SEATTLE GENETICS INC /WA
Form 10-K
February 07, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K
(Mark One)
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
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

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	Name of each exchange on which registered
Common Stock, par value $0.001	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 and post such files). YES NO
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.
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 $7.0 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 52,503,051 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 160,561,234 shares of the registrant's Common Stock issued and outstanding as of February 4, 2019.

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 2019 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," "antic "project," "believe," "estimate," "predict," "potential," "intend" or "continue," the negative of terms like these or other compar 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 treatment of several types of lymphoma. 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, 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.

Our marketed product ADCETRIS is commercially available in 72 countries, including in the U.S., Canada, members of the European Union and Japan. We commercialize ADCETRIS in the U.S. and its territories and in Canada, and we are collaborating 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. For patients with 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. For patients with T-cell lymphomas, ADCETRIS is approved as monotherapy in patients with relapsed or refractory systemic anaplastic large cell lymphoma, or sALCL, or cutaneous T-cell lymphoma, or CTCL, or in combination with chemotherapy in patients with previously untreated CD30-positive peripheral T-cell lymphoma, or PTCL. Key regulatory developments in 2018 included the approval of ADCETRIS for use in two frontline settings based on the successful outcomes of the phase 3 ECHELON-1 and ECHELON-2 clinical trials as described below:

- In March 2018, the FDA approved ADCETRIS in combination with doxorubicin, vinblastine and dacarbazine, or AVD, for patients with newly diagnosed, previously untreated Stage III/IV classical Hodgkin lymphoma based on the results of ECHELON-1 trial, or the frontline Hodgkin lymphoma indication. In the ECHELON-1 trial, ADCETRIS in combination with AVD demonstrated a statically significant improvement in the primary endpoint of modified progression-free survival, or PFS, versus the control arm, doxorubicin, bleomycin, vinblastine and dacarbazine, or ABVD. The safety profile of ADCETRIS plus AVD in the trial was consistent with that known for the single-agent components of the regimen.
- In November 2018, the FDA approved ADCETRIS in combination with cyclophosphamide, doxorubicin, and prednisone, or CHP, for patients with 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 based on the results of the ECHELON-2 trial, or the

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frontline PTCL indication. In the ECHELON-2 trial, ADCETRIS in combination with CHP demonstrated a statistically significant improvement in the primary endpoint of PFS versus the control arm, CHOP, or cyclophosphamide, doxorubicin, vincristine and prednisone. ADCETRIS plus CHP also demonstrated superior overall survival, a key secondary endpoint, compared to CHOP. The safety profile of ADCETRIS plus CHP in the trial was comparable to CHOP and consistent with the established safety profile of ADCETRIS in combination with chemotherapy.

Beyond our current labeled indications, we are evaluating ADCETRIS in several clinical trials in combination with nivolumab (Opdivo®) under a clinical collaboration with Bristol-Myers Squibb Company, or BMS. Nivolumab is a programmed death-1, or PD-1, immune checkpoint inhibitor. The trials are evaluating the combination in several settings for Hodgkin and non-Hodgkin lymphoma.

Our late-stage pipeline includes two ADCs and an oral tyrosine kinase inhibitor, or TKI, for solid tumors that are in clinical trials designed to support applications for potential regulatory approvals.

In collaboration with Astellas Pharma, Inc., or Astellas, we are developing enfortumab vedotin, which is an ADC targeting Nectin-4. We and Astellas are conducting a pivotal phase 2 trial, called EV-201, evaluating single-agent enfortumab vedotin for patients with locally advanced or metastatic urothelial cancer who were previously treated with a PD-1 or PD-L1 inhibitor. In March 2018, the FDA granted Breakthrough Therapy Designation, or BTD, to enfortumab vedotin for patients with locally advanced or metastatic urothelial cancer who were previously treated with a checkpoint inhibitor. In July 2018, we completed enrollment in the first cohort of EV-201 of approximately 120 patients who previously received both platinum chemotherapy and a PD-1 or PD-L1 inhibitor. We expect to report top-line data from this cohort in the first quarter of 2019. We believe that positive data in this cohort could support potential registration under the FDA's accelerated approval pathway. In July 2018, we and Astellas initiated a global, randomized phase 3 trial, called EV-301, for patients with metastatic urothelial cancer who previously received both platinum chemotherapy and a PD-1 or PD-L1 inhibitor. EV-301 is intended to support global regulatory applications for potential approvals and potentially serve as a confirmatory trial in the U.S. if we are able to obtain accelerated approval based on data from the EV-201 trial. We and Astellas are also conducting a phase 1b trial of enfortumab vedotin, called EV-103, in combination with either pembrolizumab or other anticancer agents as first- or second-line treatment for patients with locally advanced or metastatic urothelial cancer.

In March 2018, we obtained global rights to tucatinib, an oral TKI targeting HER2, a growth factor receptor overexpressed in many cancers, through the acquisition of Cascadian Therapeutics, Inc., or the Cascadian Acquisition. Tucatinib is currently being evaluated as part of a combination regimen in a global randomized (2:1) pivotal phase 2 trial, called HER2CLIMB, comparing tucatinib vs. placebo, each in combination with capecitabine and trastuzumab. The trial is enrolling patients with HER2-positive metastatic breast cancer who have been previously treated with trastuzumab, pertuzumab (Perjeta®) and ado-trastuzumab emtansine, or T-DM1, (Kadcyla®), including patients with or without brain metastases. We achieved enrollment of 480 patients in the trial to enable analysis of the primary endpoint of PFS, with top-line data expected to be reported in 2019. In addition, we are continuing enrollment in HER2CLIMB up to 600 patients to support the analyses of key secondary endpoints, including overall survival, or OS, as well as PFS in patients with brain metastases. We anticipate completing enrollment of the additional patients in mid-2019.

In collaboration with Genmab A/S, or Genmab, we are developing tisotumab vedotin, which is an ADC targeting tissue factor, or TF. In June 2018, we initiated 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 potential registration under the FDA's accelerated approval pathway. We expect to complete enrollment in innovaTV 204 by mid-2019. In July 2018, we initiated a phase 2 clinical trial, called innovaTV 207, for patients with other solid tumors including colorectal, non-small cell lung, pancreatic or head and neck cancers. The trial is intended to inform a potential future broad development program. We are also conducting a phase 2 clinical trial, called innovaTV 208, for patients with platinum-resistant ovarian cancer.

We are also 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 triple-negative breast cancer.

Our early-stage clinical pipeline includes SGN-CD48A, which utilizes our ADC technology, SEA-BCMA, a monoclonal antibody utilizing our sugar-engineered antibody, or SEA, technology, and SGN-2FF, which is a novel small

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molecule. In addition, we have multiple preclinical and research-stage programs that employ our proprietary technologies.

We have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including AbbVie Biotechnology Ltd., or AbbVie; Bayer Pharma AG, or Bayer; Celldex Therapeutics, Inc., or Celldex; Genentech, Inc., a member of the Roche Group, or Genentech; GlaxoSmithKline LLC, or GSK; and Progenics Pharmaceuticals Inc., or Progenics. Of these collaborators, GSK and AbbVie each have ADCs using our technology in late-stage clinical trials, and in December 2018 Roche submitted regulatory applications in the U.S. and the European Union, or EU, for approval of polatuzumab vedotin, an ADC that uses our technology, to treat patients with relapsed or refractory diffuse large B-cell lymphoma, or DLBCL. In addition, we have a collaboration with Unum Therapeutics, Inc., or Unum, to develop and commercialize novel antibody-coupled T-cell receptor, or ACTR, therapies incorporating our antibodies for the treatment of cancer. Unum is conducting a phase 1 trial evaluating Unum's ACTR087 drug candidate in combination with SEA-BCMA in patients with relapsed/refractory multiple myeloma. In 2018, we entered into a research collaboration agreement with Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals AG, or together, Pieris, to develop novel potential treatments of cancer based on bispecifics incorporating our proprietary antibodies and Pieris' proprietary technology designed to stimulate an antibody-directed immune response against solid tumors and blood cancers.

Our Antibody-Drug Conjugate (ADC) Technology

ADCETRIS 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, enfortumab vedotin, 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 ADC's 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.

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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.

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. An important near-term objective is to continue to execute our ADCETRIS commercial plan by driving market penetration and duration of therapy consistent with the current ADCETRIS label. We continue to focus our efforts on commercializing ADCETRIS in the United States and Canada through the coordinated efforts of our sales, marketing, reimbursement and market planning groups. ADCETRIS is approved by the FDA and the European Commission in several 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. Several clinical trials are evaluating ADCETRIS in combination with nivolumab, a PD-1 inhibitor, in various lymphoma settings. Clinical trials are also being conducted by us, by our collaborators and by investigators in different CD30-expressing indications, including earlier stages of Hodgkin lymphoma, novel combinations of ADCETRIS plus immuno-oncology or other anticancer agents and in other areas of medical and scientific interest.
- Advance Our Late-stage Clinical Pipeline of Oncology Drugs. We are deploying our clinical, development, regulatory and manufacturing expertise with the goal of advancing our late-stage product candidates towards regulatory approval and commercialization on a global basis. Our key efforts in this regard include:

Advance Enfortumab Vedotin including in a Pivotal Trial for Urothelial Cancer. We and Astellas are conducting several clinical trials of enfortumab vedotin in metastatic urothelial cancer. These include the pivotal EV-201 phase 2 clinical trial for patients with locally advanced or metastatic urothelial cancer who have been previously treated with PD-1 or PD-L1 inhibitor from which top-line data are expected in the first quarter of 2019. We are evaluating enfortumab vedotin in the global, randomized EV-301 phase 3 trial and in the EV-103 phase 1b trial as part of combination regimens in earlier lines of metastatic urothelial cancer. We also believe enfortumab vedotin may have application in other types of solid tumors based on the expression of Nectin-4 in cancers, such as ovarian and non-small cell lung, and we are considering potential future clinical trials.

- Advance Tucatinib in a Pivotal Trial for HER2-Positive Metastatic Breast Cancer. We are conducting the global, randomized HER2CLIMB pivotal phase 2 trial for patients with HER2-positive metastatic breast cancer who have been previously treated with HER2-targeted agents, including patients with or without brain metastases. Top-line data from HER2CLIMB are expected during 2019. We believe tucatinib may have application in earlier lines of therapy for the treatment of HER2-positive breast cancer, and in other types of HER2-positive cancers, including colorectal and gastric, and we are considering potential future clinical trials.
- 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 a phase 2 clinical trial for patients with colorectal, non-small cell lung, pancreatic or head and neck cancers. The trial is intended to inform a potential broad development program.

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- 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.
- Expand Globally. We have established operations in Zug, Switzerland and plan to establish operations in Amsterdam, the Netherlands to support our operations within the EU. We acquired global rights to tucatinib in March 2018, and in 2019 we plan to continue to develop our European presence in support of our planned global expansion for tucatinib and our other product candidates.
- 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, Bayer, Celldex, Genentech, GSK, and Progenics, as well as ADC co-development agreements with Astellas, Genmab, and Unum. ADC collaboration and co-development agreements have generated over $400 million as of December 31, 2018, primarily in the form of upfront and milestone payments. Several of these collaborators are advancing ADCs using our technology in late-stage clinical development across a range of cancer types.

ADCETRIS and Lead Clinical Development Pipeline

ADCETRIS

ADCETRIS is an ADC comprised of an anti-CD30 monoclonal antibody attached by a protease-cleavable linker to a proprietary microtubule disrupting agent, monomethyl auristatin E, or MMAE. ADCETRIS employs a linker system that is designed to be stable in the bloodstream and to release MMAE upon internalization into CD30-expressing cells. We believe that the CD30 antigen is an attractive target for cancer therapy because it is expressed on multiple types of cancer, but has limited expression on normal tissues.

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:

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Indication[1]	Approvals
ADCETRIS approvals in classical Hodgkin lymphoma (cHL)	
Previously untreated Stage III/IV cHL in combination with doxorubicin, vinblastine, and dacarbazine	US
cHL at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation	US 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	US Canada[2]
ADCETRIS approvals in T-cell lymphoma	
Previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone	US
sALCL after failure of at least one prior multi-agent chemotherapy regimen	US Canada[2]
Primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy	US 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. As of February 2019, ADCETRIS was commercially available in 72 countries.

Market Opportunities

According to the National Cancer Institute, approximately 8,500 cases of Hodgkin lymphoma were expected to be diagnosed in the United States during 2018, and an estimated 1,050 people were 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.

In March 2018, the FDA approved ADCETRIS in combination with doxorubicin, vinblastine and dacarbazine, or AVD, for patients with newly diagnosed, previously untreated Stage III/IV classical Hodgkin lymphoma based on the results of ECHELON-1 trial, or the frontline Hodgkin lymphoma indication. In the ECHELON-1 trial, ADCETRIS in combination with AVD demonstrated a statically significant improvement in the primary endpoint of modified progression-free survival, or PFS, versus the control arm, doxorubicin, bleomycin, vinblastine and dacarbazine, or ABVD. The safety profile of ADCETRIS plus AVD in the trial was consistent with that known for the single-agent components of the regimen.

Our most recent FDA approved indication for ADCETRIS was received in November 2018 for its use in combination with CHP for patients with previously untreated sALCL or other CD30-expressing PTCL, including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, or the frontline PTCL indication. Our supplemental Biologics License Application, or sBLA, was reviewed under the FDA's Real-Time Oncology Review Pilot Program leading to approval less than two weeks after submission of the complete application. The approval was based on the results of the ECHELON-2 trial. Prior to approval, in October 2018, we and Takeda announced positive

top line data from the ECHELON-2 trial. The FDA granted BTD based on the results of the ECHELON-2 trial. Additional data were reported at the 60th American Society of Hematology, or ASH, annual meeting and simultaneously published in The Lancet.

The ECHELON-2 trial enrolled 452 patients (226 in each arm) with advanced disease (80 percent) and most patients had sALCL (48 percent ALK-negative and 22 percent ALK-positive).

The trial met its primary endpoint with ADCETRIS plus CHP demonstrating a statistically significant improvement in PFS as assessed by a Blinded Independent Central Review, or BICR (hazard ratio [HR]=0.71; p-value=0.0110). This corresponds to a 29 percent reduction in the risk of progression, death or need for additional anticancer therapy for residual or progressive disease. After a median follow-up time of 36.2 months, the median PFS in the ADCETRIS plus CHP arm was 48.2 months compared to 20.8 months in the control arm per BICR assessment. OOS in the ADCETRIS plus CHP arm was statistically significant compared to CHOP (HR=0.66; p-value=0.0244). This corresponds to a 34 percent reduction in the risk of death. After a median follow-up of 42.1 months, the median OS was not reached for either arm of the study. The estimated three-year OS was 76.8 percent for ADCETRIS plus CHP compared to 69.1 percent for CHOP.

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All other key secondary endpoints, including complete response, or CR, rate and objective response rate, or ORR, in addition to PFS in patients with sALCL, were statistically significant in favor of the ADCETRIS plus CHP arm. Per BICR assessment, the CR rate (68 percent versus 56 percent, respectively) and ORR (83 percent versus 72 percent, respectively) for the ADCETRIS plus CHP arm were significantly higher than those treated with CHOP (p-value=0.0066 and p-value=0.0032, respectively).

