, 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 trading price of our common stock.

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, 2019, we had 171,993,786 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, 2019, collectively beneficially owned approximately 30% 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. On July 26, 2018, pursuant to the registration rights agreement, we registered for resale, from time to time, up to 50,977,960 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, 2019, our executive officers and directors and holders of greater than five percent of our outstanding common stock beneficially owned approximately 63% of our voting power as of December 31, 2019. 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 Seattle Genetics 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 Seattle Genetics 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 Seattle Genetics, 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 Seattle Genetics.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Our headquarters are in Bothell, Washington. Our Bothell campus comprises ten leased buildings of office 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 Amsterdam, the Netherlands, used for general and administrative purposes. All of our significant leases include renewal options. We believe that our facilities are currently adequate to meet our needs. As we continue to expand our operations, we may need to lease or purchase additional facilities.

**Item 3. Legal Proceedings**

The information set forth under the heading "Contingencies" 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 3, 2020, there were 172,259,645 shares of our common stock outstanding, which were held by approximately 63 holders of record.

***Dividend Policy***

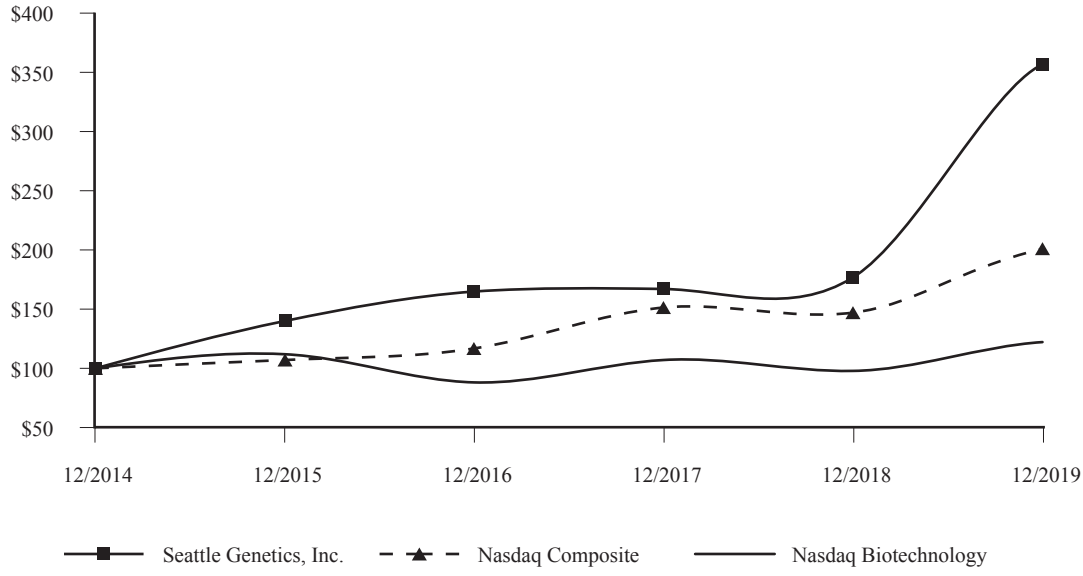
We have not paid any cash dividends on our common stock since our inception. We do not intend to pay any cash dividends in the foreseeable future, but intend to retain all earnings, if any, for use in our business operations.

***Sales of Unregistered Securities and Issuer Repurchases of Securities***

There were no unregistered sales of equity securities by us during 2019. In addition, we did not repurchase any of our equity securities during 2019.

***Stock Performance Graph***

The table below shows the cumulative total return to our stockholders during the period from December 31, 2014 through December 31, 2019 in comparison to the indicated indexes. The results assume that $100 was invested on December 31, 2014 in our common stock and each of the indicated indexes, including reinvestment of any dividends.




| | December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 |
| Seattle Genetics, Inc. | $ 100.00 | $ 139.68 | $ 164.24 | $ 166.51 | $ 176.35 | $ 355.62 |
| Nasdaq Composite | 100.00 | 106.96 | 116.45 | 150.96 | 146.67 | 200.49 |
| Nasdaq Biotechnology | 100.00 | 111.77 | 87.91 | 106.92 | 97.45 | 121.92 |

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 Seattle Genetics, 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 Loss data for the years ended December 31, 2019, 2018, and 2017, and Consolidated Balance Sheet data as of December 31, 2019 and 2018 have been derived from our audited financial statements appearing elsewhere in this Annual Report on Form 10-K. The selected Consolidated Statements of Comprehensive Loss data for the years ended December 31, 2016 and 2015 and Consolidated Balance Sheet data as of December 31, 2017, 2016, and 2015 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, | | | | |
|---|---|---|---|---|---|
| | 2019 | 2018 | 2017 | 2016 | 2015 |
| | (a) | (b) | | | |
| | (in thousands, except for per share amounts) | | | | |
| Consolidated Statements of Comprehensive Loss Data: | | | | | |
| Revenues: | | | | | |
| Net product sales | $ 627,977 | $ 476,903 | $ 307,562 | $ 265,766 | $ 226,052 |
| Collaboration and license agreement revenues | 150,245 | 94,357 | 108,632 | 84,926 | 69,770 |
| Royalty revenues | 138,491 | 83,440 | 66,056 | 67,455 | 40,980 |
| Total revenues | 916,713 | 654,700 | 482,250 | 418,147 | 336,802 |
| Costs and expenses: | | | | | |
| Cost of sales | 34,882 | 66,085 | 34,768 | 28,168 | 24,476 |
| Cost of royalty revenues | 9,070 | 22,208 | 19,350 | 14,149 | 12,964 |
| Research and development | 719,374 | 565,309 | 456,700 | 379,308 | 294,529 |
| Selling, general and administrative | 373,932 | 261,096 | 167,233 | 139,247 | 125,783 |
| Total costs and expenses | 1,137,258 | 914,698 | 678,051 | 560,872 | 457,752 |
| Loss from operations | (220,545) | (259,998) | (195,801) | (142,725) | (120,950) |
| Investment and other income, net | 61,895 | 13,652 | 36,914 | 2,614 | 464 |
| Loss before income taxes | (158,650) | (246,346) | (158,887) | (140,111) | (120,486) |
| Income tax benefit | — | 23,653 | 33,357 | — | — |
| Net loss | $ (158,650) | $ (222,693) | $ (125,530) | $ (140,111) | $ (120,486) |
| Net loss per share - basic and diluted | $ (0.96) | $ (1.41) | $ (0.88) | $ (1.00) | $ (0.93) |
| Shares used in computation of per share amounts - basic and diluted | 165,498 | 157,655 | 143,174 | 140,746 | 129,184 |

| | December 31, | | | | |
|---|---|---|---|---|---|
| | 2019 | 2018 | 2017 | 2016 | 2015 |
| | (a) | (b) | | | |
| | | | (in thousands) | | |
| Consolidated Balance Sheet Data: | | | | | |
| Cash, cash equivalents and investments | $ 868,338 | $ 459,866 | $ 413,171 | $ 618,974 | $ 712,711 |
| Working capital | 917,284 | 428,523 | 409,932 | 586,132 | 636,793 |
| Total assets | 2,205,866 | 1,503,329 | 877,949 | 838,396 | 895,095 |
| Stockholders' equity | 1,876,287 | 1,273,943 | 677,569 | 634,087 | 685,911 |

*(a)* 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 4 of the Notes to Consolidated Financial Statements included in Part II Item 8 of this Annual Report on Form 10-K.

*(b)* 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 3 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 2 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

Seattle Genetics is a biotechnology company that develops and commercializes therapies targeting cancer. We are commercializing ADCETRIS®, or brentuximab vedotin, for the treatment of certain CD30-expressing lymphomas, and PADCEV™, or enfortumab vedotin-ejfv, for the treatment of certain metastatic urothelial cancers. Additionally, we have submitted applications to the FDA, EMA and other regulatory agencies requesting approval of tucatinib for the treatment of patients with HER2-positive metastatic breast cancer. 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. We are headquartered in Bothell, Washington, and have offices in California, Switzerland and the European Union.

Also refer to Part I Item 1 "Business" for more information about our products, pipeline, technologies, research programs, including key events in 2019 and 2020 to date and future plans for our clinical programs.

*Outlook*

We recognize revenue from ADCETRIS product sales in the U.S. and Canada and PADCEV products sales in the U.S. While ADCETRIS product sales have grown over time, and our future plans assume that sales of ADCETRIS will increase, we expect lower sales growth for ADCETRIS in 2020 as compared to growth in 2019. We cannot assure you that ADCETRIS sales will continue to grow or that we can maintain sales of ADCETRIS at or near current levels. We expect that our ability to 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 and PTCL indications, and the extent to which physicians make prescribing decisions with respect to ADCETRIS. Other important factors affecting ADCETRIS sales include the extent to which Takeda obtains further regulatory approvals of ADCETRIS in its territories, 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 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 ADCETRIS, increasing competition from competing therapies and the potential future approval of ADCETRIS in any additional indications. 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 launch, 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, 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 the successful completion of the required confirmatory post-marketing study that we and Astellas are subject to as a result of an accelerated approval by the FDA, 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 and potential competition from competing therapies. In addition, due to the lack of any historical sales data and these factors, PADCEV sales are currently difficult to predict from period to period.

With respect to tucatinib, although we submitted an NDA to the FDA in December 2019 and submitted applications for regulatory approval in jurisdictions outside the U.S., we cannot predict whether our NDA or applications will be accepted for filing or approved by the regulatory authorities in a timely manner or at all. Even if approved for commercial sale, our ability to realize the anticipated benefits of our investment in tucatinib is subject to a number of risks and uncertainties, including our ability to successfully launch, market and commercialize any approved tucatinib indication, the acceptance of any approved tucatinib indication by the medical community and patients, competition from other therapies, and the extent to which coverage and reimbursement will be available from governments and other third-party payors. In addition, we have no prior experience as an organization launching or commercializing a product in markets outside the U.S. and Canada, which could adversely affect our ability to maximize the commercial potential of any approved tucatinib indication. Our ability to successfully launch and commercialize tucatinib in new markets will face additional risks and uncertainties, including our ability to build new commercial infrastructure and navigate unique country-by-country pricing and reimbursement requirements. The launch of tucatinib in new countries could be delayed due to a variety of factors, including supply constraints, delays in arranging a commercial infrastructure or delays in negotiating pricing and obtaining required reimbursement approvals. If we 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 tucatinib. In addition, if we 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 tucatinib in Europe and other regions could be negatively affected.

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. 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 earned from our collaboration agreements, including royalties, will continue to be an important source of our revenues and cash flows. These revenues 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, including our ADCETRIS collaboration with Takeda and our PADCEV collaboration with Astellas, 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.

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 2019, our total revenues increased to $916.7 million, compared to $654.7 million in 2018. This increase was driven primarily by 32% higher ADCETRIS net product sales. Net product sales of ADCETRIS increased to $627.7 million in 2019 as compared to $476.9 million in 2018, primarily driven by ADCETRIS label expansions received during 2018. Collaboration and license agreement revenues increased to $150.2 million in 2019 as compared to $94.4 million in 2018, primarily driven by the achievement of various regulatory and development milestones in 2019 as well as revenues earned under a license agreement executed in 2019. Royalty revenues increased to $138.5 million in 2019 as compared to $83.4 million in 2018, primarily driven by Takeda's achievement of a sales-based milestone during 2019.

For 2019, total costs and expenses increased to $1,137.3 million, compared to $914.7 million in 2018. This primarily reflected higher research and development expenses, due to continued investment in our late-stage pipeline, as well as higher sales, general, and administrative cost related to staffing, to support our commercialized products, and for our late-stage product candidates. For 2019, net loss of $158.7 million was favorably impacted by a net gain of $50.1 million from the change in the fair value of our equity securities.

As of December 31, 2019, we had $868.3 million in cash, cash equivalents and investments and $1.9 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 and 2017 comparative information has not been adjusted and continues to be reported under previous accounting standards. 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 March 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 5 of the Notes to Consolidated Financial Statements included in Part II Item 8 of this Annual Report on Form 10-K.

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. Accordingly, 2017 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.

We adopted "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 the cumulative effect of initially applying this ASU as an adjustment to decrease the opening accumulated deficit at January 1, 2018. Accordingly, 2017 comparative information has not been adjusted and continues to be reported under previous accounting standards. For additional information, see the section "Investments" in Note 2 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 2019 and 2018 items and year-to-year comparisons between 2019 and 2018. Discussions of 2017 items and year-to-year comparisons between 2018 and 2017 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, 2018, filed with the SEC on February 7, 2019.

**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 and PADCEV 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 and Genentech's net sales of Polivy to the extent actual information is not available

*Net product sales*

We sell ADCETRIS through a limited number of specialty distributors in the U.S. and Canada. We and our collaboration partner Astellas jointly sell PADCEV through a limited number of specialty distributors in the U.S. Customers order our products through these distributors, and we typically ship product directly to the customer. The

delivery of our products represents a single performance obligation for these transactions and we record product sales at the point in time when title and risk of loss pass, which generally occurs upon delivery of the product to the customer. The transaction price for 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. As a result of our direct-ship distribution model, we can identify the entities purchasing our products and this information enables us to 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 30 days of its expiration date or that is damaged, or within 90 days past expiration date. We estimate product returns based on our experience to-date using the expected value approach. In addition, we consider our direct-ship distribution model, our belief that product is not typically held in the distribution channel, and the expected rapid use of the product by healthcare providers. We provide financial assistance to qualifying patients that are underinsured or cannot cover the cost of commercial coinsurance amounts through SeaGen Secure. SeaGen Secure is available to patients in the U.S. and its territories who meet various financial and treatment need criteria. 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.

*Collaboration and license agreement revenues*

We have collaboration and 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 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 do not take a substantive role or control the research, development or commercialization of any products generated by our licensees, we are 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 our collaboration and license agreements involve a substantial degree of uncertainty and risk that they may never be received. In the case of our ADCETRIS collaboration with Takeda Pharmaceutical Company Limited, or Takeda, we may be involved in certain development activities; however, the achievement of milestone events under the agreement is primarily based on activities undertaken by Takeda.

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.

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.

*Royalty revenues and cost of 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 third-party royalty costs owed on its sales of ADCETRIS. This amount is included in royalty revenues. Cost of royalty revenues reflects amounts owed to our third-party licensors related to Takeda’s sales of ADCETRIS. These amounts are recognized in the period in which the related sales by Takeda occur and are based on estimates if actual information is not yet available. Since we do not take a substantive role or control the commercial sales of ADCETRIS by Takeda, estimating their net sales of ADCETRIS may require significant judgment to the extent actual information is not yet available.

**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. Specific to in-process research and development, significant estimates primarily include the number of potential patients and the market prices of future commercial products, costs required to conduct clinical trials and commercialize future products, and estimates for the probability of success and discount rate. These estimates and the resulting valuations require significant judgment.

**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 ADCETRIS 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 and in accordance with GAAP.

**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 fully 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. With the exception of deferred tax assets that were applied to offset the tax liability on goodwill resulting from the Cascadian Acquisition, 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, 2019, 2018, and 2017**

**Net product sales**

We sell ADCETRIS in the U.S. and Canada, and sell PADCEV in the U.S.

| | | | | Percentage change | |
|---|---|---|---|---|---|
| **(dollars in thousands)** | **2019** | **2018** | **2017** | **2019/2018** | **2018/2017** |
| ADCETRIS | $ 627,733 | $ 476,903 | $ 307,562 | 32% | 55% |
| PADCEV | 244 | — | — | N/A | N/A |
| Net product sales | $ 627,977 | $ 476,903 | $ 307,562 | 32% | 55% |

*N/A: No amount in comparable period or not a meaningful comparison.*

Net product sales increases in 2019 and 2018 as compared to prior years primarily resulted from higher ADCETRIS sales volumes during 2019 and, to a lesser extent, from the effect of price increases for ADCETRIS. Higher sales volume during 2019 was primarily driven by the label expansions of ADCETRIS; in particular, for the frontline Hodgkin lymphoma indication in March 2018, and for the frontline PTCL indication in November 2018.

PADCEV was approved for patients with locally advanced or metastatic urothelial cancer in December 2019.

We expect growth in net product sales in 2020 from 2019, driven by continued growth in ADCETRIS net product sales and the launch of PADCEV in December 2019. Our ability to increase ADCETRIS sales in future periods, if at all, will be primarily dependent on our ability to continue to expand ADCETRIS' utilization across all labeled indications of use.

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

| | December 31, 2019 | | | December 31, 2018 | | | December 31, 2017 | | |
|---|---|---|---|---|---|---|---|---|---|
| (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 | $ 26,968 | $ 5,604 | $ 32,572 | $ 14,374 | $ 3,521 | $ 17,895 | $ 9,500 | $ 3,198 | $ 12,698 |
| Provision related to current year sales | 253,702 | 15,298 | 269,000 | 179,394 | 11,717 | 191,111 | 105,764 | 7,778 | 113,542 |
| Adjustments for prior period sales | (392) | (464) | (856) | 440 | (478) | (38) | 1,558 | (294) | 1,264 |
| Payments/credits for current year sales | (217,905) | (11,349) | (229,254) | (155,581) | (8,248) | (163,829) | (92,947) | (5,939) | (98,886) |
| Payments/credits for prior year sales | (24,289) | (1,570) | (25,859) | (11,659) | (908) | (12,567) | (9,501) | (1,222) | (10,723) |
| Balance, end of year | $ 38,084 | $ 7,519 | $ 45,603 | $ 26,968 | $ 5,604 | $ 32,572 | $ 14,374 | $ 3,521 | $ 17,895 |

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 2019 and 2018 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, 2019 and 2018 was for 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 2020 as compared to 2019, driven by anticipated growth in ADCETRIS and PADCEV gross sales.

**Collaboration and license agreement revenues**

Collaboration and license agreement revenues reflect amounts earned under product, ADC and co-development collaborations. These revenues reflect the earned portion of 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) | 2019 | 2018 | 2017 | 2019/2018 | 2018/2017 |
| Takeda | $ 108,175 | $ 58,605 | $ 74,872 | 85% | (22)% |
| Other | 42,070 | 35,752 | 33,760 | 18% | 6 % |
| Collaboration and license agreement revenues | $ 150,245 | $ 94,357 | $ 108,632 | 59% | (13)% |

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 2019 increased compared to 2018, primarily as a result of two regulatory milestones achieved totaling $37.5 million, which were related to additional approvals of ADCETRIS in frontline Hodgkin lymphoma.

Other collaboration revenues increased in 2019 as compared to 2018 due to recognition of license and collaboration agreement revenues from BeiGene, Ltd., or BeiGene, as well as development milestones from GSK and Genentech. In 2018, other collaboration revenues included the recognition of development milestones from AbbVie, Genmab, and GSK. In November 2019, we entered into a license agreement with BeiGene for one of our preclinical product candidates. Under the license agreement, we granted BeiGene development and commercialization rights to the product candidate in certain territories. Pursuant to the agreement, we received an upfront payment of $20.0 million which was recognized as collaboration and license agreement revenues during the year ended December 31, 2019, as we determined that our performance obligation under the agreement was distinct and was satisfied. We are entitled to receive potential future milestones tied to clinical and regulatory success and royalties for potential sales of the product candidate. In addition, the parties have agreed to co-fund certain future development costs.

We expect our collaboration and license agreement revenues in 2020 to decrease compared to 2019, driven by the completion of the Takeda performance period in 2019, as well as timing of milestones achieved by our collaborators. 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. In 2018, we and Astellas entered into a joint commercialization agreement to govern the global commercialization of PADCEV. 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. Costs associated with co-development activities are included in research and development expense.

*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, 2019, our ADC collaboration and license agreements had generated approximately $425 million, primarily in the form of upfront and milestone payments. Remaining milestone payments to us under our current ADC license and collaboration agreements could total approximately $1.7 billion if all potential product candidates achieved all of their milestone events. Of this amount, approximately $0.2 billion relates to the achievement of development milestones, approximately $0.7 billion relates to the achievement of regulatory milestones and approximately $0.8 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.

Our collaboration agreement with Unum Therapeutics to develop and commercialize novel antibody-coupled T-cell receptor therapies for cancer was terminated in January 2020.

**Royalty revenues and cost of 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.

Cost of royalty revenues reflects amounts owed to our third-party licensors related to Takeda's sales of ADCETRIS.

| | | | | Percentage change | |
|---|---|---|---|---|---|
| **(dollars in thousands)** | **2019** | **2018** | **2017** | **2019/2018** | **2018/2017** |
| Royalty revenues | $ 138,491 | $ 83,440 | $ 66,056 | 66 % | 26% |
| Cost of royalty revenues | 9,070 | 22,208 | 19,350 | (59)% | 15% |

Royalty revenues increased in 2019 as compared to 2018 driven by Takeda's achievement of a $40.0 million sales-based milestone during 2019, as well as higher Takeda net sales of ADCETRIS in its territories.

Cost of royalty revenues fluctuates based on the amount of net sales of ADCETRIS by Takeda in its territories. Cost of royalty revenues decreased in 2019 compared to 2018 due to the expiration of certain third-party royalty obligations during 2018, a portion of which is paid by Takeda and is also included in royalty revenues.

We expect that royalty revenues will decrease in 2020 as compared to 2019 primarily due to the impact of the $40 million sales-based milestone earned in 2019, partially offset by royalties from anticipated increases in sales volume by Takeda.

**Cost of sales**

Cost of sales includes manufacturing costs of product sold, third-party royalty costs, gross profit share payments owed to Astellas pursuant to our collaboration, amortization of technology license costs, and distribution and other costs.

| | | | | Percentage change | |
|---|---|---|---|---|---|
| (dollars in thousands) | 2019 | 2018 | 2017 | 2019/2018 | 2018/2017 |
| Cost of sales | $ 34,882 | $ 66,085 | $ 34,768 | (47)% | 90% |

Cost of sales decreased in 2019 as compared to 2018 primarily due to an inventory write-off of $18.1 million recorded in 2018 related to in-process production that did not meet our manufacturing specifications, as well as a reduction in amounts owed to third-party technology licensors due to the expiration of certain non-exclusive licenses in 2018, offset in part by increased ADCETRIS sales volumes.

We expect cost of sales to increase in 2020 as compared to 2019, primarily due to anticipated sales growth of PADCEV and the corresponding gross profit share payment owed to Astellas pursuant to our collaboration, as well as due to expected growth in ADCETRIS net product sales.

**Research and development**

| | | | | Percentage change | |
|---|---|---|---|---|---|
| (dollars in thousands) | 2019 | 2018 | 2017 | 2019/2018 | 2018/2017 |
| Research and clinical development | $ 493,186 | $ 395,337 | $ 291,080 | 25% | 36% |
| Process sciences and manufacturing | 226,188 | 169,972 | 165,620 | 33% | 3% |
| Total research and development | $ 719,374 | $ 565,309 | $ 456,700 | 27% | 24% |

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 2019 as compared to 2018 primarily reflected increases in employee-related costs and external development costs mainly to support our 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 2019 compared to 2018 primarily reflected increases in employee-related costs and external development costs mainly to support our 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 pre-commercial milestone payments for in-licensed technology for ADCETRIS, PADCEV, 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.

| (dollars in thousands) | 2019 | 2018 | 2017 | Percentage change 2019/2018 | Percentage change 2018/2017 | 5 years ended December 31, 2019 |
|---|---|---|---|---|---|---|
| ADCETRIS (brentuximab vedotin) | $ 45,151 | $ 40,435 | $ 79,343 | 12 % | (49)% | $ 289,517 |
| PADCEV (enfortumab vedotin-ejfv) | 36,186 | 24,943 | 20,834 | 45 % | 20 % | 90,188 |
| Tucatinib | 84,277 | 40,739 | — | 107 % | N/A | 125,016 |
| Tisotumab vedotin | 30,423 | 22,253 | 6,022 | 37 % | 270 % | 58,698 |
| Ladiratuzumab vedotin | 23,178 | 24,523 | 18,483 | (5)% | 33 % | 73,512 |
| SGN-CD33A (vadastuximab talirine) | 626 | 3,150 | 34,151 | (80)% | (91)% | 103,083 |
| Other clinical stage programs | 26,705 | 32,969 | 37,088 | (19)% | (11)% | 164,823 |
| Total third-party costs for clinical stage programs | 246,546 | 189,012 | 195,921 | 30 % | (4)% | 904,837 |
| Other costs and overhead | 472,828 | 376,297 | 260,779 | 26 % | 44 % | 1,510,383 |
| Total research and development | $ 719,374 | $ 565,309 | $ 456,700 | 27 % | 24 % | $ 2,415,220 |

*N/A: No amount in comparable period or not a meaningful comparison.*

Third-party costs for ADCETRIS increased in 2019 as compared to 2018 primarily due to higher costs for drug product supplied to Takeda, offset in part by a reduction in clinical trial activities. 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 PADCEV increased in 2019 as compared to 2018 primarily due to higher clinical trial and manufacturing expenses.