The safety profile of ADCETRIS plus CHP in the trial was comparable to CHOP and consistent with the established safety profile of ADCETRIS in combination with chemotherapy. The most common treatment-related adverse events, or AEs, of any grade occurring in 20 percent or more of patients in the ADCETRIS plus CHP and CHOP arm were: nausea (46 and 38 percent, respectively), peripheral sensory neuropathy (45 and 41 percent, respectively), neutropenia (38 percent each), diarrhea (38 and 20 percent, respectively), constipation (29 and 30 percent, respectively), alopecia (26 and 25 percent, respectively), pyrexia (26 and 19 percent, respectively), vomiting (26 and 17 percent, respectively), fatigue (24 and 20 percent, respectively) and anaemia (21 and 16 percent, respectively).The most common Grade 3 or higher AEs occurring in the ADCETRIS plus CHP and CHOP arms were neutropenia (35 and 34 percent, respectively) and anaemia (13 and 10 percent, respectively).

Our Late-Stage Clinical Development Pipeline

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

Name of Product or Product Candidate	Therapeutic Area	Monotherapy/Combination	Development Status
ADCETRIS (brentuximab vedotin)	Relapsed Hodgkin lymphoma	In combination with nivolumab[1]	Phase 3 (CheckMate 812)
	Relapsed non-Hodgkin lymphoma		Phase 1/2 (CheckMate 436)
	Frontline Hodgkin lymphoma (patients 60+)		Phase 2
	Second-line Hodgkin lymphoma		Phase 1/2
	Relapsed Hodgkin lymphoma (pediatrics)		Phase 1/2 (CheckMate 744)
Enfortumab Vedotin[2]	Metastatic urothelial cancer previously treated with platinum chemotherapy and a PD-1 or PD-L1 inhibitor	Monotherapy	Pivotal Phase 2 (EV-201)
	Metastatic urothelial cancer previously treated with platinum chemotherapy and a PD-1 or PD-L1 inhibitor		Phase 3 (EV-301)
	First- or second-line metastatic urothelial cancer	In combination with platinum agents or pembrolizumab	Phase 1 (EV-103)
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)
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

ADCETRIS (brentuximab vedotin) Development Status

Beyond our current labeled indications, we are evaluating ADCETRIS in ongoing trials in combination with BMS' nivolumab (Opdivo). Nivolumab is a PD-1 inhibitor that is designed to harness the body’s own immune system to help restore antitumor immune response. A description of these trials as well as recent data from select trials are as follows:

- Phase 3 Relapsed/Refractory Hodgkin Lymphoma (CheckMate 812). We and BMS are conducting the randomized CheckMate 812 pivotal phase 3 clinical trial to evaluate the combination of ADCETRIS and nivolumab for the treatment of patients with relapsed or refractory, or transplant-ineligible, advanced classical Hodgkin lymphoma. The primary endpoint of the CheckMate 812 trial is PFS and targeted enrollment is 340 patients. The CHECKMATE 812 trial is supported by interim data from a phase 1/2 trial in second-line Hodgkin lymphoma.
- Phase 1/2 Relapsed/Refractory Non-Hodgkin Lymphoma (CheckMate 436). We and BMS are evaluating the combination of ADCETRIS and nivolumab in patients with relapsed or refractory B-cell and T-cell non-Hodgkin lymphomas, including DLBCL and rare B-cell lymphomas, including primary mediastinal B-cell lymphoma, or PMBL. Interim data from a cohort of 30 patients with relapsed or refractory PMBL who received a combination of ADCETRIS plus nivolumab after failure of frontline therapy or autologous stem cell transplant, or ASCT, were

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presented at the 2018 ASH annual meeting. Of 30 response-evaluable patients, 21 patients (70 percent) had an objective response, including eight patients (27 percent) with a CR and 13 patients (43 percent) with a partial response, or PR, three patients (10 percent) with stable disease, or SD, four patients (13 percent) with progressive disease and two patients (seven percent) unable to determine. Median duration of response, or DOR, and duration of CR were not reached. The most common AEs of any grade in at least 20 percent of patients were neutropenia and peripheral neuropathy. The most common Grade 3 or 4 AEs were neutropenia, thrombocytopenia, decreased neutrophil count, hypersensitivity, diarrhea and maculopapular rash.

- Phase 2 Frontline Hodgkin Lymphoma (patients age 60 and over). Data were presented at the 2018 International Symposium on Hodgkin Lymphoma from an ongoing phase 2 clinical trial evaluating ADCETRIS in combination with nivolumab as frontline therapy for Hodgkin lymphoma patients age 60 years or older. Data were reported from 14 patients with a median age of 71.5 years, of which the majority of patients (79 percent) had Stage III/IV disease at the time of diagnosis. Of 11 response-evaluable patients with a median follow-up time of eight months, nine patients (82 percent) had an objective response, including six patients (55 percent) with a CR and three patients (27 percent) with a PR. In addition, two patients (18 percent) had SD which equates to all 11 patients (100 percent) experiencing disease control CR + PR + SD) as a result of treatment with ADCETRIS in combination with nivolumab. The most common AEs of any grade occurring in at least 25 percent of patients were fatigue, diarrhea, constipation, nausea, arthralgia, chills, decreased appetite, pyrexia, infusion-related reaction, or IRR, increased aspartate aminotransferase and peripheral sensory neuropathy. Grade 3 or higher AEs occurred in seven patients (50 percent), and the most common were peripheral neuropathy and increased lipase (three patients each); nausea and increased alanine aminotransferase (two patients each).
- Phase 1/2 Second-line Hodgkin lymphoma. Data were reported for part 3 of this study that evaluated concurrent combination of ADCETRIS and nivolumab after failure of frontline therapy at the 2018 ASH annual meeting. Of 30 response-evaluable patients, 28 patients (93 percent) had an objective response, including 24 patients (80 percent) with a CR and four patients (13 percent) with a PR, one patient each (three percent) with SD and progressive disease. After a median follow-up time of 12.7 months, the estimated PFS at 12 months was 89 percent. The most common AEs of any grade occurring prior to ASCT or subsequent salvage therapy in at least 15 percent of patients were nausea (57 percent), diarrhea and fatigue (37 percent each), vomiting (33 percent), IRR (30 percent), headache (27 percent), pruritus and pyrexia (23 percent each), and abdominal pain and chills (20 percent each). The majority of IRR AE symptoms were Grade 1 or 2 and included no treatment discontinuations.
- Phase 1/2 Relapsed/Refractory Hodgkin Lymphoma (CHECKMATE 744; patients age 5 to 30). Interim data were reported at the 2018 ASH annual meeting from the CHECKMATE 744, risk-stratified, response-adapted study of ADCETRIS and nivolumab, followed by ADCETRIS and bendamustine for patients with suboptimal response, in children, adolescents and young adults with relapsed/refractory classical Hodgkin lymphoma, prior to ASCT. At time of analysis, all evaluable patients achieved complete metabolic remission after completing induction and, as needed, intensification therapy. The most common AEs were nausea (53 percent), diarrhea (31 percent) and pyrexia (28 percent). No AEs led to discontinuation and there were no deaths.
- Investigator-Sponsored Trials. In addition to our corporate-sponsored trials, as of December 31, 2018, there were more than 35 reported 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 such as cutaneous T-cell lymphoma, or CTCL, PTCL, DLBCL, untreated limited stage Hodgkin lymphoma and salvage therapy for patients with Hodgkin lymphoma prior to auto-HSCT. There are also numerous other investigator-sponsored trials for the use of ADCETRIS in other CD30-expressing and select CD30-undetectable settings, and in solid tumors such as mesothelioma and testicular germ cell tumors. Several investigator-sponsored trials are currently evaluating ADCETRIS with immuno-oncology compounds in Hodgkin lymphoma, and we expect additional investigator-sponsored trials might evaluate ADCETRIS in novel combination regimens.

Enfortumab Vedotin

Enfortumab vedotin 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 enfortumab vedotin as a potential treatment for solid tumors under our co-development collaboration with Astellas. This co-development collaboration is discussed in more detail under “Corporate Collaborations” in this Item 1.

Approximately 19,000 people in the United States and 29,000 in the EU Five, or EU5, countries of France, Germany, Italy, Spain and United Kingdom, are diagnosed annually with metastatic urothelial cancer. 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. There are no approved

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agents in the post-platinum-based therapy and post-checkpoint inhibitor setting, representing an unmet medical need. The FDA granted BTD in March 2018 to enfortumab vedotin for patients with locally advanced or metastatic urothelial cancer who were previously treated with a checkpoint inhibitor.

We and Astellas are conducting a pivotal, single-arm phase 2 clinical trial, called EV-201, of single-agent enfortumab vedotin for locally advanced or metastatic urothelial cancer patients who have been previously treated with PD-1 or PD-L1 inhibitor therapy. The primary endpoint of the trial is ORR per independent review. The trial will also assess OS, PFS, safety and tolerability. In July 2018, we completed enrollment in the first cohort of patients who previously received both platinum chemotherapy and a PD-1 or PD-L1 inhibitor. We expect to report top-line data from this cohort in the first quarter of 2019. We believe that positive data in this cohort could support potential registration under the FDA's accelerated approval pathway. In addition, 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 serve as the basis for a second labeled indication.

Data from a phase 1 trial, called EV-101, that evaluated enfortumab vedotin in solid tumors, primarily urothelial cancer, supported our decision to initiate the pivotal phase 2 trial. Updated data from the trial based on a data cut from April 9, 2018 were presented at the American Society for Clinical Oncology, or ASCO, 2018 annual meeting. A total of 112 patients with metastatic urothelial cancer treated with one or more prior chemotherapy agents, or who were ineligible for cisplatin, received enfortumab vedotin and were treated at the recommended dose. Sixty-three percent of patients had received two or more prior therapies in the metastatic setting. Of 112 evaluable patients, the confirmed ORR was 41 percent, including a confirmed CR rate of four percent and a confirmed PR rate of 37%. Additionally, the confirmed ORR in the 89 patients who received prior checkpoint inhibitor therapy was 40 percent. For all enrolled patients, the interim median OS was 13.6 months, the overall median DOR was 5.75 months and the median PFS was 5.4 months. The most commonly reported treatment-related AE was all grade fatigue (54 percent). Four fatal treatment-related AEs occurred (respiratory failure, urinary tract obstruction, diabetic ketoacidosis, and multi-organ failure). Additional precautionary safety measures were implemented such as dosing caps and delays, and modified patient inclusion and exclusion criteria in the EV-101 trial following these fatal AEs. The most common ≥Grade 3 AEs were anemia (eight percent), hyponatremia (seven percent), urinary tract infection (seven percent) and hyperglycemia (six percent).

In July 2018, we and Astellas initiated a global, randomized phase 3 trial, called EV-301, for patients with metastatic urothelial cancer who previously received both platinum chemotherapy and a PD-1 or PD-L1 inhibitor. The trial is designed to enroll approximately 550 patients and the primary endpoint is OS. Secondary endpoints include PFS, ORR, disease control rate, DOR and quality of life. EV-301 is intended to support global regulatory submissions for approval and potentially serve as a confirmatory trial in the U.S.

As part of our effort to evaluate enfortumab vedotin in earlier lines of therapy, we and Astellas are also conducting a phase 1b trial, EV-103, evaluating enfortumab vedotin in combination with either pembrolizumab or other anticancer agents as first- or second-line treatment for patients with locally advanced or metastatic urothelial cancer. The single-arm trial is designed to enroll up to 85 patients who are ineligible for first-line cisplatin-based chemotherapy or have progressed following treatment with a regimen containing platinum-based chemotherapy. The primary objective of the trial is to assess the safety and tolerability of enfortumab vedotin in combination with pembrolizumab or other anticancer agents. Secondary endpoints include ORR, DOR, PFS, and OS.

Tucatinib

In March 2018, we acquired global rights to tucatinib through our acquisition of Cascadian Therapeutics, Inc., or Cascadian, for a total purchase price of approximately $614.1 million. Tucatinib is an investigational oral TKI. Pre-clinical data indicate that tucatinib is highly selective for HER2 without significant inhibition of EGFR. Inhibition of EGFR has been associated with significant toxicities, including skin rash and diarrhea. HER2 is a growth factor receptor that is over-expressed in multiple cancers, including breast, colorectal, esophageal, gastric, lung and ovarian cancers. HER2 mediates cell growth, differentiation and survival. Tumors that over-express HER2 are generally more aggressive and historically have been associated with poor overall survival, compared with HER2-negative cancers. Approximately 9,000 people in the United States and 10,000 in the EU5 are diagnosed annually with metastatic

HER2-positive breast cancer.

Tucatinib is currently being evaluated as part of a combination regimen in a global randomized (2:1) pivotal phase 2 trial, called HER2CLIMB, comparing tucatinib vs. placebo, each in combination with capecitabine and trastuzumab. The trial is enrolling patients with HER2-positive metastatic breast cancer who have been previously treated with trastuzumab, pertuzumab (Perjeta®) and ado-trastuzumab emtansine, or T-DM1, (Kadcyla®), including patients with or without brain metastases. We achieved enrollment of 480 patients in the trial to enable analysis of the primary endpoint of PFS, with top-line data expected to be reported in 2019. In addition, we are continuing enrollment in HER2CLIMB up to 600 patients to support the analyses of key secondary endpoints, including OS as well as PFS in patients with brain metastases. We anticipate completing enrollment of the additional patients in mid-2019.

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Data from clinical trials including a phase 1b trial that evaluated tucatinib in combination with capecitabine and/or trastuzumab in patients with HER2-positive metastatic breast cancer, including those with or without brain metastases, supported our decision to initiate the HER2CLIMB phase 2 pivotal trial. In July 2018, results of the phase 1b trial were published in The Lancet Oncology. The objective of the study was to assess the safety, tolerability, pharmacokinetics and antitumor activity, and to determine the recommended phase 2 dose of tucatinib in combination with these agents. Once a recommended phase 2 dose of 300 mg twice a day was established in the tucatinib combination with capecitabine and trastuzumab regimen, or the triplet regimen, an expansion cohort using that regimen was opened. The trial enrolled 60 patients with HER2-positive metastatic breast cancer who had previously received a median of three prior HER2-targeted agents, such as trastuzumab, pertuzumab, lapatinib or trastuzumab emtansine (T-DM1). For patients treated with the triplet regimen at 300 mg twice per day (n=27), the median PFS was 7.8 months and the ORR was 61 percent (n=14/23) with a median DOR of 11.0 months. Median PFS for patients with brain metastases (n=11) was 6.7 months and ORR was 42 percent (n=5/12) in patients with measurable brain metastases that had received the 300 mg twice per day tucatinib dose in any combination. The triplet regimen was well-tolerated and the majority of AEs were Grade 1, with most patients being able to continue on the full dose of tucatinib. Grade 3 diarrhea was infrequent without a requirement for prophylactic anti-diarrheal medicine.

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 co-development collaboration with Genmab. This co-development collaboration is discussed in more detail under “Corporate Collaborations” in this Item 1.

Approximately 5,000 people in the United States and 5,000 in the EU5 are diagnosed annually with metastatic cervical cancer. In June 2018, we initiated a pivotal, single-arm phase 2 trial, called innovaTV 204, for patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment. The primary endpoint of the trial is ORR as assessed by independent review. Key secondary endpoints include DOR, PFS, OS, safety and tolerability. The trial will enroll approximately 100 people, and we believe that positive data could support potential registration under the FDA's accelerated approval pathway. We expect to complete enrollment in innovaTV 204 by mid-2019.