Third-party costs for tucatinib increased in 2019 as compared to 2018 due to higher clinical trial expenses, primarily for the HER2CLIMB trial, and higher manufacturing expenses.

Third-party costs for tisotumab vedotin increased in 2019 as compared to 2018 due to higher clinical trial and manufacturing expenses.

Third-party costs for ladiratuzumab vedotin decreased in 2019 as compared to 2018 primarily due to lower manufacturing expenses.

Third-party costs for other clinical stage programs were related to multiple earlier-stage development programs and were relatively consistent across 2019 and 2018.

Other costs and overhead include third-party costs of our preclinical programs and costs associated with personnel and facilities. These costs increased in 2019 as compared to 2018 due primarily to higher employee-related expenses from headcount growth and internal manufacturing costs, as well as an upfront payment to acquire a preclinical asset in 2019.

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 2020 will increase compared to 2019 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**

| (dollars in thousands) | 2019 | 2018 | 2017 | Percentage change 2019/2018 | Percentage change 2018/2017 |
|---|---|---|---|---|---|
| Selling, general and administrative | $ 373,932 | $ 261,096 | $ 167,233 | 43% | 56% |

Selling, general and administrative expenses increased in 2019 and 2018 as compared to prior years primarily due to higher staffing costs to support our commercialized products and for our late-stage product candidates.

We anticipate that selling, general and administrative expenses will increase in 2020 as compared to 2019 as we continue our commercial activities in support of the commercialization of PADCEV and ADCETRIS, pre-commercialization activities for our late-stage pipeline, and our support of general operations.

**Investment and other income, net**

| (dollars in thousands) | 2019 | 2018 | 2017 | Percentage change 2019/2018 | Percentage change 2018/2017 |
|---|---|---|---|---|---|
| Gain on equity securities | $ 50,124 | $ 7,336 | $ 33,777 | N/A | (78)% |
| Investment and other income, net | 11,771 | 6,316 | 3,137 | 86% | 101 % |
| Total investment and other income, net | $ 61,895 | $ 13,652 | $ 36,914 | N/A | (63)% |

*N/A: 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), 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 2019 was driven by a $50.1 million net gain from changes in the fair value of our equity securities.

Investment income reflects amounts earned on our investments in U.S. Treasury securities. Investment income increased in 2019 and 2018 compared to prior years due to a higher effective yield of our portfolio and higher investment balances as a result of the net proceeds from our July 2019 equity offering.

**Income taxes**

| (dollars in thousands) | 2019 | 2018 | 2017 | Percentage change 2019/2018 | Percentage change 2018/2017 |
|---|---|---|---|---|---|
| Income tax benefit | $ — | $ 23,653 | $ 33,357 | N/A | (29)% |

*N/A: No amount in comparable period or not a meaningful comparison.*

The income tax benefit in 2018 was related to the release of valuation allowance used to offset the deferred tax liability recorded in the purchase price allocation for the Cascadian Acquisition. The income tax benefit in 2017 related to unrealized gains on our Immunomedics common stock holding prior to the adoption ASU 2016-01, which was offset by an income tax provision for the same amount in other comprehensive income in stockholders' equity.

**Liquidity and capital resources**

| (dollars in thousands) | December 31, 2019 | December 31, 2018 | December 31, 2017 |
|---|---|---|---|
| Cash, cash equivalents and investments | $ 868,338 | $ 459,866 | $ 413,171 |
| Working capital | 917,284 | 428,523 | 409,932 |
| Stockholders' equity | 1,876,287 | 1,273,943 | 677,569 |

| (dollars in thousands) | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| Cash provided by (used in): | | | |
| Operating activities | $ (163,737) | $ (203,536) | $ (118,900) |
| Investing activities | (277,729) | (592,630) | 129,861 |
| Financing activities | 637,842 | 713,407 | 41,311 |

The change in net cash from operating activities from 2019 as compared to 2018 primarily was related to the change in our net loss, working capital fluctuations and changes in our non-cash expenses, all of which are highly variable.

The change in net cash from investing activities from 2019 as compared to 2018 reflected differences between the proceeds received from sale and maturity of our investments and amounts reinvested, as well as payments for business combinations. Cash used for investing activities also reflected payments for the purchases of property and equipment for all years presented. We paid $614.1 million (or $598.2 million net of the cash acquired) for the Cascadian Acquisition in March 2018, and we received $91.9 million from selling a portion of our Immunomedics common stock holdings during 2018.

The change in net cash from financing activities included proceeds from stock option exercises and our employee stock purchase plan for all years presented. Cash provided by financing activities in 2019 included $548.7 million net proceeds from our public offering in July 2019, with the primary uses for ongoing commercialization of ADCETRIS, our commercial launch activities for PADCEV, our research and development efforts to further expand the ADCETRIS label and to advance our pipeline of product candidates, as well as for general corporate purposes, including working capital. Cash provided by financing activities in 2018 included $658.2 million in net proceeds from our public offering in February 2018, with the primary use of the net proceeds used to fund the Cascadian Acquisition.

We primarily have financed our operations through the issuance of our common stock, collections from commercial sales of our products, amounts received pursuant to product collaborations and our ADC collaborations, 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, 2019, we had $811.1 million held in cash, cash equivalents and investments scheduled to mature within the next twelve months.

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, and planned global expansion, 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, 2019:

| (dollars in thousands) | Total | 2020 | 2021 | 2022 | 2023 | 2024 | Thereafter |
|---|---|---|---|---|---|---|---|
| Operating leases | $ 94,039 | $ 13,341 | $ 14,291 | $ 13,855 | $ 13,757 | $ 9,866 | $ 28,929 |
| Supply and other agreements | 256,632 | 93,225 | 44,236 | 41,160 | 25,695 | 24,828 | 27,488 |
| Total | $ 350,671 | $ 106,566 | $ 58,527 | $ 55,015 | $ 39,452 | $ 34,694 | $ 56,417 |

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 $1.4 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 2 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. We do not have any outstanding derivative financial instruments in our investment portfolio. A summary of our investment securities follows:

| | December 31, | |
|---|---|---|
| **(dollars in thousands)** | **2019** | **2018** |
| Short-term investments | $ 536,493 | $ 332,486 |
| Long-term investments | 57,283 | 49,194 |
| Total | $ 593,776 | $ 381,680 |

We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of $3.2 million in the fair value of our investments as of December 31, 2019. In addition, a hypothetical decrease of 10% in the effective yield of our investments would reduce our expected investment income by $1.2 million over the next twelve months based on our investment balance at December 31, 2019.

***Equity Price Risk***

As of December 31, 2019, we held shares of Immunomedics common stock. The fair value of the common stock fluctuates based on changes in the stock price of Immunomedics. These shares were acquired in connection with a strategic transaction in 2017. Based on our shares of Immunomedics common stock held as of December 31, 2019, a hypothetical decrease of 10% in the price of Immunomedics common stock would reduce the fair value of the investment and, accordingly, increase our net loss by approximately $16.4 million.

***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, 2019, 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 primary exposure is to fluctuations in the Euro, British Pound, Canadian Dollar and Swiss Franc. 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

### Index to Financial Statements

## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Seattle Genetics, Inc.

***Opinions on the Financial Statements and Internal Control over Financial Reporting***

We have audited the accompanying consolidated balance sheets of Seattle Genetics, Inc. and its subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with 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, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

*Changes in Accounting Principles*

As discussed in Note 2 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 2 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, 2019 are $38.1 million, with the most significant portion of the accrual related to 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 there was significant judgment by management when developing the rebate estimate, including significant assumptions related to payor mix and estimated purchases covered by the various state Medicaid programs. This led to a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating the audit evidence obtained relating to those assumptions.

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 Medicaid rebate accrual, including controls over the assumptions related to payor mix and estimated purchases covered by the various state Medicaid programs. These procedures also included, among others, testing management's process for developing the rebate estimate; evaluating the appropriateness of the approach; testing the completeness, accuracy and relevance of data used in developing the estimate; and evaluating the significant assumptions used by management. Evaluating management's assumptions related to payor mix and estimated purchases covered by the various state Medicaid programs involved evaluating whether the assumptions used were reasonable considering historical covered purchases and rebate processing times, expansion of state Medicaid programs, other industry data, and our testing of actual rebate claims processed by the Company.

/s/ PricewaterhouseCoopers LLP

Seattle, Washington
February 6, 2020

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

**Seattle Genetics, Inc.**
**Consolidated Balance Sheets**
**(In thousands, except par value)**

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 274,562 | $ 78,186 |
| Short-term investments | 536,493 | 332,486 |
| Accounts receivable, net | 236,001 | 146,281 |
| Inventories | 85,932 | 53,239 |
| Prepaid expenses and other current assets | 43,653 | 43,403 |
| Total current assets | 1,176,641 | 653,595 |
| Property and equipment, net | 155,491 | 103,820 |
| Operating lease right-of-use assets | 65,230 | — |
| Long-term investments | 57,283 | 49,194 |
| In-process research and development | 300,000 | 300,000 |
| Goodwill | 274,671 | 274,671 |
| Other non-current assets | 176,550 | 122,049 |
| Total assets | $ 2,205,866 | $ 1,503,329 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 52,292 | $ 44,179 |
| Accrued liabilities and other | 207,065 | 147,293 |
| Current portion of deferred revenue | — | 33,600 |
| Total current liabilities | 259,357 | 225,072 |
| Long-term liabilities: | | |
| Operating lease liabilities, long-term | 67,607 | — |
| Other long-term liabilities | 2,615 | 4,314 |
| Total long-term liabilities | 70,222 | 4,314 |
| 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; 171,994 shares issued and outstanding at December 31, 2019 and 160,262 shares issued and outstanding at December 31, 2018 | 172 | 160 |
| Additional paid-in capital | 3,359,124 | 2,598,411 |
| Accumulated other comprehensive income (loss) | 229 | (40) |
| Accumulated deficit | (1,483,238) | (1,324,588) |
| Total stockholders' equity | 1,876,287 | 1,273,943 |
| Total liabilities and stockholders' equity | $ 2,205,866 | $ 1,503,329 |

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

**Seattle Genetics, Inc.**
**Consolidated Statements of Comprehensive Loss**
**(In thousands, except per share amounts)**

| | Years ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Revenues: | | | |
| Net product sales | $ 627,977 | $ 476,903 | $ 307,562 |
| Collaboration and license agreement revenues | 150,245 | 94,357 | 108,632 |
| Royalty revenues | 138,491 | 83,440 | 66,056 |
| Total revenues | 916,713 | 654,700 | 482,250 |
| Costs and expenses: | | | |
| Cost of sales | 34,882 | 66,085 | 34,768 |
| Cost of royalty revenues | 9,070 | 22,208 | 19,350 |
| Research and development | 719,374 | 565,309 | 456,700 |
| Selling, general and administrative | 373,932 | 261,096 | 167,233 |
| Total costs and expenses | 1,137,258 | 914,698 | 678,051 |
| Loss from operations | (220,545) | (259,998) | (195,801) |
| Investment and other income, net | 61,895 | 13,652 | 36,914 |
| Loss before income taxes | (158,650) | (246,346) | (158,887) |
| Income tax benefit | — | 23,653 | 33,357 |
| Net loss | $ (158,650) | $ (222,693) | $ (125,530) |
| Net loss per share - basic and diluted | $ (0.96) | $ (1.41) | $ (0.88) |
| Shares used in computation of per share amounts - basic and diluted | 165,498 | 157,655 | 143,174 |
| | | | |
| Comprehensive loss: | | | |
| Net loss | $ (158,650) | $ (222,693) | $ (125,530) |
| Other comprehensive income: | | | |
| Unrealized gain on securities available-for-sale net of tax provision of $0, $0, and $33,357, respectively | 204 | 293 | 63,888 |
| Foreign currency translation gain (loss) | 65 | (50) | 11 |
| Total other comprehensive income | 269 | 243 | 63,899 |
| Comprehensive loss | $ (158,381) | $ (222,450) | $ (61,631) |

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

**Seattle Genetics, 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, 2016 | 142,193 | $ 142 | $1,701,048 | $ (63) | $(1,067,040) | $ 634,087 |
| Net loss | — | — | — | — | (125,530) | (125,530) |
| Other comprehensive income | — | — | — | 63,899 | — | 63,899 |
| Issuance of common stock for employee stock purchase plan | 172 | — | 7,303 | — | — | 7,303 |
| Stock option exercises | 1,494 | 1 | 34,007 | — | — | 34,008 |
| Restricted stock vested during the period, net | 536 | 1 | (1) | — | — | — |
| Share-based compensation | — | — | 63,802 | — | — | 63,802 |
| 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 employee stock purchase plan | 206 | — | 9,190 | — | — | 9,190 |
| Stock option exercises | 1,800 | 2 | 45,973 | — | — | 45,975 |
| 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 employee stock purchase plan | 189 | — | 11,600 | — | — | 11,600 |
| Stock option exercises | 2,432 | 3 | 77,548 | — | — | 77,551 |
| 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 |

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

**Seattle Genetics, Inc.**
**Consolidated Statements of Cash Flows**
**(In thousands)**

| | Years ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Operating activities: | | | |
| Net loss | $ (158,650) | $ (222,693) | $ (125,530) |
| Adjustments to reconcile net loss to net cash used by operating activities | | | |
| Share-based compensation | 127,349 | 78,861 | 63,802 |
| Depreciation and amortization | 23,774 | 26,032 | 24,269 |
| Amortization of premiums, accretion of discounts, and (gains) losses on debt securities | (4,916) | (2,530) | 497 |
| Amortization of right-of-use-assets | 9,740 | — | — |
| Gain on equity securities | (50,124) | (7,336) | (33,777) |
| Loss on disposals of property and equipment | 1,853 | — | — |
| Income tax benefit on unrealized loss on available-for-sale securities | — | — | (33,357) |
| Deferred income taxes | — | (23,653) | — |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable, net | (89,720) | (45,233) | (22,846) |
| Inventories | (32,693) | 6,739 | 8,146 |
| Prepaid expenses and other assets | 2,459 | (14,567) | (2,170) |
| Lease liability | (6,660) | — | — |
| Deferred revenue | (33,600) | (33,913) | (16,878) |
| Other liabilities | 47,451 | 34,757 | 18,944 |
| Net cash used by operating activities | (163,737) | (203,536) | (118,900) |
| Investing activities: | | | |
| Purchases of securities | (992,976) | (512,334) | (513,016) |
| Proceeds from maturities of securities | 786,000 | 398,722 | 653,200 |
| Proceeds from sales of securities | — | 140,352 | 60,056 |
| Purchases of property and equipment | (70,753) | (21,219) | (28,722) |
| Acquisition of manufacturing facility | — | — | (41,657) |
| Acquisition of Cascadian Therapeutics, Inc., net of cash acquired | — | (598,151) | — |
| Net cash provided (used) by investing activities | (277,729) | (592,630) | 129,861 |
| Financing activities: | | | |
| Net proceeds from issuance of common stock | 548,691 | 658,242 | — |
| Proceeds from exercise of stock options and employee stock purchase plan | 89,151 | 55,165 | 41,311 |
| Net cash provided by financing activities | 637,842 | 713,407 | 41,311 |
| Net increase (decrease) in cash and cash equivalents | 196,376 | (82,759) | 52,272 |
| Cash and cash equivalents at beginning of year | 78,186 | 160,945 | 108,673 |
| Cash and cash equivalents at end of year | $ 274,562 | $ 78,186 | $ 160,945 |

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

## 1. Organization and Business

*Organization*

We are a biotechnology company that develops and commercializes therapies targeting cancer. Our antibody-drug conjugate, or ADC, technology utilizes the targeting ability of monoclonal antibodies to deliver cell-killing agents directly to cancer cells. We are commercializing ADCETRIS®, or brentuximab vedotin, for the treatment of several types of lymphoma, and PADCEV™, or enfortumab vedotin-ejfv, for the treatment of certain adult patients with locally advanced or metastatic urothelial cancer.

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.

*Capital requirements*

To execute our growth plans, we may need to seek additional funding through public or private financings, including debt or equity financings, and through other means, including collaborations and license agreements. If we cannot maintain adequate funds, we may be required to borrow funds, delay, reduce the scope of or eliminate one or more of our development programs. Additional financing may not be available when needed, or if available, we may not be able to obtain financing on favorable terms.

## 2. Summary of Significant Accounting Policies

*Basis of presentation*

The accompanying consolidated financial statements reflect the accounts of Seattle Genetics, Inc. and its wholly-owned subsidiaries (collectively "Seattle Genetics," "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 5. 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. 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.

*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 reclassified certain prior year balances on our consolidated statements of cash flows to conform to current year presentation. Those balances related to other long-term liabilities and accounts payable and accrued liabilities. These reclassifications had no effect on our net cash used by operating activities or our consolidated statements of comprehensive 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 $11.1 million and $4.6 million of accrued capital expenditures as of December 31, 2019 and 2018, 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 year ended December 31, 2019, we recorded $40.3 million of right-of-use assets in exchange for lease liabilities, which has been treated as a non-cash operating activity. See Note 4 for additional information.

*Investments*

We hold certain equity securities that we acquired in connection with strategic agreements, which are reported at estimated fair value. Changes in the fair value of equity securities are recorded in income or loss. 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. The cost of equity securities for purposes of computing gains and losses is based on the specific identification method. 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. Accordingly, 2017 comparative information has not been adjusted and continues to be reported under previous accounting standards. The implementation of this standard increased the volatility of net income or loss to the extent that we continue to hold equity securities.

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.

*Derivative financial instruments*

We account for financial instruments as derivatives when the instrument includes an underlying and notional amount or payment provision, an initial net investment, and a net settlement. Derivative financial instruments are measured at fair value on the issuance date and are revalued on each subsequent balance sheet date. We use the Black-Scholes model using observable market inputs to estimate the fair value of derivatives. The changes in estimated fair value are recognized as current period income or loss. We do not hold derivative instruments for trading or speculative purposes and had no derivative instruments outstanding as of December 31, 2019 or 2018.

*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 and 2017 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 under the standard 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 standard had a material impact on our consolidated balance sheet, did not have an impact on our consolidated statement of comprehensive loss, and there was no cumulative-effect adjustment to the opening accumulated deficit in the period of adoption. See Note 4 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, the carrying value of the related intangible asset is amortized to cost of sales over the remaining estimated life of the asset beginning in the period in which the project is completed. 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.

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

We assess the impairment of long-lived assets, primarily 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, 2019 as there have been no events warranting an impairment analysis. Our long-lived assets are primarily located in the U.S.

*Revenue recognition*

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. Accordingly, 2017 comparative information has not been adjusted and continues to be reported under previous accounting standards. See Note 3 for additional information.

Our revenues are comprised of ADCETRIS and PADCEV 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.

*Net product sales*

We sell ADCETRIS through a limited number of specialty distributors in the U.S. and Canada. We and our collaboration partner Astellas jointly sell PADCEV through a limited number of specialty distributors in the U.S. Customers order our products through these distributors, and we typically ship product directly to the customer. The delivery of our products represents a single performance obligation for these transactions and we record product sales at the point in time when title and risk of loss pass, which generally occurs upon delivery of the product to the customer. The transaction price for 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. As a result of our direct-ship distribution model, we can identify the entities purchasing our products and this information enables us to 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 30 days of its expiration date or that is damaged, or within 90 days past expiration date. We estimate product returns based on our experience to-date using the expected value approach. In addition, we consider our direct-ship distribution model, our belief that product is not typically held in the distribution channel, and the expected rapid use of the product by healthcare providers. We provide financial assistance to qualifying patients that are underinsured or cannot cover the cost of commercial coinsurance amounts through SeaGen Secure. SeaGen Secure is available to patients in the U.S. and its territories who meet various financial and treatment need criteria. 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.

*Collaboration and license agreement revenues*

We have collaboration and 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 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 do not take a substantive role or control the research, development or commercialization of any products generated by our licensees, we are 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 our collaboration and license agreements involve a substantial degree of uncertainty and risk that they may never be received. In the case of our ADCETRIS collaboration with Takeda Pharmaceutical Company Limited, or Takeda, we may be involved in certain development activities; however, the achievement of milestone events under the agreement is primarily based on activities undertaken by Takeda.

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.

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.

*Royalty revenues and cost of 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 third-party royalty costs owed on its sales of ADCETRIS. This amount is included in royalty revenues. Cost of royalty revenues reflects amounts owed to our third-party licensors related to Takeda's sales of ADCETRIS. These amounts are recognized in the period in which the related sales by Takeda occur. Royalty revenues also reflect amounts from Genentech earned on net sales of Polivy.

*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 $33.5 million, $26.6 million, and $13.8 million in advertising expenses during 2019, 2018, and 2017, 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. We have not experienced any significant credit losses to date as a result of credit risk concentration and do not consider an allowance for doubtful accounts to be necessary.

*Major customers*

We sell our products through a limited number of distributors. Certain of these distributors, together with entities under their common control, each individually accounted for greater than 10% of total revenues and greater than 10% of accounts receivable as noted below. In addition, one of our collaborators accounted for greater than 10% of total revenues and accounts receivable as noted below. Revenues generated outside the U.S., as determined by customer location, were less than 10% of total revenues for all years presented.

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

| | Years ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Distributor A | 26% | 28% | 23% |
| Distributor B | 21% | 22% | 19% |
| Distributor C | 18% | 20% | 18% |
| Takeda | 27% | 21% | 29% |

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

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Distributor A | 24% | 32% |
| Distributor B | 19% | 21% |
| Distributor C | 16% | 23% |
| Takeda | 33% | 20% |

*Major suppliers*

The use of a relatively small number of contract manufacturers to supply drug necessary for our commercial operations and clinical trials creates a concentration of risk for us. We rely on Astellas to supply PADCEV for commercial sales and for our clinical trials, and Astellas oversees the manufacturing supply chain for PADCEV. While primarily one source of supply is utilized for certain components of ADCETRIS, PADCEV, and each of our product candidates, other sources are available should we need to change suppliers. We also endeavor to maintain reasonable levels of drug supply for our use. A change in suppliers, however, could cause a delay in delivery of drug which could result in the interruption of commercial operations 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 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 loss*

Comprehensive 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 loss is comprised of net loss, unrealized gains and losses on available-for-sale investments prior to the adoption of ASU 2016-01 in 2018, and foreign currency translation adjustments, net of any applicable income taxes.

*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.

*Net loss per share*

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

| | Years ended December 31, | | |
|---|---|---|---|
| **(in thousands)** | **2019** | **2018** | **2017** |
| Stock options and RSUs | 12,774 | 13,439 | 13,592 |

*Recent accounting pronouncements not yet 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. The standard will become effective for us beginning on January 1, 2020. We do not anticipate the adoption of this ASU to have a material impact on our 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. The standard will become effective for us beginning on January 1, 2020. We do not anticipate the adoption of this ASU to have a material impact on our financial condition, results of operations, cash flows, and financial statement disclosures.

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. The standard will become effective for us beginning on January 1, 2020. We do not anticipate the adoption of this ASU to have a material impact on our 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 will become 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, and financial statement disclosures.

**3. Revenue from contracts with customers**

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, itemized here and further described below:

| **(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 |

The cumulative effect adjustment recorded above resulted in an increase to accounts receivable, net for $16.3 million, an increase to prepaid expenses and other current assets for $12.7 million, and an increase to current portion of deferred revenue for $2.4 million as of January 1, 2018.

*Impact to net product sales*

ASC Topic 606 did not generally change the practice under which we recognize revenue from net product sales.