Data from the phase 1/2 trial, innovaTV 201, which evaluated tisotumab vedotin in solid tumors, including cervical cancer supported our decision to initiate the pivotal trial. Updated data from the cervical cancer expansion cohort of this trial were presented at the European Society of Medical Oncology, or ESMO, 2018 Congress. Of 55 patients in the cohort, an ORR of 31 percent was observed. The median DOR was 4.9 months. The most common AEs of any grade were epistaxis and fatigue (51 percent each), nausea (49 percent), conjunctivitis (42 percent) and alopecia (40 percent).

Beyond recurrent and/or metastatic cervical cancer, we believe there may be opportunities for tisotumab vedotin in earlier lines of cervical cancer and in other solid tumors that express TF. In July 2018, we initiated a phase 2 clinical trial, called innovaTV 207, for patients with colorectal, non-small cell lung, pancreatic or head and neck cancers. The trial is intended to inform a potential broad development program. We are initiating a phase 1/2 clinical trial, called innovaTV 205, for patients with recurrent and/or metastatic cervical cancer as first- and second-line treatment in combination with other anticancer agents. We are also conducting a phase 2 clinical trial, called innovaTV 208, for patients with platinum-resistant ovarian cancer.

Early-stage clinical product candidates and other collaborations

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 triple-negative breast cancer.

Our early-stage clinical pipeline includes SGN-CD48A, which utilizes our ADC technology, SEA-BCMA, which is based on our SEA technology, and SGN-2FF, which is a novel small molecule. In November 2018, we initiated a phase 1 clinical trial evaluating SEA-BCMA for patients with relapsed or refractory multiple myeloma. SGN-2FF is

being evaluated in a phase 1 clinical trial for patients with advanced solid tumors. As a result of recent portfolio prioritization decisions, we are no longer developing SEA-CD40.

We have a collaboration with Unum to develop and commercialize novel antibody-coupled T-cell receptor, or ACTR, therapies incorporating our antibodies for the treatment of cancer. We and Unum are conducting a phase 1 clinical trial studying Unum's ACTR087 in combination with SEA-BCMA for the treatment of relapsed or refractory multiple myeloma.

In addition, we have multiple preclinical and research-stage programs that employ our proprietary technologies.

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Research Programs

In addition to our pipeline of product candidates and antibody-based and SEA technologies, we have internal research programs directed toward developing new classes of potent, cell-killing agents and stable linkers, identifying novel antigen targets, monoclonal antibodies and other targeting molecules, and advancing our antibody engineering initiatives.

New Cell-Killing Agents. We continue to study new cell-killing agents that can be linked to antibodies, such as the auristatins that we currently use in our ADC technology, and new classes of cell-killing agents.

New Stable Linkers. We are conducting research with the intent to develop new linker systems that are more stable in the bloodstream and more effective at releasing the cell-killing agent once inside targeted cancer cells.

Novel Monoclonal Antibodies and Antigen Targets. We are actively engaged in internal efforts to identify and develop monoclonal antibodies and other targeting molecules and ADCs with novel specificities and activities against selected antigen targets. We focus on antigen targets that are highly expressed on the surface of cancer cells that may serve as targets for monoclonal antibodies or ADCs. We may then create and screen panels of cancer-reactive monoclonal antibodies in our laboratories to identify those with the desired specificity. 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 co-development collaborations with Astellas and Genmab.

Antibody Engineering. We have substantial internal expertise in antibody engineering, both for antibody humanization and non-fucosylation, as well as engineering of 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 the robustness and 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 Co-Development Collaboration

In 2009, we entered into an agreement with Takeda for the global co-development of ADCETRIS and the commercialization of ADCETRIS by Takeda in its territory. We retained commercial rights for ADCETRIS in the U.S. and its territories and in Canada, and we granted to Takeda commercial rights in the rest of the world.

As of December 31, 2018, we had received an upfront payment of $60.0 million and had achieved milestone payments totaling $80.0 million related to regulatory and commercial progress by Takeda. As of December 31, 2018, we were entitled to receive additional progress- and sales-dependent milestone payments of up to $155.0 million based on Takeda’s achievement of significant events under the collaboration in addition to tiered royalties with percentages ranging from the mid-teens to the mid-twenties based on net sales of ADCETRIS within Takeda’s licensed territories. Takeda also bears a portion of third-party royalty costs owed on sales of ADCETRIS in its territory. We and Takeda equally co-fund the cost of selected development activities conducted under the collaboration. Although we are funding half of the development activities conducted under the collaboration, Takeda is responsible for the achievement of the progress- and sales-dependent milestone payments that we may receive. 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.

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Astellas Co-Development Collaboration

In 2007, we entered into an agreement with Agensys, which subsequently became an affiliate of Astellas, to 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. We and Astellas are co-funding all development costs for enfortumab vedotin.

In October 2018, we and Astellas entered into a joint commercialization agreement to govern the global commercialization of enfortumab vedotin, if approved for commercial sale:

- In the U.S., we and Astellas will jointly promote enfortumab vedotin. We will record sales of enfortumab vedotin in the U.S. and be responsible for all U.S. distribution activities. The companies will share equally in costs incurred, and any profits realized, in the U.S.
- Outside the U.S., we will commercialize in all countries in North and South America, and Astellas will commercialize in rest of the world, including Europe, Asia, Australia and Africa. The agreement is intended to provide that we and Astellas will effectively share equally 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 cost and profit share for both parties.

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 (a) the expiration of all payment obligations pursuant to the collaboration agreement, or (b) the day upon which we and Astellas cease to develop and commercialize products under the agreement. Either party may also opt out of co-development and profit-sharing in return for receiving milestones and royalties from the continuing party.

Genmab Co-Development Collaboration

In 2011, we entered into an agreement with Genmab, under which Genmab has rights to utilize our ADC technology with its HuMax-TF antibody targeting the TF antigen, which is expressed on numerous types of solid tumors. Under this agreement, we exercised a co-development option for the TF-targeted ADC, tisotumab vedotin, in August 2017. We and Genmab will share all costs and potential future 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, while 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 in return for receiving milestones and royalties from the continuing party.

Other ADC Collaborations and Co-Development Collaborations

We have other active ADC collaborations with a number of companies to allow them to use our proprietary ADC technology. Under these collaborations, which we have entered into in the ordinary course of business, we typically receive or are entitled to receive upfront cash payments, progress- and sales-dependent milestones for the achievement by our collaborators 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 ADC collaborators 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.

In December 2018, Roche submitted regulatory applications in the US and the EU for approval of polatuzumab vedotin, an ADC that uses our technology, to treat patients with relapsed or refractory DLBCL. In addition, GSK and AbbVie each are developing ADCs using our technology that are in late-stage clinical trials. Our other ADC collaborations are at various stages of clinical and preclinical development. Our ability to generate significant future revenues from our ADC collaboration agreements will largely depend on products that incorporate our technologies entering late-stage clinical

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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 addition, we have a co-development collaboration with Unum to develop and commercialize novel antibody-coupled T-cell receptor, or ACTR, therapies incorporating our antibodies for the treatment of cancer. Unum is conducting a phase 1 trial evaluating Unum's ACTR087 drug candidate in combination with SEA-BCMA in patients with relapsed/refractory multiple myeloma. In 2018, we entered into a research collaboration agreement with Pieris to develop novel potential treatments of cancer based on bispecifics incorporating our proprietary antibodies and Pieris' proprietary technology designed to stimulate an antibody-directed immune response against solid tumors and blood cancers.

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 March 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.
- University of Miami License. In September 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.
- Array BioPharma, Inc. We are a party to a license agreement with Array BioPharma, Inc. or Array. 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, 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 ADCETRIS and each of our 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, enfortumab vedotin 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 and our development 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 ADCETRIS and our pipeline (in addition to certain patents covering our early-stage product candidates):

- For ADCETRIS and our related ADC technology, we own eleven patents in the United States and Europe that will expire between 2020 and 2031.

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- For enfortumab vedotin 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 rights to 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. This list above does not identify all patents that may be related to ADCETRIS and our 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

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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 to commercialize our product candidates. Our challenges to patents of other organizations may not be successful, which may affect our ability to commercialize ADCETRIS 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 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, 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 nature and extent of the governmental review process for our product candidates will vary, depending on the regulatory categorization of particular product candidates and various other factors.

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 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 marketing authorization application in the form of a BLA or New Drug Application, 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 for Good Clinical Practice, or GCP, compliance; and

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- FDA review and approval of the marketing authorization application and 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. IND submissions may be authorized by the FDA, for example, to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted 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 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 the application, while priority review is eight months from submission of the 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. Accordingly, if enfortumab vedotin, tisotumab vedotin or any of our other product candidates receives accelerated approval from the FDA, we will be required to submit data post-approval that verifies the product's clinical benefit for the indications for which the product is approved. In addition, the FDA currently 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

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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 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 Product 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. This policy is described in an August 2014 FDA guidance document. 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 commercial approval for ADCETRIS 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.

We and Takeda have formed a collaboration with Ventana under which Ventana is working to develop, manufacture and commercialize a companion diagnostic test with the goal of identifying patients who might respond to treatment with ADCETRIS based on CD30 expression levels in their tissue specimens. While the FDA did not require the concurrent approval of a CD30 companion diagnostic for approval of ADCETRIS in the frontline PTCL indication or in any other of its approved indications, the FDA's approval of ADCETRIS in the 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. If Ventana develops an in-vitro diagnostic device that we are able to clinically validate, the FDA may revise our label for the frontline PTCL indication to require the use of the in-vitro test as a companion diagnostic or to include additional clinical data regarding the use of the in-vitro test as a complementary diagnostic. If the FDA or another regulatory authority requires a companion diagnostic in the ADCETRIS label for the frontline PTCL indication or in connection with or as a condition of future regulatory approvals, such a requirement 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.

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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 and commercial sales, manufacturing and distribution 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, such as Canada, 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 than 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 apply in 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, or EEA, which is comprised of the 28 member states of the EU plus 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

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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.

The making available or placing on the EU market of unauthorized medicinal products is generally prohibited. However, the competent authorities of the EU member states may exceptionally and temporarily allow the supply of such products, either on a named patient basis or through a compassionate use process, to individual patients or a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by an authorized medicinal product.

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 ability to operate 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

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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 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

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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 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 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 from 15.1% to 23.1%, 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 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 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

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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 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 dtates of the criteria taken into account in the conduct of HTA and their impact on pricing and reimbursement decisions.

Healthcare Reform

PPACA substantially changes 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 make changes to the coverage requirements under the Medicare Part D program. We cannot yet predict the full impact of PPACA at this time for many reasons including that many of its provisions require the promulgation of detailed implementing regulations, which are subject to review and revision.

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.

Since its enactment, there have been 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

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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. The potential impact of these efforts to repeal or defer and delay enforcement of PPACA on our business remains unclear. Congress also could consider subsequent legislation to replace elements of PPACA that are repealed. While Congress has not passed repeal or replace legislation, the tax reform legislation signed into law on December 22, 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." Based on the repeal of the individual mandate, in December 2018, a federal district court in Texas ruled that the PPACA is unconstitutional. Congress in turn may seek legislation to intervene in the Texas litigation in support of the PPACA. Because of the continued uncertainty about the implementation of the PPACA, including the potential for further legal challenges or repeal of PPACA, we cannot quantify or predict with any certainty the likely impact of the PPACA or its repeal on our business, prospects, financial condition or results of operations.

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 2025 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 recently enacted Drug Supply Chain Security Act imposes on manufacturers of certain pharmaceutical products new obligations related to product tracking and tracing, among others, which will be phased in over several years beginning in 2015. Among the requirements of this legislation, manufacturers subject to this federal law will be required 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. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Covered manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, covered manufacturers will 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.

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 ADCETRIS 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

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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 Roche's atezolizumab, and 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 stem cell transplant, combination chemotherapy, clinical trials with experimental agents and single-agent regimens.

With respect to enfortumab vedotin, treatment in relapsed metastatic urothelial cancer is limited to checkpoint inhibitor monotherapy or generic chemotherapy. There are other investigational agents that, if approved, could be competitive with enfortumab vedotin, including Immunomedics' sacituzumab govitecan, Lilly's ramucirumab, and Janssen's erdafitinib. Treatment in front line metastatic urothelial cancer is evolving and includes two approved checkpoint inhibitor therapies with several trials of investigational agents in combination with chemotherapy potentially reporting data in 2019.

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 ado-trastuzumab emtansine or T-DM1 (Kadcyla®). In addition, lapatinib (Tykerb®) is a dual EGFR/HER2 oral kinase inhibitor for the treatment of metastatic breast cancer and neratinib (Nerlynx®) is an EGFR/HER2/HER4 inhibitor indicated for extended adjuvant use that is also being studied for use in pre-treated HER2-positive metastatic breast cancer. In addition, Daiichi Sankyo and Synthon each have 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.

With respect to tisotumab vedotin, in June 2018, Merck's pembrolizumab (Keytruda®) 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, includingAgenus, 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.

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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 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, enfortumab vedotin, 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, enfortumab vedotin, 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, enfortumab vedotin, 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

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

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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 the completion of the tenth contract year following the initial commercial order 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.

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 intend to 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 enfortumab vedotin and tisotumab vedotin, our collaborators for much of the manufacturing to supply drug product for our clinical trials. With respect to enfortumab vedotin and tisotumab vedotin, the manufacturing supply chain is overseen by our collaborators and we rely on Astellas and Genmab to supply sufficient supplies of drug product. For enfortumab vedotin and tisotumab vedotin, we believe that the existing supplies of drug product and the contract manufacturing relationships of our collaborators will be sufficient to accommodate ongoing and future clinical trials. However, we or our collaborators will likely need to obtain additional manufacturing arrangements or increase manufacturing capability to meet potential future commercial needs with respect to these agents, which could require additional capital investment by us or cause us potential delays if our collaborators encounter challenges in negotiating commercially reasonable arrangements with these manufacturers. With respect to tucatinib, we rely on third party contract manufacturers to produce drug supply for our clinical trials. In this regard, 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 will also need to put in place additional manufacturing arrangements with third party manufacturers to meet potential future commercial needs and while we are currently negotiating those arrangements, we cannot assure you that we can enter into such arrangements on commercially reasonable terms or at all.

Commercial Operations

We have allocated commercial resources, including sales, marketing, supply chain management and reimbursement capabilities, to commercialize ADCETRIS in the United States and Canada. We believe the U.S. and Canadian markets for ADCETRIS in its approved indications are addressable with a targeted sales and marketing organization, and we intend to continue promoting ADCETRIS ourselves in the United States and Canada for these and any additional indications we may obtain in the future. Takeda has commercial rights in the rest of the world. As of February 2019, we and Takeda had received marketing authorizations by regulatory authorities in 72 countries, and

Takeda continues to pursue marketing authorizations in multiple other countries.

We sell ADCETRIS through a limited number of pharmaceutical distributors. Health care providers order ADCETRIS 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—

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AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation—each accounted for 10% or more of our total revenue in 2018, 2017 and 2016.

Employees

As of December 31, 2018, we had 1,302 employees. Of these employees, 898 were engaged in or support research, development and clinical activities, 241 were in administrative and business related positions, and 163 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 30th Drive SE, Bothell, Washington 98021. Our telephone number is (425) 527-4000, and our website address is www.seattlegenetics.com. Seattle Genetics® and ADCETRIS® are our registered trademarks in the United States. All other trademarks, tradenames and service marks included in this Annual Report on Form 10-K are the property of their respective owners.