*Impact to collaboration and license agreement revenues*

The achievement of development milestones under our collaborations is recorded during the period their achievement becomes most likely, which may result in earlier recognition as compared to previous accounting principles.

The Takeda ADCETRIS collaboration was the only ongoing collaboration that was significantly impacted by the adoption of ASC Topic 606. The Takeda ADCETRIS collaboration provides for the global co-development of ADCETRIS and the commercialization of ADCETRIS by Takeda in its territory. Under this collaboration, we have commercial rights for ADCETRIS in the U.S. and its territories and in Canada, and Takeda has commercial rights in the rest of the world and pays us a royalty. Our performance obligations under the collaboration included providing intellectual property licenses, performing technology transfer, providing research and development services for co-funded activities, allowing access to data, submitting regulatory filings and other information for co-funded activities, and providing manufacturing support including supply of ADCETRIS drug components, finished ADCETRIS product, and know-how. We determined that our performance obligations under the collaboration as evaluated at contract inception were not distinct and represented a single performance obligation, and that the obligations for goods and services provided would be completed over the performance period of the agreement. Any payments received from Takeda, including the upfront payment, progress-dependent development and regulatory milestone payments, reimbursement for drug supplied, and net development cost reimbursement payments, were recognized as revenue upon transfer of control of the goods or services over the ten-year development period (December 2009 through November 2019) of the collaboration, within collaboration and license agreement revenues. Updates to the Takeda ADCETRIS collaboration transaction price for variable consideration, such as approval of the co-development annual budget and binding production forecast, were considered at each reporting period as to whether they are not subject to significant future reversal. Shipments of drug supply that occurred after the expiration of the drug supply agreement in September 2018 were recorded as a separate performance obligation.

*Impact to royalty revenues*

Commercial sales-based milestones and sales royalties, primarily earned under the Takeda ADCETRIS collaboration, are recorded in the period of the related sales by Takeda, based on estimates if actual information is not yet available, rather than recording them as reported by the customer one quarter in arrears under previous accounting guidance. Takeda also bears a portion of third-party royalty costs owed on its sales of ADCETRIS which is included in royalty revenues.

*Disaggregation of total revenues*

We have two marketed products, ADCETRIS and PADCEV. Substantially all of our product revenues during the years ended December 31, 2019, 2018, and 2017 were for ADCETRIS and recorded in the U.S. Substantially all of our royalty revenues are from our collaboration with Takeda. Collaboration and license agreement revenues by collaborator are summarized as follows:

| | Years ended December 31, | | |
|---|---|---|---|
| **(dollars in thousands)** | **2019** | **2018** | **2017** |
| Takeda | $ 108,175 | $ 58,605 | $ 74,872 |
| Other | 42,070 | 35,752 | 33,760 |
| Collaboration and license agreement revenues | $ 150,245 | $ 94,357 | $ 108,632 |

In November 2019, we entered into a license agreement with BeiGene, Ltd., or BeiGene, for one of our preclinical product candidates. Under the license agreement, we granted BeiGene development and commercialization rights to the product candidate in certain territories. Pursuant to the agreement, we received an upfront payment of $20.0 million which was recognized as collaboration and license agreement revenues during the year ended December 31, 2019 as we determined that our performance obligation under the agreement was distinct and was satisfied. We are entitled to receive potential future milestones tied to clinical and regulatory success and royalties for potential sales of the product candidate. In addition, the parties have agreed to co-fund certain future development costs. 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, 2019, and we had no contract assets as of December 31, 2018. Contract liabilities as of December 31, 2018 consisted of deferred revenue primarily related to our remaining performance obligations under the Takeda ADCETRIS collaboration. Deferred revenue is presented as a line item on the consolidated balance sheet.

We recognized collaboration and license agreement revenues of $33.6 million and $34.5 million during the years ended December 31, 2019 and 2018, respectively, that were included in deferred revenue as of the beginning of the respective years. For the year ended December 31, 2019, collaboration and license agreement revenues from Takeda also included $37.5 million for two regulatory milestones achieved, which were related to additional approvals of ADCETRIS in frontline Hodgkin lymphoma received by Takeda.

*Impacts to December 31, 2018 consolidated financial statements*

| (dollars in thousands) | As reported | Adjustments | Balances without the adoption of Topic 606 |
|---|---|---|---|
| Consolidated Balance Sheet data: | | | |
| Accounts receivable, net | $ 146,281 | $ (18,501) | $ 127,780 |
| Prepaid expenses and other current assets | 43,403 | — | 43,403 |
| Current portion of deferred revenue | 33,600 | — | 33,600 |
| Accumulated deficit | (1,324,588) | (18,501) | (1,343,089) |
| Consolidated Statements of Comprehensive Loss data: | | | |
| Collaboration and license agreement revenues | $ 94,357 | $ 10,282 | $ 104,639 |
| Royalty revenues | 83,440 | (1,634) | 81,806 |
| Total revenues | 654,700 | 8,648 | 663,348 |
| Cost of royalty revenues | 22,208 | 592 | 22,800 |
| Net loss | (222,693) | 8,056 | (214,637) |

## 4. 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. As of December 31, 2019, our operating lease liabilities and operating lease right-of-use assets were $77.1 million and $65.2 million, respectively. The increases in operating lease liabilities and operating lease right-of-use assets during 2019 reflected new facilities leases that commenced during the period. 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, 2019.

Supplemental operating lease information was as follows:

| (dollars in thousands) | Year ended December 31, 2019 |
|---|---|
| Operating lease cost | $ 13,590 |
| Variable lease cost | 2,958 |
| Total lease cost | $ 16,548 |
| Cash paid for amounts included in measurement of lease liabilities | $ 10,197 |

Rent expense attributable to non-cancelable operating leases totaled approximately $14.6 million, $8.7 million, and $6.6 million for the years ended December 31, 2019, 2018, and 2017, respectively. As of December 31, 2019, the weighted average remaining lease term for our operating leases was 7.04 years, and the weighted average discount rate for our operating leases was 5.4%.

As of December 31, 2019, future minimum lease payments under the lease agreements were as follows:

| (dollars in thousands) | |
|---|---|
| Years ending December 31, | |
| 2020 | $ 13,341 |
| 2021 | 14,291 |
| 2022 | 13,855 |
| 2023 | 13,757 |
| 2024 | 9,866 |
| Thereafter | 28,929 |
| Total future minimum lease payments | 94,039 |
| Less: imputed interest | (16,987) |
| Total | $ 77,052 |

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

| (dollars in thousands) | December 31, 2019 |
|---|---|
| Accrued liabilities and other | $ 9,445 |
| Operating lease liabilities, long-term | 67,607 |
| Total | $ 77,052 |

**5. Acquisition of Cascadian**

In March 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 tucatinib.

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 tucatinib-based regimen, costs required to conduct clinical trials and potentially commercialize tucatinib, as well as estimates for probability of success and the discount rate. Goodwill primarily was attributed to tucatinib'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.

The financial information in the table below summarizes the combined results of operations of Seattle Genetics and Cascadian on a pro forma basis, for the period in which the acquisition occurred and the comparative period as though the companies had been combined as of January 1, 2017. Pro forma adjustments have been made primarily related to acquisition-related transaction costs and employee costs. The following unaudited pro forma financial information is presented for informational purposes only and is not necessarily indicative of the results of operations that would have been achieved had the acquisition occurred as of January 1, 2017 or indicative of future results:

| | Years ended December 31, | |
|---|---|---|
| (dollars in thousands) | 2018 | 2017 |
| Revenues | $ 654,700 | $ 482,250 |
| Net loss | (251,626) | (212,364) |

## 6. 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 fair value hierarchy of assets carried at fair value and measured on a recurring basis was as follows:

| | 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, 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 |
| December 31, 2018 | | | | |
| Short-term investments—U.S. Treasury securities | $ 332,486 | $ — | $ — | $ 332,486 |
| Long-term investments—U.S. Treasury securities | 49,194 | — | — | 49,194 |
| Other non-current assets—equity securities | 113,812 | — | — | 113,812 |
| Total | $ 495,492 | $ — | $ — | $ 495,492 |

Our equity securities primarily comprised common stock of Immunomedics, purchased in connection with a strategic collaboration. The collaboration agreement with Immunomedics was terminated in 2017.

Our debt securities consisted of the following:

| (dollars in thousands) | Amortized cost | Gross unrealized gains | Gross unrealized losses | Fair value |
|---|---|---|---|---|
| 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 |
| December 31, 2018 | | | | |
| U.S. Treasury securities | $ 381,673 | $ 133 | $ (126) | $ 381,680 |
| Contractual maturities (at date of purchase): | | | | |
| Due in one year or less | $ 246,440 | | | $ 246,402 |
| Due in one to two years | 135,233 | | | 135,278 |
| Total | $ 381,673 | | | $ 381,680 |

## 7. Investment and Other Income, Net

Investment and other income, net consisted of the following:

| | Years ended December 31, | | |
|---|---|---|---|
| (dollars in thousands) | 2019 | 2018 | 2017 |
| Gain on equity securities | $ 50,124 | $ 7,336 | $ 33,777 |
| Investment and other income, net | 11,771 | 6,316 | 3,137 |
| Total investment and other income, net | $ 61,895 | $ 13,652 | $ 36,914 |

Gain on equity securities includes the realized and unrealized holding gains and losses on our equity securities. Our equity securities are described in more detail in Note 6. As disclosed in Note 2, we adopted “ASU 2016-01, Financial Instruments: Overall” on January 1, 2018.

During 2019, the gain on equity securities was driven by net unrealized gains on equity securities held at December 31, 2019 of $50.1 million. During 2018, the gain on equity securities was driven by the realized gain from selling a portion of our Immunomedics common stock holding for $91.9 million, offset in part by net unrealized losses on equity securities still held at December 31, 2018 of $20.9 million. During 2017, the gain on equity securities related to changes in the fair value of an Immunomedics warrant derivative prior to the warrant's exercise by us in December 2017.

## 8. Inventories

Inventories consisted of the following:

| | December 31, | |
|---|---|---|
| (dollars in thousands) | 2019 | 2018 |
| Raw materials | $ 78,285 | $ 43,986 |
| Finished goods | 7,647 | 9,253 |
| Total | $ 85,932 | $ 53,239 |

In 2018, we recorded a charge to cost of sales for $18.1 million related to in-process ADCETRIS inventory that did not meet our manufacturing specifications. This inventory adjustment did not impact availability of product supply required to meet demand for ADCETRIS.

## 9. Property and equipment

Property and equipment consisted of the following:

| (dollars in thousands) | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Leasehold improvements | $ 154,606 | $ 101,743 |
| Laboratory and manufacturing equipment | 68,226 | 62,947 |
| Building | 23,341 | 23,341 |
| Computers, software and office equipment | 37,154 | 25,159 |
| Furniture and fixtures | 11,758 | 7,043 |
| Land | 4,771 | 4,771 |
| | 299,856 | 225,004 |
| Less: accumulated depreciation and amortization | (144,365) | (121,184) |
| Total | $ 155,491 | $ 103,820 |

Depreciation and amortization expenses on property and equipment totaled $23.8 million, $25.3 million, and $23.5 million for the years ended December 31, 2019, 2018, and 2017, respectively. Leasehold improvements included $62.2 million and $18.4 million of construction in process at December 31, 2019 and 2018, respectively.

## 10. Accrued liabilities

Accrued liabilities consisted of the following:

| (dollars in thousands) | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Employee compensation and benefits | $ 74,835 | $ 49,788 |
| Clinical trial and related costs | 37,418 | 38,692 |
| Contract manufacturing | 13,866 | 9,215 |
| Gross-to-net deductions and third-party royalties | 37,662 | 32,908 |
| Operating lease liability, current | 9,445 | — |
| Professional services and other | 33,839 | 16,690 |
| Total | $ 207,065 | $ 147,293 |

## 11. Income taxes

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

| (dollars in thousands) | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| U.S. | $ (160,189) | $ (226,626) | $ (71,698) |
| Foreign | 1,539 | (19,720) | (87,189) |
| Total | $ (158,650) | $ (246,346) | $ (158,887) |

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

| | Years ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Statutory federal income tax rate | (21.0)% | (21.0)% | (35.0)% |
| Tax credits | (11.0) | (6.0) | (11.0) |
| Foreign rate differential | — | (8.0) | 14.0 |
| State income taxes and other | (2.0) | (3.0) | (1.0) |
| Valuation allowance | 37.0 | 44.0 | (55.0) |
| Stock compensation | (9.0) | (4.0) | (5.0) |
| Non-deductible asset basis | 6.0 | — | — |
| Worthless stock deduction | — | (12.0) | — |
| Impact of the Act | — | — | 72.0 |
| Effective tax rate, before impact in other comprehensive income | — | (10.0) | (21.0) |
| Impact in other comprehensive income | — | — | 21.0 |
| Effective tax rate, after impact in other comprehensive income | 0.0 % | (10.0)% | 0.0 % |

We did not record any income tax expense or benefit due to a tax loss position in 2019. 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. In 2017, we recorded a deferred income tax benefit of $33.4 million due to unrealized gains on our common stock investment in Immunomedics, which was offset by an income tax provision for the same amount in other comprehensive income.

The Tax Cuts and Jobs Act, or the Act, was enacted on December 22, 2017, which reduced the U.S. federal corporate tax rate from 35% to 21%, among other changes. This resulted in a $114.8 million reduction in our net deferred tax assets as of December 31, 2017 to reflect the new statutory rate. The rate adjustment also resulted in a decrease in the valuation allowance.

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 impact on the effective tax rate is primarily due to the decrease in the U.S. tax rate of 35% in 2017 to 21% in 2018 and 2019, and an increase in pre-tax earnings from our operations in Europe and Canada. At December 31, 2019, unremitted earnings of our foreign subsidiaries, which were insignificant, 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, 2019 | December 31, 2018 |
|---|---|---|
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 331,124 | $ 283,888 |
| Foreign net operating loss carryforwards | 3,527 | 12,766 |
| Tax credit carryforwards | 193,552 | 175,702 |
| Deferred revenue | — | 2,553 |
| Share-based compensation | 34,869 | 29,354 |
| Allowance and accruals | 26,625 | 18,854 |
| Operating lease liabilities | 18,597 | — |
| Inventory | 3,815 | — |
| Capitalized research and development | 4,732 | 1,362 |
| Depreciation | 9,430 | 8,456 |
| Other | 1,133 | 1,773 |
| Total deferred tax assets | 627,404 | 534,708 |
| Less: valuation allowance | (536,316) | (477,834) |
| Total deferred tax assets, net of valuation allowance | 91,088 | 56,874 |
| Deferred tax liability: | | |
| Right-of-use assets | (17,125) | — |
| Intangibles and amortization | (50,725) | (48,819) |
| Realized and unrealized gain on available-for-sale securities | (20,064) | (8,055) |
| Other | (3,174) | |
| Net deferred tax assets (liability) | $ — | $ — |

Our deferred tax assets primarily consist of net operating loss (NOL) carryforwards, tax credit carryforwards, share-based compensation, allowance and accruals, operating lease, 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. Accordingly, the deferred tax assets have been fully offset by a valuation allowance. At December 31, 2019, we had gross federal NOL carryforwards of $1.4 billion, of which $383.6 million may be carried forward indefinitely and $1.0 billion of which expire from 2020 to 2038 if not utilized, gross state NOL carryforwards of $547.0 million, gross foreign NOL carryforwards of $39.6 million and tax credit carryforwards of $217.6 million expiring from 2020 to 2039.

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, 2018 and believe that it is likely that utilization of its NOLs would not be limited under Section 382 as of December 31, 2018. 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 increased by $58.5 million in 2019, increased by $113.3 million in 2018, and decreased by $16.8 million in 2017, which was mostly related to the changes in our deferred tax asset balances. The 2019 increase in the valuation allowance is primarily related to the current year 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 decrease in the valuation allowance in 2017 included the $114.8 million decrease to reflect the new statutory rate and the $33.4 million decrease related to the unrealized gain on the Immunomedics common stock investment recorded through other comprehensive income, offset by the $70.9 million increase in connection with the adoption of ASU 2016-09 and a $60.5 million increase for the current year loss, tax credits and other activity.

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) | 2019 | 2018 | 2017 |
| Balance at January 1 | $ 20,706 | $ 18,172 | $ 16,023 |
| Increase (decrease) related to prior year tax positions | — | 108 | (1,292) |
| Increase related to current year tax positions | 3,312 | 2,426 | 3,441 |
| Balance at December 31 | $ 24,018 | $ 20,706 | $ 18,172 |

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 2019 remain subject to future examination for federal income taxes.

**12. 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 3.

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 $76.8 million, $54.9 million, and $36.3 million for the years ended December 31, 2019, 2018, and 2017, 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. Gross profit share payments owed to Astellas in the U.S. are recorded in cost of sales.
- 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.

*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. We and Genmab will share all future costs and profits for development and commercialization of tisotumab vedotin on an equal basis. Costs associated with co-development activities are included in research and development expense and amounted $48.5 million, $33.8 million, and $6.8 million for the years ended December 31, 2019, 2018, and 2017, respectively.

We will be responsible for tisotumab vedotin commercialization activities in the U.S., Canada, and Mexico. Genmab will be responsible for commercialization activities in all other territories.

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.

*Other collaboration and license agreements*

We have other collaboration and 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. 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.

Our collaboration agreement with Unum Therapeutics to develop and commercialize novel antibody-coupled T-cell receptor therapies for cancer was terminated in January 2020.

**13. 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.

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.

**14. Commitments and contingencies**

*Commitments.* We have certain non-cancelable obligations under various agreements, including supply agreements relating to the manufacture of ADCETRIS, PADCEV, and our product candidates that contain annual minimum purchase commitments and other firm commitments when a binding forecast is provided. As of December 31, 2019, our future obligations related to supply and other agreements were as follows:

| **(dollars in thousands)** | |
|---|---|
| Years ending December 31, | |
| 2020 | $ 93,225 |
| 2021 | 44,236 |
| 2022 | 41,160 |
| 2023 | 25,695 |
| 2024 | 24,828 |
| Thereafter | 27,488 |
| Total | $ 256,632 |

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 4 for our future obligations related to operating leases as of December 31, 2019.

*Contingencies.*

On March 8, 2018, three purported stockholders of Cascadian filed a Verified Complaint to Compel Inspection of Books and Records under 8 Del. C. §220 in the Delaware Court of Chancery against Cascadian, seeking to inspect books and records in order to determine whether wrongdoing or mismanagement has taken place such that it would be appropriate to file claims for breach of fiduciary duty, and to investigate the independence and disinterestedness of the former Cascadian directors with respect to our acquisition of Cascadian. We filed our answer to this complaint on March 28, 2018. On February 20, 2019, we entered into an agreement regarding production and confidentiality of books and records with plaintiffs, pursuant to which we produced relevant books and records on April 22, 2019. As a result of this lawsuit, we have incurred and may incur additional litigation expenses and may potentially incur indemnification expenses in the future.

We are engaged in a dispute with Daiichi Sankyo Co. Ltd., or Daiichi Sankyo, regarding the ownership of certain technology used by Daiichi Sankyo in its metastatic breast cancer drug fam-trastuzumab deruxtecan-nxki (Enhertu®), among other product candidates. We contend that the linker and other ADC technology used in 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 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. 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. As a result of this dispute, we have incurred and will continue to incur litigation expenses.

In addition, from time to time in the ordinary course of business we become involved in various 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. 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 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.

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.

At December 31, 2019, shares of common stock reserved for future issuance are as follows:

| **(in thousands)** | |
|---|---|
| Stock options and RSUs outstanding | 13,169 |
| Shares available for future grant under the 2007 Equity Incentive Plan | 4,072 |
| Employee stock purchase plan shares available for future issuance | 1,194 |
| Total | 18,435 |

**16. 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 2018 to reserve an additional 6,000,000 shares thereunder, such that an aggregate of 33,000,000 shares of our common stock were authorized for issuance as of December 31, 2019, and to extend the term of the 2007 Plan through May 2028 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 $127.3 million, $78.9 million, and $63.8 million for the years ended December 31, 2019, 2018, and 2017, respectively, including share-based compensation expense associated with our LTIPs. No tax benefit was recognized related to share-based compensation expense since we have not reported taxable income to date and have established a valuation allowance to offset all of the 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 | | | Employee Stock Purchase Plan | | |
|---|---|---|---|---|---|---|
| | Years ended December 31, | | | Years ended December 31, | | |
| | 2019 | 2018 | 2017 | 2019 | 2018 | 2017 |
| Risk-free interest rate | 1.5% | 2.8% | 1.8% | 2.2% | 1.7% | 0.8% |
| Expected lives in years | 5.6 | 5.6 | 5.7 | 0.5 | 0.5 | 0.5 |
| Expected dividends | 0% | 0% | 0% | 0% | 0% | 0% |
| Expected volatility | 44% | 42% | 42% | 43% | 36% | 46% |

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, 2018 | 10,875,112 | $ 41.03 | | |
| Granted | 1,495,541 | $ 72.29 | | |
| Exercised | (2,432,550) | $ 31.88 | | |
| Forfeited/expired | (377,593) | $ 56.77 | | |
| Balance at December 31, 2019 | 9,560,510 | $ 47.62 | 6.21 | $ 637,096 |
| Expected to vest | 9,242,994 | $ 47.00 | 6.12 | $ 621,676 |
| Options exercisable | 5,951,964 | $ 38.56 | 4.85 | $ 450,550 |

The weighted average grant-date fair values of options granted with exercise prices equal to market were $30.51, $30.77, and $20.34 for the years ended December 31, 2019, 2018, and 2017, 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, 2019. The aggregate intrinsic value of options exercised was $128.4 million during 2019, $73.3 million during 2018, and $52.9 million during 2017, determined as of the date of option exercise. As of December 31, 2019, there was approximately $45.8 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 1.34 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, 2018 | 2,680,241 | $ 59.11 |
| Granted | 1,474,456 | $ 75.58 |
| Vested | (896,800) | $ 53.69 |
| Forfeited | (266,335) | $ 61.22 |
| Non-vested at December 31, 2019 | 2,991,562 | $ 68.66 |

The weighted average grant-date fair values of RSUs granted were $75.58, $70.78, and $50.12 for the years ended December 31, 2019, 2018, and 2017, respectively. The total fair value of RSUs that vested during 2019, 2018, and 2017 (measured on the date of vesting) was $67.1 million, $42.4 million, and $27.5 million, respectively. As of December 31, 2019, there was approximately $103.7 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 equity activity*

We have various LTIPs, which contain performance-based equity compensation.

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 now time-based and is included in the *"Stock option 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 now time-based and is included in the *"RSU activity"* table above.

A summary of RSU activity related to the LTIPs is as follows:

| | Share equivalent | Weighted-average grant date fair value |
|---|---|---|
| Non-vested at December 31, 2018 | 239,817 | $ 58.14 |
| Granted | 405,523 | $ 114.26 |
| Vested | — | $ — |
| Forfeited | (28,697) | $ 58.14 |
| Non-vested at December 31, 2019 | 616,643 | $ 95.05 |

As of December 31, 2019, the estimated unrecognized compensation cost related to all LTIPs was approximately $79 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. 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. 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.

**17. 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 $11.9 million in 2019, $7.7 million in 2018, and $5.7 million in 2017.

**18. 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:

| (dollars in thousands, except per share data) | Three months ended | | | |
|---|---|---|---|---|
| | March 31, | June 30, | September 30, | December 31, |
| | 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 |
| | 2018 | | | |
| Total revenues | $ 140,590 | $ 170,173 | $ 169,424 | $ 174,513 |
| Net income (loss) | $ (111,715) | $ 76,273 | $ (67,446) | $ (119,805) |
| Net income (loss) per share - basic | $ (0.73) | $ 0.48 | $ (0.42) | $ (0.75) |
| Net income (loss) per share - diluted | $ (0.73) | $ 0.47 | $ (0.42) | $ (0.75) |

**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, 2019 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, 2019.

The effectiveness of our internal control over financial reporting as of December 31, 2019 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**

None.