We file electronically with the Securities and Exchange Commission, or SEC, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at www.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 occur, 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 near-term prospects are substantially dependent on ADCETRIS. If we and/or Takeda are unable to effectively commercialize ADCETRIS for the treatment of patients in its approved indications and to continue to expand its labeled indications of use, our ability to generate significant revenue and our prospects for profitability will be adversely affected.

ADCETRIS is our only product approved for marketing and our ability to generate revenue from product sales and our prospects for profitability are substantially dependent on our ability to effectively commercialize ADCETRIS for the treatment of patients in its approved indications and our ability to continue to expand its labeled indications of use. We may not be able to fully realize the commercial potential of ADCETRIS for a number of reasons, including:

- we may be unable to effectively commercialize ADCETRIS in any new indications for which we receive marketing approval, including in the newly diagnosed, previously untreated Stage III and IV classical Hodgkin lymphoma indication approved in March 2018, 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 approved in November 2018, or the frontline PTCL indication;
- we and/or Takeda Pharmaceutical Company Limited, or Takeda, our collaborator in the development and commercialization of ADCETRIS, may not be able to obtain and maintain regulatory approvals to market ADCETRIS in its currently approved indications or for any additional indications in our respective territories,

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including in frontline Hodgkin lymphoma and frontline PTCL outside the U.S., which would limit sales of, and the commercial potential of, ADCETRIS;

- we may not be able to establish or demonstrate in the medical community the safety, efficacy, or value of ADCETRIS and its potential advantages compared to existing and future therapeutics in the frontline Hodgkin lymphoma and frontline PTCL indications as well as other approved indications;
- new competitive therapies, including immuno-oncology agents such as PD-1 inhibitors (e.g., nivolumab and pembrolizumab), have been approved by regulatory authorities or may be submitted in the near term to regulatory authorities for approval in ADCETRIS' labeled indications, and these competitive products could negatively impact our commercial sales of ADCETRIS;
- our commercial sales of ADCETRIS could be lower than our projections due to a lower market penetration rate, increased competition by alternative products or biosimilars, a shorter duration of therapy in patients in ADCETRIS' approved indications, or for other reasons;
- there may be additional changes to the label for ADCETRIS, including ADCETRIS' boxed warning, that further restrict how we market and sell ADCETRIS, including as a result of data collected from any of the clinical trials that we and/or Takeda are conducting or may in the future conduct for ADCETRIS, including investigator-sponsored studies and in the post-approval confirmatory studies that Takeda is required to conduct as a condition to the conditional marketing authorization of ADCETRIS granted by the European Commission, or the EC;
- the estimated incidence rate of new patients in ADCETRIS' approved indications may be lower than our projections;
- there may be adverse results or events reported in any of the clinical trials that we, Takeda and/or BMS are conducting or may in the future conduct for ADCETRIS;
- we may be unable to continue to effectively market, sell and distribute ADCETRIS;
- ADCETRIS 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 ADCETRIS may be higher than alternative treatment options, and therefore its reimbursement may be limited by private and governmental insurers;
- physicians may be reluctant to prescribe ADCETRIS due to side effects associated with its use or until long 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 ADCETRIS; and
- we may not be able to obtain adequate commercial supplies of ADCETRIS to meet demand or at an acceptable cost.

In 2009, we entered into 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. The success of this collaboration and the activities of Takeda will significantly impact the commercialization of ADCETRIS in countries other than the United States and in Canada. In October 2012, Takeda announced that it had received conditional marketing authorization for ADCETRIS from the EC for patients with relapsed Hodgkin lymphoma or relapsed systemic anaplastic large cell lymphoma, or sALCL, and has since obtained marketing approvals for ADCETRIS in many other countries. Conditional marketing authorization by the EC includes obligations to provide additional clinical data at a later stage to confirm the positive benefit-risk balance. We cannot control the amount and timing of resources that Takeda dedicates to the commercialization of ADCETRIS, or to its marketing and distribution, and our ability to generate revenues from ADCETRIS product sales by Takeda depends on Takeda's ability to achieve market acceptance of, and to otherwise effectively market, ADCETRIS for its approved indications in Takeda's territory. Further, foreign sales of ADCETRIS could be adversely affected by the imposition of

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governmental controls, political and economic instability, trade restrictions or barriers and changes in tariffs, including as a result of the United Kingdom's planned 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 cannot assure you that, even with the recent expansions to the prescribing label for ADCETRIS in the United States, which now includes, the frontline Hodgkin lymphoma and frontline PTCL indications, ADCETRIS sales will continue to grow or that we can maintain sales of ADCETRIS at or near current levels. We also expect that our ability to grow ADCETRIS sales, if at all, will depend primarily on our ability to establish or demonstrate in the medical community the value of ADCETRIS and its potential advantages compared to existing and future therapeutics in the frontline Hodgkin lymphoma and frontline PTCL indications, and the extent to which physicians make prescribing decisions with respect to ADCETRIS in these indications. Further, our ability to grow ADCETRIS sales will be affected by our ability to continue to expand ADCETRIS' utilization across all labeled indications of use. In addition, Takeda may be unable to obtain regulatory approvals of ADCETRIS in the ECHELON-1 treatment setting in its territories (other than in Japan where ADCETRIS is approved in combination with AVD as a frontline treatment option for CD30-positive Hodgkin lymphoma patients), and of ADCETRIS in the ECHELON-2 treatment setting in its territories, which also would limit their sales of, and the commercial potential of, ADCETRIS.

We and Takeda have formed a collaboration with Ventana Medical Systems, Inc., or Ventana, under which Ventana is working to develop, manufacture and commercialize a companion diagnostic test with the goal of identifying patients who might respond to treatment with ADCETRIS based on CD30 expression levels in their tissue specimens. The Food and Drug Administration, or FDA, and similar regulatory authorities outside the United States regulate companion diagnostics. Companion diagnostics may require separate or coordinated regulatory approval prior to or in association with commercialization of the related therapeutic product. While the FDA did not require the concurrent approval of a CD30 companion diagnostic for approval of ADCETRIS in the frontline PTCL indication or in any other of its approved indications, the FDA's approval of ADCETRIS in the 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. If Ventana develops an in-vitro diagnostic device that we are able to clinically validate, the FDA may revise our label for the frontline PTCL indication to require the use of the in-vitro test as a companion diagnostic or to include additional clinical data regarding the use of the in-vitro test as a complementary diagnostic. If the FDA or another regulatory authority requires a companion diagnostic in the ADCETRIS label for the frontline PTCL indication or in connection with or as a condition of future regulatory approvals, such a requirement 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.

Even if we and Takeda receive the required regulatory approvals to market ADCETRIS for any additional indications or in additional jurisdictions, we and Takeda may not be able to effectively commercialize ADCETRIS, including for the reasons set forth above. Our ability to grow ADCETRIS product sales in future periods is also dependent on price increases and we periodically increase the price of ADCETRIS. Price increases on ADCETRIS and negative publicity regarding drug pricing and price increases generally, whether on ADCETRIS or products distributed by other pharmaceutical companies, could negatively affect market acceptance of, and sales of, ADCETRIS. 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 ADCETRIS sales.

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

Reports of adverse events or safety concerns involving ADCETRIS could interrupt, delay or halt clinical trials of ADCETRIS, including the post-approval confirmatory studies that Takeda is required to conduct as a condition of the marketing authorization of ADCETRIS by the EC. In addition, reports of adverse events or safety concerns involving ADCETRIS could result in regulatory authorities limiting, denying or withdrawing approval of ADCETRIS for any or all indications, including the use of ADCETRIS for the treatment of patients in its approved indications. For example, there

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was an increased incidence of febrile neutropenia and peripheral neuropathy in the ADCETRIS plus AVD arm of the ECHELON-1 trial. The ADCETRIS label provides for use of prophylactic growth factors, or G-CSF, 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 will not experience serious adverse events in the future. Further, there are no assurances that patients receiving ADCETRIS 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 ADCETRIS. We may be required to further update the ADCETRIS prescribing information, including boxed warnings, based on reports of adverse events or safety concerns or implement a Risk Evaluation and Mitigation Strategy, or REMS, which could adversely affect ADCETRIS' acceptance in the market, make competition easier or make it more difficult or expensive for us to distribute ADCETRIS. For example, the prescribing information for ADCETRIS also includes pancreatitis, impaired hepatic function, impaired renal function, pulmonary toxicity, and gastrointestinal complications as known adverse events as well as a boxed warning related to the risk that JC virus infection resulting in progressive multifocal leukoencephalopathy, or PML, 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 ADCETRIS or our product candidates could interrupt, delay or halt clinical trials of such product candidates, or could result in our inability to obtain regulatory approvals for any of our product candidates. For example, in June 2017, we discontinued the phase 3 CASCADE clinical trial of SGN-CD33A based on unexpected adverse events following a higher rate of deaths in the SGN-CD33A containing arm versus the control arm of this trial, and the Investigational New Drug application, or IND, for SGN-CD33A was subsequently placed on hold by the FDA. We subsequently discontinued our SGN-CD33A program altogether and do not expect to receive any return on our investment in SGN-CD33A.

In addition, we are conducting pivotal trials for enfortumab vedotin, tucatinib and tisotumab vedotin based on only limited phase 1 clinical data. There may be important facts about the safety, efficacy, and risk versus benefit of these 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 addition, in response to safety events observed in our clinical trials of enfortumab vedotin 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 pivotal or other later-stage trials that could delay or prevent us from advancing the clinical development of enfortumab vedotin, tucatinib or tisotumab vedotin and may adversely affect our business, results of operations and prospects.

Concerns regarding the safety of ADCETRIS or our 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 or the applicable product candidate. Undesirable side effects caused by ADCETRIS or our 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 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 ADCETRIS or our product candidates or result in potential product liability claims. Any of these events could prevent us from developing or commercializing ADCETRIS or the particular product candidate, and could significantly harm our business, results of operations and prospects.

Even though we and Takeda have obtained regulatory approvals to market ADCETRIS, we and Takeda are subject to extensive ongoing regulatory obligations and review, including post-approval requirements that could result in the withdrawal of ADCETRIS from certain geographic markets in certain indications if such requirements are not met. ADCETRIS is approved for treating patients in the relapsed sALCL and relapsed Hodgkin lymphoma indications with conditions in Canada, and approved under conditional marketing authorization in relapsed Hodgkin lymphoma and sALCL in Europe, in each case under regulations which allow for approval of products for cancer or other serious or life

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threatening illnesses based on a surrogate endpoint or on a clinical endpoint other than survival or irreversible morbidity. For the European indications, Takeda is subject to certain post-approval requirements, including the requirement to conduct clinical trials to confirm clinical benefit. In Canada, the ECHELON-1 results may be sufficient to confirm the clinical benefit of ADCETRIS in relapsed Hodgkin lymphoma, and the ECHELON-2 results may be sufficient to confirm the clinical benefit of ADCETRIS in relapsed sALCL. In Europe, 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.

In addition, 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 in each of its 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 ADCETRIS and any future-approved product. For example, we and Astellas are conducting a pivotal phase 2 trial of enfortumab vedotin, called the EV-201 trial, for patients with locally advanced or metastatic urothelial cancer who were previously treated with checkpoint inhibitor therapy. In July 2018, we completed enrollment in the first cohort of patients who previously received both platinum chemotherapy and a checkpoint inhibitor (PD-1 or PD-L1). We believe that positive data in this cohort could support potential registration under the FDA's accelerated approval pathway. As a condition of any potential approval under the FDA's accelerated approval pathway, the FDA may require that we and/or Astellas perform confirmatory post-marketing studies to verify and describe the clinical benefit of enfortumab vedotin. Moreover, in connection with any such accelerated approval, the labeling, packaging, adverse event reporting, storage, advertising and promotion of enfortumab vedotin would be subject to extensive regulatory requirements, all of which would entail significant expense and could negatively impact the potential future commercialization of enfortumab vedotin.

We and the manufacturers of ADCETRIS are also 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 ADCETRIS, 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 ADCETRIS, including adverse events of unanticipated severity or frequency, or problems with the facilities where ADCETRIS is manufactured, may result in restrictions on the marketing of ADCETRIS, up to and including withdrawal of ADCETRIS from the market. If our manufacturing facilities or those of our 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;

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- 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 ADCETRIS in any additional indications 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 Takeda might not be permitted to market ADCETRIS and our business would suffer.

If we or our collaborators are not able to obtain or maintain required regulatory approvals, we or our collaborators will not be able to successfully commercialize ADCETRIS or our product candidates.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor our collaborators are permitted to market our product candidates in the United States or foreign countries until we obtain marketing approval from the FDA or other foreign regulatory authorities, and we or our collaborators may never receive regulatory approval for the commercial sale of any of our product candidates. In addition, part of our strategy is to continue to explore the use of ADCETRIS in CD30-expressing lymphomas, and we are currently conducting multiple clinical trials for ADCETRIS. However, we and/or Takeda may be unable to obtain or maintain any regulatory approvals for the commercial sale of ADCETRIS for any additional indications. Obtaining marketing approval is a lengthy, expensive and uncertain process and approval is never assured, and we have only limited experience in preparing and submitting the applications necessary to gain regulatory approvals. Further, the FDA and other foreign regulatory agencies have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any product candidate we develop, including any regulatory approvals for the potential commercial sale of ADCETRIS in additional indications or in any additional territories. In this regard, even if we believe the data collected from clinical trials of ADCETRIS and our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other foreign regulatory authority. In addition, the FDA or their advisors may disagree with our interpretations of data from preclinical studies and clinical trials. 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. For example, the label approved by the FDA based on our phase 3 ALCANZA trial covered only primary cutaneous anaplastic large cell lymphoma, or pcALCL, and CD30-expressing mycosis fungoides, or MF, which are two subtypes of cutaneous T-cell lymphoma, or CTCL. Additionally, the FDA may grant approval subject to the performance of post-approval studies or REMS for a product candidate. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of ADCETRIS in any additional indications.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols and/or any related potential future Special Protocol Assessment, or SPA, agreements to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards, or IRBs, for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In addition, as part of the U.S. 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 targeted action dates and if the FDA were to fail to meet a PDUFA targeted action date in the future for ADCETRIS or any of our product candidates, the commercialization of the affected product candidate or of ADCETRIS in any additional indications could be delayed or impaired. Due to these and other factors, ADCETRIS and our product candidates could take a significantly longer time to gain regulatory approvals than we expect or may never gain new regulatory approvals, which could delay or eliminate any potential product revenue from sales of our product candidates or of ADCETRIS in any additional indications, which could significantly delay or prevent us from achieving profitability.

The successful commercialization of ADCETRIS 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.

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Successful sales of ADCETRIS and any future 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 greater 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 ADCETRIS and any other product candidate 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 ADCETRIS and any other product candidates that we commercialize, their marketability will be negatively and materially impacted. For example, we cannot be certain that third-party payors will provide coverage and adequate reimbursement for ADCETRIS in the frontline Hodgkin lymphoma indication based on the relative price or 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.

Moreover, 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 ADCETRIS and any of our future 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 ADCETRIS or the pricing of pharmaceutical products generally, the prices that we charge for ADCETRIS and any future approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of ADCETRIS 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 ADCETRIS. 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 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 approved regimens including ADCETRIS or our future 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 ADCETRIS or our potential future products.

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

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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 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, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. 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 addition, citing legal guidance from the U.S. Department of Justice, the U.S. Department of Health and Human Services, has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the PPACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until such appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the PPACA. While Congress is considering legislation to appropriate funds for CSR payments, the future of that legislation is uncertain. We continue to evaluate the effect that the PPACA and its possible repeal and replacement has on our business.

Further, on March 23, 2018, the Centers for Medicare & Medicaid Services, or 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 ADCETRIS, or any future approved product, 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 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 ADCETRIS or any future approved product, 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 products, including ADCETRIS. 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. 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

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negotiating prices with manufacturers, and updating the Medicare drug-pricing dashboard to make price increases and generic competition more transparent. In addition, the Department of Health and Human Services, or HHS, released a Request for Information, or RFI, soliciting public input on ways to lower drug pricing. Together, the recommendations in the Blueprint and RFI, if enacted by Congress and 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 the proposed measures will require authorization through additional legislation 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. For example, in November 2018, CMS issued a proposed regulation that would, require Part D plans to include drug pricing information and lower cost therapeutic alternatives as well as allow “step therapy” in Medicare Advantage for Part B drugs. The rule also proposes exceptions to the current Part D coverage requirements for six “protected classes” of drugs (immunosuppressants , antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics) by allowing Part D sponsors to use certain formulary management, exclude certain new formulations of protected class drugs from the formulary and exclude a protected class drug from formulary if the price of the drug increased beyond a certain threshold over a specified look-back period. 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 ADCETRIS 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 ADCETRIS and negative publicity regarding drug pricing and price increases generally, whether on ADCETRIS or products distributed by other pharmaceutical companies, could negatively affect market acceptance of, and sales of, ADCETRIS. 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 2027 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 ADCETRIS or any future approved products earlier than otherwise would have occurred. Increased competition may negatively impact coverage and pricing of ADCETRIS, which could negatively affect our financial condition or results of operations.

We also expect to experience pricing pressures in connection with the sale of ADCETRIS 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 recently 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

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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 has 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 ADCETRIS purchases 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 ADCETRIS.

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 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 ADCETRIS or any potential future approved 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.

To help patients afford our products, 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 of the U.S. Department of Health & Human Services, or OIG, 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, or DOJ, and other enforcement authorities seeking information related to their patient assistance programs and support, and certain of these organizations have entered into, or have otherwise agreed to, 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.

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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 ADCETRIS and our product candidates and we plan to commence additional trials of ADCETRIS and our product candidates in the future. In this regard, we and Astellas are conducting the EV-201 trial and a phase 3 clinical trial of enfortumab vedotin, called the EV-301 trial, in metastatic urothelial cancer patients who previously received both platinum chemotherapy and a checkpoint inhibitor (PD-1 or PD-L1). Additionally, we are conducting a pivotal phase 2 trial of tucatinib for patients with HER2-positive, or HER2+, metastatic breast cancer who have been previously treated with HER2-targeted agents, including patients with or without brain metastases, which we refer to as the HER2CLIMB trial, and a pivotal phase 2 trial of tisotumab vedotin with Genmab in patients with recurrent and/or metastatic cervical cancer, which we refer to as the innovaTV 204 trial. Each of these trials was initiated based on only limited phase 1 clinical data. Enfortumab vedotin, tucatinib and tisotumab vedotin have not previously been evaluated in later-stage clinical trials and we cannot be certain that the design of, or data collected from, these trials will be adequate to demonstrate the safety and efficacy of enfortumab vedotin, tucatinib or tisotumab vedotin, or will otherwise be sufficient to support FDA or any foreign regulatory approvals. In addition, we do not have SPA 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 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, Genmab and other collaborators, which may delay the commencement or 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, other 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 ADCETRIS or our 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, other foreign governmental agencies or the applicable data safety monitoring boards, IRBs and Ethics Committees could delay, suspend, halt or modify our clinical trials of ADCETRIS or any of our product candidates, and we, our collaborators and/or the FDA could terminate or modify any related SPA agreements, for numerous reasons, including:

- ADCETRIS 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;
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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;

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- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- the time required to determine whether ADCETRIS 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 or the applicable product candidate may not appear to be more effective than current therapies;
- the quality or stability of ADCETRIS 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 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 and/or expand ADCETRIS into additional indications. In particular, negative or inconclusive results in our EV-201 trial would negatively impact or preclude altogether our ability to obtain regulatory approval of enfortumab vedotin in the locally advanced or metastatic urothelial cancer treatment setting. In addition, negative or inconclusive results in our HER2CLIMB trial would negatively impact or preclude altogether our ability to obtain any regulatory approvals of tucatinib, which could result in our failure to realize the anticipated benefits of our acquisition of Cascadian Therapeutics, Inc., or Cascadian, referred to as the Cascadian Acquisition, and negatively impact our plans to build a commercial infrastructure in Europe. In addition, clinical trial results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Although we reported positive top-line data in both our ECHELON-1 and ECHELON-2 trials, regulatory agencies outside of the U.S., or their advisors, may disagree with Takeda's interpretations of data from the ECHELON-1 and ECHELON-2 trials. Based upon those interpretations, regulatory agencies outside of the U.S. may not approve the expansion of ADCETRIS' labeled indications of use to the ECHELON-1 and ECHELON-2 treatment settings. 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, result in our failure to expand ADCETRIS into additional indications, adversely affect our ability to market ADCETRIS, and may result in other negative consequences to us, including the inclusion of unfavorable information in

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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 current 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 enfortumab vedotin, tucatinib, and tisotumab vedotin, which are in pivotal trials based on only limited phase 1 clinical data. Our earlier-stage clinical pipeline includes ladiratuzumab vedotin, which is in phase 2 clinical development, and SGN-CD48A, SEA-BCMA and SGN-2FF, which are in phase 1 clinical development. As a result of recent portfolio prioritization decisions, we are no longer developing SEA-CD40. In addition, we have multiple preclinical and research-stage programs that employ our proprietary technologies. Enfortumab vedotin, tucatinib, tisotumab vedotin, and our other product candidates will require significant further development, financial resources and personnel to pursue and obtain regulatory approval and to develop them into commercially viable products, if at all.

If a product candidate fails at any stage of development 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. In this regard, if we are unable to successfully complete the development of, obtain regulatory approvals for and commercialize tucatinib, we will not realize the anticipated benefits of the Cascadian Acquisition. Moreover, we still have only limited data from our early 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 are conducting the EV-201 and EV-301 trials of enfortumab vedotin with Astellas, the HER2CLIMB trial of tucatinib and the innovaTV 204 trial of tisotumab vedotin with Genmab in each case based on only limited phase 1 clinical data. Enfortumab vedotin, tucatinib and tisotumab vedotin have not previously been evaluated in later stage clinical trials 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, enfortumab vedotin, tucatinib and tisotumab vedotin may fail to demonstrate sufficient efficacy in our pivotal trials despite the results observed in earlier-stage trials. In addition, there may be important facts about the safety, efficacy, and risk versus benefit of these 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 particular, in response to safety events observed in our clinical trials of enfortumab vedotin 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 enfortumab vedotin, 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 phase 2 trials for enfortumab vedotin, tucatinib and tisotumab vedotin. We have not yet completed any late-stage clinical trials for our current product candidates, and if we or our collaborators fail to produce positive results in our ongoing or planned clinical trials of any

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of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial 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 current 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.

We depend on collaborative relationships with other companies to assist in the development and commercialization of ADCETRIS and for the development and commercialization of 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 ADCETRIS, develop and commercialize other 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 ADCETRIS and some of our current and future 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 50:50 co-development collaborations with Astellas for the development of enfortumab vedotin, and with Genmab for the development of tisotumab vedotin. We are also collaborating with Bristol-Myers Squibb Co., or BMS, with respect to the CHECKMATE 812 pivotal phase 3 clinical trial evaluating the combination of Opdivo (nivolumab) with ADCETRIS for the treatment of relapsed or refractory, or transplant-ineligible, advanced classical Hodgkin lymphoma. In addition, we have antibody-drug conjugate, or ADC, collaborations with AbbVie, Bayer, Celldex, Genentech, GSK, and Progenics, and we have entered into a collaboration agreement with Unum Therapeutics, Inc., or Unum, to develop and commercialize novel antibody-coupled T-cell receptor, or ACTR, therapies incorporating our antibodies for the treatment of cancer and with Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals AG, or together, Pieris, to develop targeted bispecific immuno-oncology therapies for the treatment of cancer. Our dependence on collaborative arrangements to assist in the development and commercialization of ADCETRIS and for the development and commercialization of 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 devote to the development or commercialization of products and product candidates utilizing or incorporating our technologies, including enfortumab vedotin and tisotumab vedotin, and because control of development and commercialization is shared with our collaborators, we do not have sole discretion and control over the development and commercialization of these product candidates;
- disputes may arise between us and our collaborators 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 and our 50:50 co-development and related agreements with Astellas and 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, which may result in the delay or termination of the research, development or commercialization of the applicable products and product candidates, including

ADCETRIS, enfortumab vedotin and tisotumab vedotin;

- our current and potential future collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

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- significant delays in the development of product candidates by current and potential collaborators 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 to effectively commercialize these product candidates;
- our relationships with our collaborators 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 may not be successful in their efforts to obtain regulatory approvals in a timely manner, or at all;
- our current and potential future collaborators 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 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 business strategy may adversely affect such party's willingness or ability to complete its obligations under any arrangement;
- a collaborator 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 either independently or in collaboration with others, including our competitors;
- our current and potential collaborators may experience financial difficulties; and
- our collaborations may be terminated, breached or allowed to expire, or our collaborators 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 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 enfortumab vedotin 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 development of the impacted product candidate 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, enfortumab vedotin or tisotumab vedotin, which are now being co-funded by our collaboration partners. Moreover, in the future, we may not be able to locate third-party collaborators to develop and market products and product candidates utilizing or incorporating our technologies, and we may lack the capital and resources necessary to develop and market these products and product candidates alone.

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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 Roche's atezolizumab and 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 stem cell transplant, combination chemotherapy, clinical trials with experimental agents and single-agent regimens.

With respect to enfortumab vedotin, treatment in pretreated metastatic urothelial cancer is limited to checkpoint inhibitor monotherapy or generic chemotherapy. There are other investigational agents that, if approved, could be competitive with enfortumab vedotin, including Immunomedics' sacituzumab govitecan, Lilly's ramucirumab, and Janssen's erdafitinib. Treatment in front line metastatic urothelial cancer is evolving and includes two approved checkpoint inhibitor therapies with several trials of investigational agents in combination with chemotherapy potentially reporting data in 2019.

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 ado-trastuzumab emtansine or T-DM1 (Kadcyla®). In addition, lapatinib (Tykerb®) is a dual EGFR/HER2 oral kinase inhibitor for the treatment of metastatic breast cancer and neratinib (Nerlynx®) is an EGFR/HER2/HER4 inhibitor indicated for extended adjuvant use that is also being studied for use in pre-treated HER2-positive metastatic breast cancer. In addition, Daiichi Sankyo and Synthon each have 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.

With respect to tisotumab vedotin, in June 2018, Merck's pembrolizumab (Keytruda®) 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,

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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 Biologics License Application, or 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, enfortumab vedotin, 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, enfortumab vedotin, 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, enfortumab vedotin, 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, including due to our receipt of marketing approvals for ADCETRIS in three additional indications since November 2017. As a result, although we provide sales guidance for ADCETRIS from time to time, you should not rely on ADCETRIS 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 sales in indications for which we have recently received marketing approval. Moreover, sales of ADCETRIS have, on occasion, been below the expectations of securities analysts and investors and have been below prior period sales, and sales of ADCETRIS 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 ADCETRIS, which may vary significantly from period to period;
- the overall level of demand for ADCETRIS, including the impact of any competitive or biosimilar products and the duration of therapy for patients receiving ADCETRIS;

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- the extent to which coverage and reimbursement for ADCETRIS 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 ADCETRIS and its potential advantages compared to existing and future therapies in the frontline Hodgkin lymphoma and frontline PTCL indications and ADCETRIS' other approved indications;
- 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 ADCETRIS at the discounted government price or to obtain government-mandated rebates on purchases of ADCETRIS;
- changes in our cost of sales;
- the incidence rate of new patients in ADCETRIS' approved indications;
- the timing, cost and level of investment in our sales and marketing efforts to support ADCETRIS sales;
- the timing, cost and level of investment in our research and development and other activities involving ADCETRIS, enfortumab vedotin, tucatinib, tisotumab vedotin and our other product candidates by us or our collaborators;
- changes in the prices of the Immunomedics, Inc., or Immunomedics, and Unum common stock that affect the valuation of the common stock of those companies 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, we have entered into licensing and collaboration agreements with other companies that include development funding and milestone 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, 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, 2018, we held 7.7 million shares of Immunomedics common stock and 0.8 million shares of Unum common stock. Beginning on January 1, 2018, we adopted ASU 2016-01 "Financial Instruments: Overall," and as a result, we record changes in the fair value of our equity securities, including the Immunomedics and Unum common stock that we hold, in net income or loss, which is expected to increase the volatility of net income or loss to the extent that we continue to hold common stock or other equity securities.

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For these and other reasons, it is difficult for us to accurately forecast future sales of ADCETRIS, 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 ADCETRIS as well as commercializing ADCETRIS for the treatment of patients in its approved indications. In addition, we expect to make substantial expenditures to further develop and potentially commercialize enfortumab vedotin, tucatinib, tisotumab vedotin and our other product candidates. Likewise, in connection with the Cascadian Acquisition and the integration of Cascadian's business, we have incurred and expect to incur substantial expenses, including to further develop and potentially commercialize tucatinib. 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 ADCETRIS product sales and we continue to earn amounts under our collaboration agreements, our revenue and profit potential is unproven and our limited commercialization history makes our future operating results difficult to predict. Even if we do achieve profitability in the future, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

We 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.

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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 acquisition or in-licensing transactions such as the Cascadian Acquisition 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. For example, as a result of the Cascadian Acquisition, we now operate our historical core business along with the Cascadian business as one combined organization utilizing common information and communication systems, operating procedures, financial controls and human resources practices. There may be substantial difficulties, costs and delays involved in the integration of our historical core business with the Cascadian business, including as a result of challenges relating to the diversion of management's attention, the possibility of faulty assumptions underlying expectations regarding the integration process, retaining and attracting business and operational relationships, eliminating duplicative operations and inconsistent standards and procedures and increased or unforeseen liabilities or costs relating to the Cascadian Acquisition or the Cascadian business. We have also incurred substantial expenses in connection with and as a result of completing the Cascadian Acquisition, and, we expect to incur substantial additional expenses in connection with coordinating the businesses, operations, policies and procedures of the combined company. 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. The loss of our collaborators, especially Takeda, 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.

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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.

In the United States and Canada, we sell ADCETRIS through a limited number of pharmaceutical distributors. Customers order ADCETRIS through these distributors. We generally receive orders from distributors and ship product directly to the customer. We do not promote ADCETRIS to these distributors and they do not set or determine demand for ADCETRIS; however, our ability to effectively commercialize ADCETRIS 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 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 ADCETRIS and our 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. 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 for use in our clinical trials and for commercial sale. If our contract manufacturers or other third parties fail to deliver ADCETRIS 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 ADCETRIS. Moreover, contract manufacturers have a limited number of facilities in which ADCETRIS 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 ADCETRIS supply, or limit our ability to sell our products in the U.S. and Canada or for Takeda to sell ADCETRIS in its territories. Moreover, we and Takeda depend on outside vendors for the supply of raw materials used to produce ADCETRIS. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have ADCETRIS manufactured to meet clinical and commercial requirements would be adversely affected.