## 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 2019 fiscal year pursuant to Regulation 14A for our 2020 Annual Meeting of Stockholders, or the 2020 Proxy Statement, and the information to be included in the 2020 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 2020 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 2020 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 2020 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 2020 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 2020 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 2020 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 2020 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 2020 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. 4—Ratification of Appointment of Independent Registered Public Accounting Firm" appearing in the 2020 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†** | Asset Purchase Agreement, dated July 31, 2017, between Bristol-Myers Squibb Company and Seattle Genetics, Inc | 10-Q/A | 000-32405 | 2.1 | 4/13/2018 |
| 2.2** | Agreement and Plan of Merger, dated January 30, 2018, among 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 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 Seattle Genetics, Inc. | 8-K | 000-32405 | 3.3 | 5/26/2011 |
| 3.3 | Amended and Restated Bylaws of Seattle Genetics, Inc. | 8-K | 000-32405 | 3.1 | 1/16/2020 |
| 4.1+ | Description of Securities of Seattle Genetics, Inc. | — | — | — | — |
| 4.2 | Specimen Stock Certificate. | S-1/A | 333-50266 | 4.1 | 2/8/2001 |
| 4.3 | Investor Rights Agreement dated July 8, 2003 among 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 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 Seattle Genetics, Inc. and Millennium Pharmaceuticals, Inc. (a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited) dated December 14, 2009. | — | — | — | — |
| 10.2† | Collaboration and License Agreement dated January 7, 2007 between 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 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 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 Seattle Genetics, Inc | 10-Q/A | 000-32405 | 10.3 | 4/13/2018 |
| 10.6 | License Agreement dated March 30, 1998 between Seattle Genetics, Inc. and Bristol-Myers Squibb Company. | 10-K/A | 000-32405 | 10.1 | 11/26/2010 |
| 10.7 | Amendment Letter to the Bristol-Myers Squibb Company License Agreement dated July 29, 1999 between Seattle Genetics, Inc. and Bristol-Myers Squibb Company. | 10-K/A | 000-32405 | 10.2 | 11/26/2010 |
| 10.8 | Amendment Agreement to the Bristol-Myers Squibb Company License Agreement dated July 26, 2000 between Seattle Genetics, Inc. and Bristol-Myers Squibb Company. | S-1/A | 333-50266 | 10.7 | 12/5/2000 |

| Exhibit Number | Exhibit Description | Incorporation By Reference | | | |
|---|---|---|---|---|---|
| | | Form | SEC File No. | Exhibit | Filing Date |
| 10.9† | Amendment to License Agreement to the Bristol-Myers Squibb Company License Agreement dated December 18, 2015 between Seattle Genetics, Inc. and Bristol-Myers Squibb Company. | 10-K | 000-32405 | 10.4 | 2/19/2016 |
| 10.10 | License Agreement dated September 20, 1999 between Seattle Genetics, Inc. and the University of Miami. | 10-K/A | 000-32405 | 10.6 | 11/26/2010 |
| 10.11 | Amendment No. 1 to the University of Miami License Agreement dated August 4, 2000 between Seattle Genetics, Inc. and the University of Miami. | 10-K/A | 000-32405 | 10.7 | 11/26/2010 |
| 10.12† | Letter Agreement Regarding Royalty between the University of Miami and Seattle Genetics, Inc. dated April 11, 2016 | 10-Q | 000-32405 | 10.1 | 7/26/2016 |
| 10.13 | License Agreement between Cascadian Therapeutics, Inc. and Array BioPharma Inc. dated December 11, 2014. | 10-Q | 000-32405 | 10.1 | 4/26/2018 |
| 10.14† | Commercial Supply Agreement dated December 1, 2010 between Seattle Genetics, Inc. and SAFC, an operating division of Sigma-Aldrich, Inc. | 10-Q | 000-32405 | 10.1 | 11/4/2011 |
| 10.15† | First Amendment to Commercial Supply Agreement effective as of January 20, 2014 between Seattle Genetics, Inc. and SAFC, an operating division of Sigma-Aldrich, Inc. | 10-K | 000-32405 | 10.17 | 2/21/2017 |
| 10.16† | Second Amendment to Commercial Supply Agreement effective as of December 2, 2016 between Seattle Genetics, Inc. and SAFC, an operating division of Sigma-Aldrich, Inc. | 10-K | 000-32405 | 10.18 | 2/21/2017 |
| 10.17† | Third Amendment to Commercial Supply Agreement effective as of July 1, 2019 between Seattle Genetics, Inc. and SAFC, an operating division of Sigma-Aldrich, Inc. | 10-Q | 000-32405 | 10.20 | 10/30/2019 |
| 10.18 | Development and Supply Agreement dated February 23, 2004 between Seattle Genetics, Inc. and Abbott Laboratories. | 10-K | 000-32405 | 10.15 | 2/27/2015 |
| 10.19† | First Amendment to Development and Supply Agreement dated April 17, 2008 between Seattle Genetics, Inc. and Abbott Laboratories, Inc. | 10-Q | 000-32405 | 10.1 | 8/8/2008 |
| 10.20† | Second Amendment to Development and Supply Agreement dated June 15, 2009 between Seattle Genetics, Inc. and Abbott Laboratories, Inc. | 10-Q | 000-32405 | 10.4 | 11/4/2011 |
| 10.21† | Third Amendment to Development and Supply Agreement dated November 5, 2009 between Seattle Genetics, Inc. and Abbott Laboratories, Inc. | 10-Q | 000-32405 | 10.5 | 11/4/2011 |
| 10.22† | Fourth Amendment to Development and Supply Agreement dated April 18, 2010 between Seattle Genetics, Inc. and Abbott Laboratories, Inc. | 10-Q | 000-32405 | 10.6 | 11/4/2011 |
| 10.23† | Fifth Amendment to Development and Supply Agreement dated August 24, 2010 between Seattle Genetics, Inc. and Abbott Laboratories, Inc. | 10-Q | 000-32405 | 10.7 | 11/4/2011 |
| 10.24† | Sixth Amendment to Development and Supply Agreement dated November 18, 2010 between Seattle Genetics, Inc. and Abbott Laboratories, Inc. | 10-Q | 000-32405 | 10.8 | 11/4/2011 |
| 10.25† | Seventh Amendment to Development and Supply Agreement dated January 2, 2013 between Seattle Genetics, Inc. and Abbott Laboratories, Inc. | 10-K | 000-32405 | 10.42 | 2/27/2013 |
| 10.26† | Eighth Amendment to Development and Supply Agreement dated July 7, 2015 between Seattle Genetics, Inc. and AbbVie Inc. (formerly part of Abbott Laboratories, Inc.). | 10-Q | 000-32405 | 10.2 | 7/30/2015 |

| Exhibit Number | Exhibit Description | Incorporation By Reference | | | |
|---|---|---|---|---|---|
| | | Form | SEC File No. | Exhibit | Filing Date |
| 10.27† | Ninth Amendment to Development and Supply Agreement, effective as of August 28, 2016 between Seattle Genetics, Inc. and AbbVie Inc. (formerly part of Abbott Laboratories, Inc.). | 10-Q | 000-32405 | 10.1 | 10/27/2016 |
| 10.28† | Tenth Amendment to Development and Supply Agreement, effective as of December 26, 2016 between Seattle Genetics, Inc. and AbbVie, Inc. (formerly part of Abbott Laboratories, Inc.). | 10-K | 000-32405 | 10.29 | 2/21/2017 |
| 10.29+†† | Eleventh Amendment to Development and Supply Agreement effective July 12, 2018 between Seattle Genetics, Inc. and AbbVie Inc. (formerly part of Abbott Laboratories, Inc.). | — | — | — | — |
| 10.30† | Twelfth Amendment to Development and Supply Agreement, effective as of April 25, 2019 between Seattle Genetics, Inc. and AbbVie, Inc. (formerly part of Abbott Laboratories, Inc.). | 10-Q | 000-32405 | 10.2 | 7/16/2019 |
| 10.31 | Lease Agreement dated December 1, 2000 between Seattle Genetics, Inc. and WCM 132-302, LLC. | S-1/A | 333-50266 | 10.21 | 1/4/2001 |
| 10.32 | First Amendment to Lease dated May 28, 2003 between Seattle Genetics, Inc. and B&N 141-302, LLC. | 10-Q | 333-50266 | 10.1 | 8/12/2003 |
| 10.33† | Second Amendment to Lease dated July 1, 2008 between Seattle Genetics, Inc. and B&N 141-302, LLC. | 10-Q | 000-32405 | 10.1 | 11/7/2008 |
| 10.34† | Third Amendment to Lease dated May 9, 2011 between Seattle Genetics, Inc. and B&N 141-302, LLC. | 10-Q | 000-32405 | 10.2 | 8/5/2011 |
| 10.35† | Fourth Amendment to Lease dated October 24, 2017 between 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 |
| 10.36† | Office Lease dated May 9, 2011 between Seattle Genetics, Inc. and WCM Highlands II, LLC. | 10-Q | 000-32405 | 10.1 | 8/5/2011 |
| 10.37† | First Amendment to Office Lease dated October 24, 2017 between 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 |
| 10.38† | 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 |
| 10.39 | Assignment and Assumption of Purchase Agreement, dated July 30, 2017, between ZymoGenetics, Inc. and Seattle Genetics, Inc. | 10-Q | 000-32405 | 10.2 | 11/6/2017 |
| 10.40* | Form of Indemnification Agreement between Seattle Genetics, Inc. and each of its officers and directors. | S-1/A | 333-50266 | 10.29 | 1/4/2001 |
| 10.41* | Amended and Restated Employment Agreement dated October 25, 2018, between Seattle Genetics, Inc. and Clay Siegall. | 10-Q | 000-32405 | 10.1 | 10/26/2018 |
| 10.42* | Amended and Restated Employment Agreement dated October 25, 2018, between Seattle Genetics, Inc. and Todd Simpson. | 10-Q | 000-32405 | 10.2 | 10/26/2018 |
| 10.43* | Amended and Restated Employment Agreement dated October 25, 2018, between Seattle Genetics, Inc. and Roger Dansey. | 10-Q | 000-32405 | 10.3 | 10/26/2018 |
| 10.44* | Amended and Restated Employment Agreement dated October 25, 2018, between Seattle Genetics, Inc. and Vaughn Himes. | 10-Q | 000-32405 | 10.4 | 10/26/2018 |

| Exhibit Number | Exhibit Description | Incorporation By Reference | | | |
|---|---|---|---|---|---|
| | | Form | SEC File No. | Exhibit | Filing Date |
| 10.45* | Amended and Restated Employment Agreement dated October 25, 2018, between Seattle Genetics, Inc. and Darren Cline. | 10-Q | 000-32405 | 10.5 | 10/26/2018 |
| 10.46* | Amended and Restated Employment Agreement dated October 25, 2018, between Seattle Genetics, Inc. and Jean Liu. | 10-Q | 000-32405 | 10.6 | 10/26/2018 |
| 10.47* | Employment Agreement, dated May 20, 2019, between Seattle Genetics, Inc. and Robin Taylor. | 10-Q | 000-32405 | 10.3 | 7/16/2019 |
| 10.48* | Seattle Genetics, Inc. Amended and Restated 1998 Stock Option Plan, effective as of August 5, 2009. | 10-Q | 000-32405 | 10.1 | 8/10/2009 |
| 10.49* | Seattle Genetics, Inc. 2000 Directors' Stock Option Plan, as amended February 5, 2010. | 10-K | 000-32405 | 10.13 | 3/12/2010 |
| 10.50* | Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan, effective as of May 18, 2012. | 10-Q | 000-32405 | 10.1 | 8/8/2012 |
| 10.51* | Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan, effective as of May 16, 2014. | 10-Q | 000-32405 | 10.1 | 8/8/2014 |
| 10.52* | Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan, effective as of May 20, 2016. | 10-Q | 000-32405 | 10.4 | 7/26/2016 |
| 10.53* | Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan, effective as of May 18, 2018. | 10-Q | 000-32405 | 10.2 | 7/26/2018 |
| 10.54* | Seattle Genetics, Inc. Long Term Incentive Plan for ECHELON-1, effective as of May 9, 2016. | 10-Q | 000-32405 | 10.2 | 7/26/2016 |
| 10.55* | Seattle Genetics, Inc. Long Term Incentive Plan for EV and TV, effective as of September 29, 2017. | 10-Q | 000-32405 | 10.4 | 11/6/2017 |
| 10.56* | Seattle Genetics, Inc. Long Term Incentive Plan for Tucatinib, effective as of October 24, 2018. | 10-Q | 000-32405 | 10.7 | 10/26/2018 |
| 10.57* | Seattle Genetics, Inc. Senior Executive Annual Bonus Plan, as amended February 4, 2019 | 10-K | 000-32405 | 10.69 | 02/07/2019 |
| 10.58* | Seattle Genetics, Inc. Amended and Restated 2000 Employee Stock Purchase Plan, effective as of May 20, 2019. | S-8 | 333-232397 | 99.1 | 6/27/2019 |
| 10.59* | Form Notice of Grant and Stock Option Agreement under Seattle Genetics, Inc. Amended and Restated 1998 Stock Option Plan. | 10-K | 000-32405 | 10.11 | 3/15/2005 |
| 10.60* | Form Notice of Grant and Stock Option Agreement under Seattle Genetics, Inc. 2000 Directors' Stock Option Plan. | 10-K | 000-32405 | 10.12 | 3/15/2005 |
| 10.61* | Form Stock Option Agreement for employees under Seattle Genetics, Inc. 2007 Equity Incentive Plan. | 10-K | 000-32405 | 10.44 | 3/13/2009 |
| 10.62* | 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 |
| 10.63* | Form of Stock Unit Grant Notice and Stock Unit Agreement for employees under Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan. | 8-K | 000-32405 | 10.1 | 8/30/2011 |
| 10.64* | 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 |
| 10.65* | Form of Stock Option Agreement for Long Term Incentive Plan for ECHELON-1 under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan. | 10-Q | 000-32405 | 10.3 | 7/26/2016 |

| Exhibit Number | Exhibit Description | Incorporation By Reference | | | |
|---|---|---|---|---|---|
| | | Form | SEC File No. | Exhibit | Filing Date |
| 10.66* | 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 |
| 10.67* | 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 |
| 10.68* | 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 |
| 10.69* | 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 |
| 10.70* | Form of Performance-Based Stock Option Agreement for employees under Seattle Genetics, Inc. 2007 Equity Incentive Plan (approved May 18, 2018). | 10-Q | 000-32405 | 10.7 | 7/26/2018 |
| 10.71* | Form of Time-Based Stock Option Agreement for employees under Seattle Genetics, Inc. 2007 Equity Incentive Plan (approved May 18, 2018). | 10-Q | 000-32405 | 10.8 | 7/26/2018 |
| 10.72* | Form of Performance-Based Stock Unit Grant Notice and Stock Unit Agreement for employees under Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved May 18, 2018). | 10-Q | 000-32405 | 10.9 | 7/26/2018 |
| 10.73* | Form of Time-Based Stock Unit Grant Notice and Stock Unit Agreement for employees under Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved May 18, 2018). | 10-Q | 000-32405 | 10.10 | 7/26/2018 |
| 10.74* | Form of Stock Option Agreement for U.S. Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved August 30, 2018). | 10-Q | 000-32405 | 10.8 | 10/26/2018 |
| 10.75* | Form of Stock Option Agreement for non-US Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved August 30, 2018). | 10-Q | 000-32405 | 10.9 | 10/26/2018 |
| 10.76* | Form of Performance-Based Stock Unit Agreement for U.S. Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved August 30, 2018). | 10-Q | 000-32405 | 10.10 | 10/26/2018 |
| 10.77* | Form of Stock Unit Grant Notice and Stock Unit Agreement for US Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved October 24, 2018). | 10-Q | 000-32405 | 10.11 | 10/26/2018 |
| 10.78* | Form of Stock Unit Grant Notice and Stock Unit Agreement for non-US Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved October 24, 2018). | 10-Q | 000-32405 | 10.12 | 10/26/2018 |
| 10.79* | Form of Performance-Based Stock Unit Grant Notice and Stock Unit Agreement under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved August 26, 2019). | 10-Q | 000-32405 | 10.1 | 10/30/2019 |
| 10.80*+ | Form of Stock Option Agreement for U.S. Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved December 19, 2019). | — | — | — | — |

| Exhibit Number | Exhibit Description | Incorporation By Reference | | | |
|---|---|---|---|---|---|
| | | Form | SEC File No. | Exhibit | Filing Date |
| 10.81*+ | Form of Stock Option Agreement for Non-US Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved December 19, 2019). | — | — | — | — |
| 10.82*+ | Form of Time-Based Stock Unit Grant Notice and Stock Unit Agreement for employees under Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved December 19, 2019). | — | — | — | — |
| 10.83*+ | Form of Stock Unit Grant Notice and Stock Unit Agreement for non-US Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved December 19, 2019). | — | — | — | — |
| 10.84*+ | Form of Performance-Based Stock Unit Agreement for U.S. Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved December 19, 2019). | — | — | — | — |
| 10.85*+ | Form of Stock Unit Grant Notice for US Participants Long Term Incentive Plan for EV and TV (approved December 19, 2019). | — | — | — | — |
| 10.86*+ | Form of Stock Unit Grant Notice for Non-US Participants Long Term Incentive Plan for EV and TV (approved December 19, 2019). | — | — | — | — |
| 10.87*+ | Form of Performance-Based Stock Unit Notice and Stock Unit Agreement for U.S. Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved December 24, 2019). | — | — | — | — |
| 10.88*+ | Form of Performance-Based Stock Unit Notice and Stock Unit Agreement for Non-U.S. Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved December 24, 2019). | — | — | — | — |
| 21.1+ | Subsidiaries of Seattle Genetics, 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, 2019, formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive 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 brackets in the Exhibit, has been omitted, because it is both not material and would likely cause competitive harm if publicly disclosed. |
| * | 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.

SEATTLE GENETICS, INC.

Date: February 6, 2020 By: /S/ CLAY B. SIEGALL

Clay B. Siegall
*President & Chief Executive Officer*
*(Principal Executive Officer)*

Date: February 6, 2020 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<br>Clay B. Siegall | Director, President & CEO (Principal Executive Officer) | February 6, 2020 |
| /S/ TODD E. SIMPSON<br>Todd E. Simpson | Chief Financial Officer (Principal Financial and Accounting Officer) | February 6, 2020 |
| /S/ SRINIVAS AKKARAJU<br>Srinivas Akkaraju | Director | February 6, 2020 |
| /S/ FELIX J. BAKER<br>Felix J. Baker | Director | February 6, 2020 |
| /S/ DAVID W. GRYSKA<br>David W. Gryska | Director | February 6, 2020 |
| /S/ MARC E. LIPPMAN<br>Marc E. Lippman | Director | February 6, 2020 |
| /S/ JOHN A. ORWIN<br>John A. Orwin | Director | February 6, 2020 |
| /S/ Alpna Seth<br>Alpna Seth | Director | February 6, 2020 |
| /S/ NANCY A. SIMONIAN<br>Nancy A. Simonian | Director | February 6, 2020 |
| /S/ DANIEL G. WELCH<br>Daniel G. Welch | Director | February 6, 2020 |

**Exhibit 31.1**

**CERTIFICATIONS**

I, Clay B. Siegall, certify that:

1. I have reviewed this Annual Report on Form 10-K of Seattle Genetics, 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 6, 2020

**Exhibit 31.2**

**CERTIFICATIONS**

I, Todd E. Simpson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Seattle Genetics, 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 6, 2020

**Exhibit 32.1**

**SEATTLE GENETICS, 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 Seattle Genetics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019, 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 6, 2020

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 Seattle Genetics, 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**

**SEATTLE GENETICS, 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 Seattle Genetics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019, 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 6, 2020

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 Seattle Genetics, 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.

# CORPORATE INFORMATION

## EXECUTIVE MANAGEMENT

**Clay B. Siegall, Ph.D.**
President, Chief Executive Officer and Chairman of the Board

**Roger D. Dansey, M.D.**
Chief Medical Officer

**Vaughn B. Himes, Ph.D.**
Chief Technical Officer

**Todd E. Simpson**
Chief Financial Officer

**Jean I. Liu, J.D.**
General Counsel, Executive Vice President, Legal Affairs

**Christopher P. Pawlowicz**
Executive Vice President, Human Resources

**Rachel P. Lenington**
Senior Vice President, Program and Portfolio Management

**Natasha A. Hernday**
Senior Vice President, Corporate Development

## BOARD OF DIRECTORS

**Clay B. Siegall, Ph.D.**
President, Chief Executive Officer and Chairman of the Board, Seattle Genetics, Inc.

**Srinivas Akkaraju, M.D., Ph.D.**
Managing General Partner, Samsara BioCapital

**Felix J. Baker, Ph.D.**
Co-Managing Member, Baker Brothers Advisors

**David W. Gryska**
Former Executive Vice President and Chief Financial Officer, Incyte Corporation

**Marc E. Lippman, M.D.**
Professor of Oncology at Georgetown University Medical Center's Lombardi Comprehensive Cancer Center

**John A. Orwin**
President and Chief Executive Officer, Atreca

**Alpna H. Seth, Ph.D.**
President and Chief Executive Officer, Proneurotech

**Nancy A. Simonian, M.D.**
Chief Executive Officer, Syros Pharmaceuticals

**Daniel G. Welch**
Biotechnology Advisor; former Executive Partner of Sofinnova Ventures

## CORPORATE HEADQUARTERS

Seattle Genetics, Inc.
21823 30th Drive Southeast
Bothell, WA 98021
(425) 527-4000

## WEBSITE

www.seattlegenetics.com

## TRANSFER AGENT & REGISTRAR

Computershare
P.O. BOX 505000
Louisville, KY 40233
(877) 419-8489
www.computershare.com/investor

## LEGAL COUNSEL

Cooley LLP
Seattle, Washington

## INDEPENDENT AUDITORS

PricewaterhouseCoopers LLP
Seattle, Washington

## STOCK LISTING

The Company's common stock is traded on the Nasdaq Global Select Market under the symbol SGEN.

## STOCKHOLDER INQUIRIES

Communications regarding transfer requirements, lost stock certificates or changes of address should be directed to our Transfer Agent and Registrar. Inquiries regarding the Company and its activities, or requests for a copy of financial documents, such as this annual report and the Form 10-K, may be directed to the Corporate Secretary or the Investor Relations department at our corporate headquarters.

SeattleGenetics®

seattlegenetics.com Nasdaq: SGEN @SeattleGenetics Find us on LinkedIn

**FORWARD-LOOKING STATEMENTS** This 2019 Annual Report, including Seattle Genetics' Annual Report on Form 10-K for the year ended December 31, 2019 included with the 2019 Annual Report, 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, such as those, among others, relating to the Company's 2020 outlook, the Company's potential to achieve the noted development and regulatory milestones in 2020 and future periods, the Company's potential to bring a third product to market in the United States and other countries and effectively commercialize the Company's products; anticipated activities related to the Company's planned and ongoing clinical trials, including clinical trial initiation, enrollment and data availability and the expected timing thereof, including with respect to innovaTV 204, EV-301, EV-302, HER-2CLIMB-02, MOUNTAINEER and other clinical trials; the potential for the Company's clinical trials to support further development, regulatory submissions and potential marketing approvals; the opportunities for, and the therapeutic and commercial potential of ADCETRIS, PADCEV, tucatinib, and tisotumab vedotin and the Company's other product candidates and those of its licensees and collaborators; as well as other statements that are not historical facts. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include the risks that the Company's net sales, revenue, expense, and other financial guidance may not be as expected, as well as risks and uncertainties associated with maintaining or increasing sales of ADCETRIS and PADCEV due to competition, unexpected adverse events, regulatory action, reimbursement, market adoption by physicians, the impacts of the COVID-19 pandemic or other factors. The Company may also be delayed in its planned clinical trial initiations, enrollment in and conduct of its clinical trials, obtaining data from clinical trials, planned regulatory submissions, regulatory approvals and launch in each case for a variety of reasons including the difficulty and uncertainty of pharmaceutical product development, the impacts of the COVID-19 pandemic, negative or disappointing clinical trial results, unexpected adverse events or regulatory discussions or actions and the inherent uncertainty associated with the regulatory approval process and the pricing and reimbursement process when applicable. Seattle Genetics discusses many of these risks, uncertainties and other factors in greater detail under the heading "Item 1A-Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2019 included with this 2019 Annual Report. Seattle Genetics disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise except as required by applicable law.