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. With respect to enfortumab vedotin and tisotumab vedotin specifically, we rely on drug product supply provided by our collaborators 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 contract manufacturers and, in the case of enfortumab vedotin and tisotumab vedotin, on our collaborators, for manufacturing of clinical supplies. If our third-party manufacturers and collaborators 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 and an adverse effect on our business. In addition, 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.

For enfortumab vedotin and tisotumab vedotin, we or our collaborators will likely need to obtain additional manufacturing arrangements or increase manufacturing capability to meet potential future commercial needs with respect to these product candidates, which could require additional capital investment by us or cause potential delays if our collaborators encounter challenges in negotiating commercially reasonable arrangements with these manufacturers.

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Likewise, with respect to tucatinib, we will need to put in place additional 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. We or our collaborators may also encounter difficulties in meeting the regulatory requirements applicable to the manufacturing process for these agents, and in managing the additional complexity of manufacturing for a number of markets outside the U.S. Any failures or delays to meet these requirements could substantially delay or impede our ability to obtain regulatory approvals for and 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. As an organization, we have no prior experience operating a manufacturing facility.

We own a biologics manufacturing facility located in Bothell, Washington, which we acquired in October 2017. We have commenced using this facility to support our clinical supply needs. As an organization, we have no prior experience manufacturing for ourselves and 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 ADCETRIS and our product candidates.

We are subject to various state and federal and foreign laws and regulations, including healthcare, privacy and data security 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.

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. 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 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 are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs.

The federal civil and criminal false claims laws, including the civil False Claims Act, prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false claim to, or the knowing use of false statements to obtain payment from or approval by the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease, or conceal an obligation to pay money to the federal government. PPACA 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

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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 and teaching hospitals, and physician ownership and investment interests.

There are foreign and state law versions of these laws and regulations, such as anti-kickback, false claims, and 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. The GDPR has increased our responsibility and potential liability in relation to personal data that we process compared to prior EU law, 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 security, 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 security, 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 data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue

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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 United Kingdom. In particular, it is unclear whether the United Kingdom will enact data protection legislation equivalent to the GDPR, how data transfers to and from the United Kingdom will be regulated 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, including ADCETRIS, for off-label uses we may be subject to significant liability, including 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 rules and the evolution of new theories of liability under those statutes. 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

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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, including beginning on December 22, 2018, 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 subsidiaries in Australia, Canada, Ireland, Luxembourg, the Netherlands, Switzerland and the United Kingdom, 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

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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 further setbacks in our ADC development program would negatively affect our business and financial position.

ADCETRIS and our enfortumab vedotin, 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 collaborations with AbbVie, Astellas, Bayer, Celldex, Genentech, GSK, and Progenics, and our collaboration agreements with Takeda, Astellas, and Genmab. Although ADCETRIS has received marketing approval in the United States, Canada, the European Union, Japan and other countries, ADCETRIS is our first and only ADC product that has been approved for commercial sale in any jurisdiction. In addition, certain of our ADC product candidates include additional proprietary technologies that have not yet been proven in late stage clinical development. Any failures or further 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 ADCETRIS in its 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.

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.

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 defense of these and potential future litigations, and we may not prevail. Monitoring and defending against 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.

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We may need to raise significant amounts of 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, support our development, manufacturing and clinical trial activities for ADCETRIS and our other pipeline programs, as well as commercialize ADCETRIS and prepare to potentially commercialize additional product candidates. 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. We also anticipate continuing to commit substantial capital resources to development and commercialization activities related to enfortumab vedotin, tucatinib and tisotumab vedotin. Our commitment of resources to the continuing development, regulatory and commercialization activities for ADCETRIS, the research, continued development and manufacturing of our product candidates and the anticipated expansion of our pipeline and operations will likely require us to raise substantial amounts of 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;
- the time and costs involved in obtaining regulatory approvals of ADCETRIS in additional indications, if any;
- 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;
- the cost of establishing and maintaining clinical and commercial supplies of ADCETRIS;
- the costs associated with acquisitions or licenses of additional technologies, products, or companies as well as licenses we may need to commercialize our products;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- expenses associated with the pending and potential additional related purported 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 and the Cascadian Acquisition, 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

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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 rely on license agreements for certain aspects of ADCETRIS, our 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 ADCETRIS and our 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. If our licensors terminate our license agreements or if we are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize ADCETRIS or our product candidates, including tucatinib. Further, we have had in the past, and may in the future have, disputes with our licensors, which may impact our ability to develop and commercialize ADCETRIS or our product candidates or require us to enter into additional licenses. An adverse result in potential future disputes with our licensors may impact our ability to develop and commercialize ADCETRIS and our 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 ADCETRIS and our 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 ADCETRIS or 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

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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 ADCETRIS 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 ADCETRIS or future commercialization of our product candidates in development. 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 ADCETRIS 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 ADCETRIS or our 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

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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. With respect to tucatinib, we expect to rely on the experience and expertise of personnel formerly employed by Cascadian in the development of tucatinib. If we were to lose the services of a significant portion or key individuals of this team, such development activities could be adversely impacted and our business could be adversely affected.

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 ADCETRIS, 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. 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 commercialize ADCETRIS in earlier lines of therapy, including in the frontline PTCL indication, to build a commercial infrastructure in Europe or to support the commercialization of our product candidates alone or jointly with our collaborators.

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 the Cascadian Acquisition, our operation of a manufacturing facility and our continuing international expansion. This growth 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. 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 or control deficiencies. 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.

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 ADCETRIS by us and our corporate collaborators in clinical trials and the sale of ADCETRIS, 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 manufacture 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,

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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. However, 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 ADCETRIS could materially adversely affect our business by rendering us unable to sell ADCETRIS for some time and by adversely affecting our reputation.

Risks associated with our expanding operations in foreign countries could materially adversely affect our business.

We are expanding our operations internationally. We currently have subsidiaries in Australia, Canada, Ireland, Luxembourg, Switzerland and the United Kingdom, and we plan to build a commercial infrastructure in Europe. Consequently, we are, and will continue to 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, 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;
- 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, our business and corporate structure has and will become substantially more complex. There can be no assurance that we will effectively manage the increased complexity without experiencing operating inefficiencies or control deficiencies. Significant management time and effort is required to effectively manage the increasing complexity of our company, 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 U.K. is derived from European Union directives and regulations, Brexit 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 and potential future marketing authorizations for our product candidates. We may also face new regulatory costs and challenges as result of Brexit that could have an adverse effect on our operations, including the need to change the location of our release of clinical product supplies into the European Union from the U.K. to a location that will be within the European Union following Brexit, potential stresses and constraints on the capacity of service providers providing product release services in new locations outside of the U.K., and potential challenges with releasing clinical

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product supplies into the U.K. any of which could potentially impede our ability to timely supply clinical product to our clinical trials, 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. Moreover, we do not currently have certainty as to the terms of the U.K.'s future relationship with the European Union and if the U.K. withdraws from the European Union without a ratified withdrawal agreement in place, there will be a period of considerable uncertainty particularly in relation to U.K, financial and banking markets as well as on the regulatory process in Europe. In addition, the U.K. could lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers which could make our and Takeda's doing business in Europe more difficult. 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 Takeda's 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.

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 in Bothell and Seattle, Washington. 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 ADCETRIS. 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

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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 ADCETRIS and our 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 ADCETRIS and our product candidates or about the diseases that ADCETRIS 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.

For example, in May 2014, the Financial Accounting Standards Board, or FASB, issued “ASU 2014-09, Revenue from Contracts with Customers” which replaced previous revenue recognition guidance under U.S. GAAP when it became effective for us on January 1, 2018. The new standard did not generally change the way in which we recognize product revenue from sales of ADCETRIS. However, sales-based royalties and commercial sales-based milestones are now recorded in the period of the related sale based on estimates, rather than recording them as reported by the customer. In addition, the achievement of development milestones under our collaborations will be recorded in the period their achievement becomes probable, which may result in their recognition earlier than under prior accounting principles. Additionally, on January 1, 2018, we adopted ASU 2016-01 “Financial Instruments: Overall,” and as a result, we now record changes in the fair value of equity securities in net income or loss, which is expected to increase the

volatility of net income or loss to the extent that we continue to hold common stock or other equity securities. In any event, 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

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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, 2018, we had recorded $574.7 million of in-process research and development and goodwill related to 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, 2018, our closing stock price fluctuated between $48.13 and $82.76 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 level of ADCETRIS sales in the United States, Canada, the European Union, Japan and other countries in which Takeda has received approval by relevant regulatory authorities;
- announcements regarding the results of discovery efforts and preclinical, clinical and commercial activities by us, or those of our competitors;
- announcements of FDA or foreign regulatory approval or non-approval of ADCETRIS, 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 the clinical trials we, Takeda and/or BMS are conducting or may in the future conduct for ADCETRIS, including the CHECKMATE 812 trial;
- announcements regarding the results of the clinical trials we and our collaborators are conducting for enfortumab vedotin, tucatinib and tisotumab vedotin;
- announcements regarding, or negative publicity concerning, adverse events or safety concerns associated with the use of ADCETRIS or our product candidates;
- issuance of new or changed analysts' reports and recommendations regarding us or our competitors;
- termination of or changes in our existing collaborations or licensing arrangements, especially our ADCETRIS collaboration with Takeda, our enfortumab vedotin co-development and joint commercialization collaboration with Astellas and our tisotumab vedotin co-development 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;

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- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;
- developments or disputes concerning our proprietary rights;
- developments regarding the pending and potential additional related 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 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, 2018, we had 160,262,000 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, 2018, collectively beneficially owned approximately 32% of our common stock. Under the registration rights agreement, if at any time and from time to time the Baker

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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, 2018, our executive officers and directors and holders of greater than five percent of our outstanding common stock beneficially owned approximately 42% of our voting power as of December 31, 2018. 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.

The U.S. comprehensive tax reform bill passed in 2017 could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act of 2017, or the Tax Act, which significantly revises the Internal Revenue Code of 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, our business and financial condition could be adversely affected in future periods by the overall impact of the Tax Act. In addition, the Tax Act could be amended or subject to technical correction, possibly with retroactive effect, which could change the financial impacts that were recorded at December 31, 2018, or are expected to be recorded in future periods. Additionally, further guidance may be forthcoming from the Financial Accounting Standards Board and SEC, as well as regulations, interpretations and rulings from federal and state tax agencies, which could result in additional impacts, possibly with retroactive effect. Any such changes or potential additional impacts could adversely affect our business and financial condition.

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

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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 seven leased buildings of office space that we use for laboratory, discovery, research and development and general and administrative purposes, a biologics manufacturing facility which we own, and an additional four leases for buildings that will commence in 2019. We also have leased space in Seattle, WA, and Zug, Switzerland, used for general and administrative purposes, and committed leased space in South San Francisco that will commence in 2019, to be used for general and administrative purposes. All of our significant leases include renewal options. We believe that our facilities and committed leased space are currently adequate to meet our needs. As we continue to expand our operations, we may need to lease additional or alternative facilities.

Item 3. Legal Proceedings

The information required to be set forth under this Item 3 is incorporated by reference to “Note 14. Commitments and contingencies” of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Item 4. Mine Safety Disclosures

Not applicable.

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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 4, 2019, there were 160,561,234 shares of our common stock outstanding, which were held by approximately 66 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 the year ended December 31, 2018. In addition, we did not repurchase any of our equity securities during 2018.

Stock Performance Graph

The table below shows the cumulative total return to our stockholders during the period from December 31, 2013 through December 31, 2018 in comparison to the indicated indexes. The results assume that $100 was invested on December 31, 2013 in our common stock and each of the indicated indexes, including reinvestment of any dividends.

	December 31,					
	2013	2014	2015	2016	2017	2018
Seattle Genetics, Inc.	$100.00	$80.55	$112.51	$132.29	$134.12	$142.04
Nasdaq Composite	100.00	114.62	122.81	133.19	172.11	165.84
Nasdaq Pharmaceutical	100.00	130.42	135.08	107.58	122.18	111.73
Nasdaq Biotechnology	100.00	131.71	140.56	112.25	133.67	121.24

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

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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, 2018, 2017, and 2016, and Consolidated Balance Sheet data as of December 31, 2018 and 2017 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, 2015 and 2014 and Consolidated Balance Sheet data as of December 31, 2016, 2015, and 2014 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,				
	2018(a)	2017	2016	2015	2014
	(in thousands, except for per share amounts)				
Consolidated Statements of Comprehensive Loss Data:					
Revenues:					
Net product sales	$476,903	$307,562	$265,766	$226,052	$178,198
Collaboration and license agreement revenues	94,357	108,632	84,926	69,770	68,556
Royalty revenues	83,440	66,056	67,455	40,980	40,004
Total revenues	654,700	482,250	418,147	336,802	286,758
Costs and expenses:					
Cost of sales	66,085	34,768	28,168	24,476	17,513
Cost of royalty revenues	22,208	19,350	14,149	12,964	11,545
Research and development	565,309	456,700	379,308	294,529	230,743
Selling, general and administrative	261,096	167,233	139,247	125,783	104,320
Total costs and expenses	914,698	678,051	560,872	457,752	364,121
Loss from operations	(259,998)	(195,801)	(142,725)	(120,950)	(77,363)
Investment and other income, net	13,652	36,914	2,614	464	1,222
Loss before income taxes	(246,346)	(158,887)	(140,111)	(120,486)	(76,141)
Income tax benefit	23,653	33,357	—	—	—
Net loss	$(222,693)	$(125,530)	$(140,111)	$(120,486)	$(76,141)
Net loss per share - basic and diluted	$(1.41)	$(0.88)	$(1.00)	$(0.93)	$(0.62)
Shares used in computation of per share amounts - basic and diluted	157,655	143,174	140,746	129,184	123,408

	December 31,				
	2018(a)	2017	2016	2015	2014
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investment securities	$459,866	$413,171	$618,974	$712,711	$313,413
Working capital	428,523	409,932	586,132	636,793	282,093
Total assets	1,503,329	877,949	838,396	895,095	458,965
Stockholders' equity	1,273,943	677,569	634,087	685,911	210,834

(a) On March 9, 2018, we completed the acquisition of Cascadian Therapeutics, Inc., or Cascadian, for a total purchase price of approximately $614.1 million. The results of operations of the acquired Cascadian business, along with the estimated fair values of the assets acquired and liabilities assumed in the acquisition, have been included in our consolidated financial statements since the closing of the acquisition. 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 of the offering was to fund the acquisition of Cascadian.

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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," "int 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 several types of lymphoma. 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, 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.

Our marketed product ADCETRIS is commercially available in 72 countries, including in the U.S., Canada, members of the European Union and Japan. We commercialize ADCETRIS in the U.S. and its territories and in Canada, and we are collaborating 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. For patients with 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. For patients with T-cell lymphomas, ADCETRIS is approved as monotherapy in patients with relapsed or refractory systemic anaplastic large cell lymphoma, or sALCL, or cutaneous T-cell lymphoma, or CTCL, or in combination with chemotherapy in patients with previously untreated CD30-positive peripheral T-cell lymphoma, or PTCL. Key regulatory developments in 2018 included the approval of ADCETRIS for use in two frontline settings based on the successful outcomes of the phase 3 ECHELON-1 and ECHELON-2 clinical trials as described below:

- In March 2018, the FDA approved ADCETRIS in combination with doxorubicin, vinblastine and dacarbazine, or AVD, for patients with newly diagnosed, previously untreated Stage III/IV classical Hodgkin lymphoma based on the results of ECHELON-1 trial, or the frontline Hodgkin lymphoma indication. In the ECHELON-1 trial, ADCETRIS in combination with AVD demonstrated a statically significant improvement in the primary endpoint of modified progression-free survival, or PFS, versus the control arm, doxorubicin, bleomycin, vinblastine and dacarbazine, or ABVD. The safety profile of ADCETRIS plus AVD in the trial was consistent with that known for the single-agent components of the regimen.
- In November 2018, the FDA approved ADCETRIS in combination with cyclophosphamide, doxorubicin, and prednisone, or CHP, for patients with previously untreated systemic anaplastic large-cell lymphoma, or sALCL or

other CD30-expressing peripheral T-cell lymphomas, or PTCL, including angioimmunoblastic T-

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cell lymphoma and PTCL not otherwise specified based on the results of the ECHELON-2 trial, or the frontline PTCL indication. In the ECHELON-2 trial, ADCETRIS in combination with CHP demonstrated a statistically significant improvement in the primary endpoint of PFS versus the control arm, CHOP, or cyclophosphamide, doxorubicin, vincristine and prednisone. ADCETRIS plus CHP also demonstrated superior overall survival, a key secondary endpoint, compared to CHOP. The safety profile of ADCETRIS plus CHP in the trial was comparable to CHOP and consistent with the established safety profile of ADCETRIS in combination with chemotherapy.

Beyond our current labeled indications, we are evaluating ADCETRIS in several clinical trials in combination with nivolumab (Opdivo) under a clinical collaboration with Bristol-Myers Squibb Company, or BMS. Nivolumab is a programmed death-1, or PD-1, immune checkpoint inhibitor. The trials are evaluating the combination in several settings for Hodgkin and non-Hodgkin lymphoma.

Our late-stage pipeline includes two ADCs and an oral tyrosine kinase inhibitor, or TKI, for solid tumors that are in clinical trials designed to support applications for potential regulatory approvals.

In collaboration with Astellas Pharma, Inc., or Astellas, we are developing enfortumab vedotin, which is an ADC targeting Nectin-4. We and Astellas are conducting a pivotal phase 2 trial, called EV-201, evaluating single-agent enfortumab vedotin for patients with locally advanced or metastatic urothelial cancer who were previously treated with a PD-1 or PD-L1 inhibitor. In March 2018, the FDA granted Breakthrough Therapy Designation, or BTD, to enfortumab vedotin for patients with locally advanced or metastatic urothelial cancer who were previously treated with a checkpoint inhibitor. In July 2018, we completed enrollment in the first cohort of EV-201 of approximately 120 patients who previously received both platinum chemotherapy and a PD-1 or PD-L1 inhibitor. We expect to report top-line data from this cohort in the first quarter of 2019. We believe that positive data in this cohort could support potential registration under the FDA's accelerated approval pathway. In July 2018, we and Astellas initiated a global, randomized phase 3 trial, called EV-301, for patients with metastatic urothelial cancer who previously received both platinum chemotherapy and a PD-1 or PD-L1 inhibitor. EV-301 is intended to support global regulatory applications for potential approvals and potentially serve as a confirmatory trial in the U.S. if we are able to obtain accelerated approval based on data from the EV-201 trial. We and Astellas are also conducting a phase 1b trial of enfortumab vedotin, called EV-103, in combination with either pembrolizumab or other anticancer agents as first- or second-line treatment for patients with locally advanced or metastatic urothelial cancer.

In March 2018, we obtained global rights to tucatinib, an oral TKI targeting HER2, a growth factor receptor overexpressed in many cancers, through the acquisition of Cascadian Therapeutics, Inc., or the Cascadian Acquisition. Tucatinib is currently being evaluated as part of a combination regimen in a global randomized (2:1) pivotal phase 2 trial, called HER2CLIMB, comparing tucatinib vs. placebo, each in combination with capecitabine and trastuzumab. The trial is enrolling patients with HER2-positive metastatic breast cancer who have been previously treated with trastuzumab, pertuzumab (Perjeta®) and ado-trastuzumab emtansine, or T-DM1, (Kadcyla®), including patients with or without brain metastases. We achieved enrollment of 480 patients in the trial to enable analysis of the primary endpoint of PFS, with top-line data expected to be reported in 2019. In addition, we are continuing enrollment in HER2CLIMB up to 600 patients to support the analyses of key secondary endpoints, including overall survival, or OS, as well as PFS in patients with brain metastases. We anticipate completing enrollment of the additional patients in mid-2019.

In collaboration with Genmab A/S, or Genmab, we are developing tisotumab vedotin, which is an ADC targeting tissue factor, or TF. In June 2018, we initiated 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 potential registration under the FDA's accelerated approval pathway. We expect to complete enrollment in innovaTV 204 by mid-2019. In July 2018, we initiated a phase 2 clinical trial, called innovaTV 207, for patients with other solid tumors including colorectal, non-small cell lung, pancreatic or head and neck cancers. The trial is intended to inform a potential future broad development program. We are also conducting a phase 2 clinical trial, called innovaTV 208, for patients with platinum-resistant ovarian cancer.

We are also 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 triple-negative breast cancer.

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Our early-stage clinical pipeline includes SGN-CD48A, which utilizes our ADC technology, SEA-BCMA, a monoclonal antibody utilizing our sugar-engineered antibody, or SEA, technology, and SGN-2FF, which is a novel small molecule. In addition, we have multiple preclinical and research-stage programs that employ our proprietary technologies.

We have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including AbbVie Biotechnology Ltd., or AbbVie; Bayer Pharma AG, or Bayer; Celldex Therapeutics, Inc., or Celldex; Genentech, Inc., a member of the Roche Group, or Genentech; GlaxoSmithKline LLC, or GSK; and Progenics Pharmaceuticals Inc., or Progenics. Of these collaborators, GSK and AbbVie each have ADCs using our technology in late-stage clinical trials, and in December 2018 Roche submitted regulatory applications in the U.S. and the European Union, or EU, for approval of polatuzumab vedotin, an ADC that uses our technology, to treat patients with relapsed or refractory diffuse large B-cell lymphoma, or DLBCL. In addition, we have a collaboration with Unum Therapeutics, Inc., or Unum, to develop and commercialize novel antibody-coupled T-cell receptor, or ACTR, therapies incorporating our antibodies for the treatment of cancer. Unum is conducting a phase 1 trial evaluating Unum's ACTR087 drug candidate in combination with SEA-BCMA in patients with relapsed/refractory multiple myeloma. In 2018, we entered into a research collaboration agreement with Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals AG, or together, Pieris, to develop novel potential treatments of cancer based on bispecifics incorporating our proprietary antibodies and Pieris' proprietary technology designed to stimulate an antibody-directed immune response against solid tumors and blood cancers.

Outlook

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, primarily as a result of activities related to the commercialization of ADCETRIS and the continued development of ADCETRIS, enfortumab vedotin, tucatinib, and tisotumab vedotin. Enfortumab vedotin, tucatinib, tisotumab vedotin, and our other product candidates will require significant further development, financial resources and personnel to pursue and obtain regulatory approval and to develop them into commercially viable products, if at all. Our other product candidates are in relatively early stages of development. 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 ADCETRIS, the research, continued development and manufacturing of our product candidates, and the anticipated expansion of our pipeline and operations will likely require us to raise substantial amounts of additional capital, and our operating expenses may fluctuate as a result of such activities. We may also incur significant milestone payment obligations to certain of our licensors as our product candidates progress through clinical trials towards potential commercialization.

We recognize revenue from ADCETRIS product sales in the U.S. and Canada. Our future ADCETRIS product sales are difficult to accurately predict from period to period and are dependent on the incidence flow of patients eligible for treatment with ADCETRIS. In this regard, our product sales have varied, and may continue to vary, significantly from period to period and may be affected by a variety of factors. Such factors include the approval of ADCETRIS in additional indications, the extent to which coverage and reimbursement for ADCETRIS is available from government and other third-party payors, competition, the incidence rate of new patients in ADCETRIS' approved indications, customer ordering patterns, physicians' perception and adoption of ADCETRIS, the overall level of demand for ADCETRIS, and the duration of therapy for patients receiving ADCETRIS. In particular:

- Obtaining and maintaining appropriate coverage and reimbursement for ADCETRIS is increasingly challenging due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the U.S. and worldwide, as well as increasing legislative and enforcement interest in the U.S. with respect to pharmaceutical drug pricing practices. We anticipate that healthcare reform measures that 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 ADCETRIS. We also 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, any of which could negatively affect our revenue or sales of ADCETRIS or any future approved products.

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- The competition ADCETRIS faces from competing therapies is intensifying, and 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.

While we expect continued growth in ADCETRIS sales in 2019 as compared to 2018, for the above and other reasons, we expect that our ability to grow ADCETRIS sales, if at all, will depend primarily on our ability to establish or demonstrate in the medical community the value of ADCETRIS and its potential advantages compared to existing and future therapeutics in the frontline Hodgkin lymphoma indication and the frontline PTCL indication, and the extent to which physicians make prescribing decisions with respect to ADCETRIS in these indications. Further, our ability to grow ADCETRIS sales will be affected by our ability to continue to expand ADCETRIS' utilization across all labeled indications of use. In addition, Takeda may be unable to obtain regulatory approvals of ADCETRIS in the ECHELON-1 treatment setting in its territories (other than in Japan where ADCETRIS is approved in combination with AVD as a frontline treatment option for CD30-positive Hodgkin lymphoma patients), and of ADCETRIS in the ECHELON-2 treatment setting in its territories, which also would limit their sales of, and the commercial potential of, ADCETRIS.

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, as well as by entering into potential new collaboration and license agreements. 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

Total revenues increased to $654.7 million in 2018, compared to $482.3 million in 2017. This increase was driven primarily by higher ADCETRIS net product sales that increased to $476.9 million in 2018 as compared to $307.6 million in 2017. Total costs and expenses increased to $914.7 million in 2018, compared to $678.1 million in 2017. This primarily reflected higher research and development expenses, due to continued investment in our late-stage pipeline and upfront payments for in-license agreements, as well as higher selling, general, and administrative expenses, including costs to support ADCETRIS launches in March 2018 and November 2018 for the frontline Hodgkin lymphoma indication and the frontline PTCL indication, respectively, and costs related to the Cascadian Acquisition. In addition, our costs and expenses included Cascadian operations subsequent to March 9, 2018. Net loss for the year ended December 31, 2018 of $222.7 million was favorably impacted by an income tax benefit of $23.7 million related to the release of the valuation allowance equal to the deferred tax liability recorded in the purchase price allocation for the Cascadian Acquisition.

Total revenues increased to $482.3 million in 2017, compared to $418.1 million in 2016. This increase was driven primarily by ADCETRIS net product sales that increased to $307.6 million in 2017 as compared to $265.8 million in 2016, and by collaboration and license agreement revenues that increased to $108.6 million in 2017 as compared to $84.9 million in 2016. Total costs and expenses increased to $678.1 million in 2017, compared to $560.9 million in 2016. This primarily reflected increased investment in our pipeline of preclinical and clinical-stage programs, increased drug supply to Takeda, and higher staffing costs to support our continued growth. Net loss for the year ended December 31, 2017 of $125.5 million was favorably impacted by a gain of $33.8 million resulting from the change in the fair value of an Immunomedics warrant derivative and an income tax benefit of $33.4 million related to the change in the fair value of our Immunomedics common stock holding, which was offset by an income tax provision of $33.4 million in other comprehensive income.

As of December 31, 2018, we had $459.9 million in cash, cash equivalents and investments and $1.3 billion in total stockholders' equity.

Comparability

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 on the Cascadian Acquisition, 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.

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We adopted Accounting Standards Codification Topic 606—Revenue from Contracts with Customers, or Topic 606, on January 1, 2018, resulting in a change to our accounting policy for revenue recognition. We used the modified retrospective method and recognized the cumulative effect of initially applying Topic 606 as an adjustment to decrease the opening accumulated deficit at January 1, 2018. Accordingly, comparative information has not been adjusted and continues to be reported under previous accounting standards.For additional information on Topic 606, 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 Accounting Standards Update, or ASU, "ASU 2016-01, Financial Instruments: Overall" on January 1, 2018, which addressed certain aspects of 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 and recognized the cumulative effect of initially applying this ASU as an adjustment to decrease the opening accumulated deficit at January 1, 2018. Accordingly, comparative information has not been adjusted and continues to be reported under previous accounting standards. For additional information on this ASU, 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.

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

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

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

Net product sales

We sell ADCETRIS through a limited number of pharmaceutical distributors in the U.S. and Canada. Customers order ADCETRIS through these distributors, and we typically ship product directly to the customer. The delivery of ADCETRIS to the end-user site represents a single performance obligation for these transactions. 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

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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 from ADCETRIS.

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 ADCETRIS. Medicaid rebates are invoiced to us by the various state Medicaid programs. We estimate Medicaid rebates using the most-likely-amount approach, based on a variety of factors, including our experience to-date.

We have also completed a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of ADCETRIS. 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 ADCETRIS. 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 ADCETRIS and this information enables us to estimate expected chargebacks for FSS and PHS purchases based on 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 most-likely-amount 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 with pharmaceutical and biotechnology and companies. Our proprietary technology for linking cytotoxic agents to monoclonal antibodies called antibody-drug conjugates, or ADCs, is the basis for many of these collaboration and license agreements, including the ADC collaborations that we have entered into in the ordinary course of business, under which we granted our collaborators research and commercial licenses to our technology and typically provide technology transfer services, technical advice, supplies and services for a period of time.

Our collaboration and license agreements include contractual milestones. Generally, the milestone events coincide with the progression of the collaborators' product candidates. These consist of development milestones (such as designation of a product candidate or initiation of preclinical studies and the initiation of phase 1, phase 2, or phase 3 clinical trials), regulatory milestones (such as the filing of regulatory applications for marketing approval), and commercialization milestones (such as first commercial sale in a particular market and product sales in excess of a pre-specified threshold). Our ADC collaborators are solely responsible for the development of their product candidates, and the achievement of milestones in any of the categories identified above is based solely on the collaborators' efforts. Since we do not take a substantive role or control the research, development or commercialization of any products generated by our ADC collaborators, we are not able to reasonably estimate when, if at all, any milestone payments or royalties may be payable to us by our ADC collaborators. As such, the milestone payments associated with our ADC collaborations 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.

ADC collaborations 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

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significant future reversal and, therefore, should be included in the transaction price at the inception of the contract. 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 ADC collaborations, 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 our current ADC collaborations is not distinct from the perspective of our collaborators at the time of initial transfer, since we 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 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 our current ADC collaborations as evaluated at contract inception were not distinct and represented a single performance obligation. 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 as revenue 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. The sales royalties relate predominantly to the license of intellectual property and royalty revenues may also include commercial sales-based milestones if achieved by Takeda or our ADC collaborators. 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 sales volume. 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,

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and estimates for the probability of success and discount rate. These estimates and the resulting valuations require significant judgment.

Investments. We have investments in debt and equity securities. We invest our available cash reserves in debt securities and have acquired equity securities in connection with strategic relationships with other companies. We classify our investments as available-for-sale, which are reported at estimated fair value with the changes in fair value included in accumulated other comprehensive income and loss in stockholders' equity. Upon our adoption of the Accounting Standards Update entitled "ASU 2016-01, Financial Instruments: Overall" as of January 1, 2018, we record changes in the fair value of equity securities as a component of net income or loss. The fair value of our investments is subject to volatility and could adversely affect our future operating results.

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 ADCETRIS and 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.

Research and Development. Research and development expenses consist of salaries, benefits and other headcount-related costs of our research and development staff, preclinical activities, clinical trials and related manufacturing costs, lab supplies, contract and outside service fees, and facilities and overhead expenses. Research and development 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 activities 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 research and development co-development collaborations are reflected in research and development expense. In-licensing fees, milestones, maintenance fees, and other costs to acquire technologies utilized in research and development 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 research and development activities are capitalized and recognized as expense as the related goods are delivered or the related services are performed.

Share-based Compensation. Share-based compensation cost is based on the fair value of the award on the date of grant. We use the Black-Scholes option pricing model to determine the fair value of options on the date of grant which requires certain estimates to be made by management, including the expected forfeiture rate and expected term of the options. We also make decisions regarding the method of calculating the expected stock price volatility and the risk free interest rate used in the model. Fluctuations that affect these estimates could have an impact on the resulting compensation cost. We recognize this estimated fair value over the vesting period of the arrangement using the graded-vesting attribution method for stock options which vest ratably over the vesting period. For performance-based stock options, we recognized this estimated fair value over the service period of the award when we believe vesting of the performance-based stock options is considered probable. Once vesting of performance-based stock options is considered probable, we record compensation expense based on the portion of the service period elapsed to date, with

a cumulative catch-up, net of estimated forfeitures, and recognize remaining compensation expense, if any, over the remaining estimated service period.

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The fair value of each restricted stock unit, or RSU, equals the closing price of our common stock on the date of grant. RSUs granted to date vest 100% at a single point in time. We therefore amortize the value of RSUs, net of estimated forfeitures, to expense on a straight-line basis over the vesting period of the award.

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 full 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.

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. We began capitalizing ADCETRIS production costs into inventory following its accelerated approval by the FDA in 2011. ADCETRIS inventory that is deployed into 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 ADCETRIS. We would write-down inventory cost to net realizable value if we were to determine that we had any excess, obsolete or unsalable inventory.

Loss Contingencies. We are involved in various legal proceedings in the normal course of our 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 of the amount of the ultimate loss. Loss contingencies that we determine to be reasonably possible, but not probable, are disclosed but not recorded. Changes in these estimates could materially affect our financial position and results of operations. Legal fees incurred as a result of our involvement in legal proceedings are expensed as incurred.

Results of Operations - Years Ended December 31, 2018, 2017, and 2016

Net product sales

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

				Percentage change	
(dollars in thousands)	2018	2017	2016	2018/2017	2017/2016
Net product sales	$476,903	$307,562	$265,766	55%	16 %

Net product sales increased in 2018 and 2017 as compared to prior years primarily due to increases in sales volumes and, to a lesser extent, price increases. The increase in sales volume during 2018 was primarily driven by the label expansion of ADCETRIS in the US for frontline Stage III or IV Hodgkin lymphoma obtained in March 2018.

The increase in sales volume during 2017 primarily was driven by increased use of ADCETRIS across multiple lines of therapy in Hodgkin lymphoma and for the treatment of other malignancies.

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ADCETRIS was also approved in the frontline PTCL indication in November 2018.

We expect continued growth in ADCETRIS sales in 2019 as compared to 2018. 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, particularly in newly diagnosed and previously untreated Stage III and IV classical Hodgkin lymphoma and frontline sALCL and other CD30-expressing PTCL, including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified.

We sell ADCETRIS through a limited number of pharmaceutical distributors in the U.S. and Canada. Customers order ADCETRIS through these distributors, and we typically ship product directly to the customer. The delivery of ADCETRIS to the end-user site represents a single performance obligation for these transactions. 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 from ADCETRIS.

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

	December 31, 2018			December 31, 2017			December 31, 2016		
(in thousands)	Rebates & 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	$14,374	$ 3,521	$17,895	$9,500	$ 3,198	$12,698	$7,111	$ 2,359	$9,470
Provision related to current year sales	179,394	11,717	191,111	105,764	7,778	113,542	74,075	6,522	80,597
Adjustments for prior period sales	440	(478)	(38)	1,558	(294)	1,264	(1,043)	(141)	(1,184)
Payments/credits for current year sales	(155,581)	(8,248)	(163,829)	(92,947)	(5,939)	(98,886)	(65,598)	(4,733)	(70,331)
Payments/credits for prior year sales	(11,659)	(908)	(12,567)	(9,501)	(1,222)	(10,723)	(5,045)	(809)	(5,854)
Balance, end of year	$26,968	$ 5,604	$32,572	$14,374	$ 3,521	$17,895	$9,500	$ 3,198	$12,698

Mandatory government discounts are the most significant component of our total gross-to-net deductions and the discount percentage has been increasing. These discount percentages increased during 2018 and 2017 as a result of price increases we instituted that exceeded the rate of inflation and, to a lesser extent in 2017 as a result of an increase in the proportion of our sales eligible for government mandated rebates or chargebacks. Generally, the change in government prices is limited to the rate of inflation. 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 2019 as compared to 2018, driven by anticipated growth in ADCETRIS 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.

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Collaboration and license agreement revenues by collaborator were as follows:

				Percentage change	
(dollars in thousands)	2018	2017	2016	2018/2017	2017/2016
Takeda	$58,605	$74,872	$44,384	(22)%	69 %
AbbVie	13,000	23,260	25,676	(44)%	(9)%
Genmab	7,000	—	—	N/A	N/A
GSK	6,000	—	—	N/A	N/A
Other	9,752	10,500	14,866	(7)%	(29)%
Collaboration and license agreement revenues	$94,357	$108,632	$84,926	(13)%	28 %

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

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 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. In this regard, collaboration revenues from Takeda in 2018 included substantially all of a $10.0 million regulatory milestone achieved in September 2018. Total collaboration revenues from Takeda decreased in 2018 as compared to 2017 primarily due to a decrease in drug supply activities to Takeda. As of December 31, 2018, we recorded $33.3 million of deferred revenue related to our collaboration with Takeda, which we will recognize as the remaining performance obligations are satisfied through November 2019. Collaboration revenues from Takeda increased in 2017 as compared to 2016 primarily due to an increase in drug supply activities to Takeda.

Changes in collaboration revenues from AbbVie, Genmab, and GSK reflected the timing of development milestones from our ADC collaborations with each respective collaborator. The development milestone from Genmab recorded in 2018 was related to a product candidate other than tisotumab vedotin. The decrease in collaboration revenues from AbbVie in 2017 as compared to 2016 also was impacted by a decrease in the earned portion of milestone payments achieved in prior years.

Other collaboration revenues were relatively consistent in 2018 as compared to 2017. Changes in other collaboration revenues in 2017 as compared to 2016 reflected the timing and the earned portion of development milestones and licensing fees.

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 timing of milestones achieved and our ability to enter into additional collaborations. We expect our collaboration and license agreement revenues in 2019 to be relatively consistent with 2018, a portion of which will be driven by the timing of milestones achieved by our collaborators.

Collaboration agreements

Takeda

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, and Takeda has commercial rights in the rest of the world. Additionally, the companies equally co-fund the cost of selected development activities conducted under the collaboration, with the exception of Japan where Takeda is solely responsible for development costs. Costs associated with co-development activities are included in research and development expense.

We recognize payments received from Takeda, including the upfront payment, progress-dependent development and regulatory milestone payments, reimbursement for drug supplied, and net development cost reimbursement

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payments from Takeda as collaboration and license agreement revenues upon transfer of control of the goods or services over the ten-year development period of the collaboration, which ends in 2019. 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, where royalties are based on a percentage of Takeda's net sales of ADCETRIS in its licensed territories ranging from the mid-teens to the mid-twenties based on sales volume, 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.

As of December 31, 2018, total future potential milestone payments to us under the ADCETRIS collaboration could total approximately $155.0 million. Of the remaining amount, up to approximately $7.0 million relates to the achievement of development milestones, up to approximately $108.0 million relates to the achievement of regulatory milestones and $40.0 million relates to the achievement of a commercial milestone. As of December 31, 2018, $80.0 million in milestones had been achieved as a result of regulatory and commercial progress by Takeda.

Astellas

We have an agreement with Agensys, which subsequently became an affiliate of Astellas, to research, develop and commercialize ADCs for the treatment of several types of cancer. The collaboration encompasses combinations of our ADC technology with antibodies developed by Astellas. We and Astellas are co-funding all development costs for enfortumab vedotin. Costs associated with co-development activities are included in research and development expense.

In October 2018, we and Astellas entered into a joint commercialization agreement to govern the global commercialization of enfortumab vedotin, if approved for commercial sale:

- In the U.S., we and Astellas will jointly promote enfortumab vedotin. We will record sales of enfortumab vedotin in the U.S. and be responsible for all U.S. distribution activities. The companies will share equally in costs incurred, and any profits realized, in the U.S.
- Outside the U.S., we will commercialize and record product revenues of enfortumab vedotin in all countries in North and South America, and Astellas will commercialize in rest of the world, including Europe, Asia, Australia and Africa. The agreement is intended to provide that we and Astellas will share equally 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 cost and profit share for both parties.

Either party may opt out of co-development and profit-sharing in return for receiving milestones and royalties from the continuing party.

Genmab

We have an agreement with Genmab to develop and commercialize ADCs for the treatment of several types of cancer, under which we exercised a co-development option for tisotumab vedotin in August 2017. We and Genmab will share all costs and potential future 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.

We will be responsible for tisotumab vedotin commercialization activities in the U.S., Canada, and Mexico, while 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 opt out of co-development and profit-sharing in return for receiving milestones and royalties from the continuing party.

Unum

We have an agreement with Unum to develop and commercialize novel ACTR therapies for cancer. We and Unum are developing two ACTR product candidates that combine Unum’s ACTR technology with our antibodies, and we have an option to include a third product candidate upon payment of an additional fee. Unum is conducting research and

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clinical development activities through phase 1 clinical trials, and we are providing funding for these activities. The agreement calls for us and Unum to co-develop and jointly fund programs after phase 1 clinical trials unless either company opts out. Costs associated with co-development activities are included in research and development expense.

We and Unum would co-commercialize any product candidates and share any profits equally in the U.S. We have exclusive commercial rights outside of the U.S., paying Unum a royalty that is a high single digit to mid-teens percentage of ex-U.S. sales.

The potential future licensing and progress-dependent milestone payments to Unum under the collaboration may total up to $400.0 million for the ACTR programs, payment of which is triggered by the achievement of development, regulatory and commercial milestones.

Other collaboration agreements

We have other active ADC collaborations with a number of companies to allow them to use our proprietary ADC technology. Under these collaborations, which we have entered into in the ordinary course of business, we have granted research and commercial licenses to use our technology in conjunction with the collaborator's technology. We also have agreed to conduct limited development activities and to provide other materials, supplies and services to our ADC collaborators during the performance obligation period of the collaboration. We receive upfront cash payments, progress- and sales-dependent milestones for the achievement by our collaborators 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 ADC collaborators 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.

As of December 31, 2018, our ADC collaborations had generated more than $400.0 million, primarily in the form of upfront and milestone payments. Total milestone payments to us under our current ADC collaborations could total up to approximately $2.6 billion if all potential product candidates achieved all of their milestone events. Of this amount, approximately $0.4 billion relates to the achievement of development milestones, approximately $1.0 billion relates to the achievement of regulatory milestones and approximately $1.2 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 milestone payments or royalties may be payable by our collaborators and we do not anticipate that all of these milestones will be achieved. 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 milestone payments associated with our ADC collaborations and co-development 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 significant milestone payments under these agreements.

In February 2018, we executed an agreement with Pieris to develop novel potential treatments of cancer based on bispecifics incorporating our proprietary antibodies and Pieris' proprietary technology designed to stimulate an antibody-directed immune response against solid tumors and blood cancers. Pieris is conducting preclinical research, and we are providing funding for these activities. Following this research phase, we will have the option to select up to three product candidates for further development. We would develop the product candidates independently, subject to a limited opt in right by Pieris. Under that opt in right, we and Pieris would co-develop and co-commercialize one of the product candidates and share equally in costs and profits associated with that co-developed product candidate. Pieris would be responsible for commercialization in the U.S., and we would be responsible for commercialization in all other territories. For any commercialized product candidates that we developed independently, we would owe Pieris royalties in the mid-single to low-double digits. Under the terms of the agreement, we paid Pieris a $30.0

million upfront fee in 2018, which was recorded in research and development expenses. The potential future licensing and progress-dependent milestone payments to Pieris under the collaboration for the three product candidates total up to $1.2 billion based on the achievement of development, regulatory and commercial milestones.

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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 depending on sales volumes. Takeda bears a portion of third-party royalty costs owed on its sales of ADCETRIS. This amount is included in our royalty revenues. Cost of royalty revenues reflect amounts owed to our third-party licensors related to Takeda's sales of ADCETRIS.

(dollars in thousands)	2018	2017	2016	Percentage change 2018/2017	2017/2016
Royalty revenues	$83,440	$66,056	$67,455	26%	(2)%
Cost of royalty revenues	22,208	19,350	14,149	15%	37 %

Royalty revenues increased in 2018 as compared to 2017 primarily driven by higher net sales volume of ADCETRIS by Takeda in its territories. Royalty revenues decreased in 2017 as compared to 2016, as 2016 included a one-time $20.0 million sales-based milestone triggered by Takeda. This decrease was partially offset by higher net sales volume of ADCETRIS by Takeda in its territories and a higher royalty rate in 2017.

Cost of royalty revenues fluctuates based on the amount of net sales of ADCETRIS by Takeda in its territories.

We expect that royalty revenues will increase in 2019 as compared to 2018 primarily due to anticipated increases in sales volume by Takeda. We expect the cost of royalties to decrease in 2019 as compared to 2018, due to the expiration of certain technology in-license agreements.

Cost of sales

ADCETRIS cost of sales includes manufacturing costs of product sold, third-party royalty costs, amortization of technology license costs, and distribution and other costs.

(dollars in thousands)	2018	2017	2016	Percentage change 2018/2017	2017/2016
Cost of sales	$66,085	$34,768	$28,168	90%	23 %

Cost of sales increased in 2018 and 2017 as compared to prior years. The increase from 2017 to 2018 reflected higher ADCETRIS sales volumes in addition to an inventory write-off of $18.1 million recorded in the fourth quarter of 2018 related to in-process production that did not meet our manufacturing specifications. This inventory adjustment did not impact availability of product supply required to meet demand for ADCETRIS. Otherwise, we expect cost of sales to decrease in 2019 as compared to 2018, primarily due to a reduction in royalties owed under technology license agreements.

Cost of sales increased in 2017 as compared to 2016, primarily due to higher third-party royalty costs that were driven by increased sales volumes.

Research and development

(dollars in thousands)	2018	2017	2016	Percentage change 2018/2017	2017/2016
Research and clinical development	$395,337	$291,080	$236,930	36%	23 %
Process sciences and manufacturing	169,972	165,620	142,378	3 %	16 %
Total research and development	$565,309	$456,700	$379,308	24%	20 %

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

Research and clinical development expenses include, among other things, 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 increases in 2018 and 2017 as compared to prior years primarily reflected increases in internal and co-development costs to support our late-stage pipeline of product candidates and, for 2018, also included $35.0 million of upfront in-licensing payments.

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Process sciences and manufacturing expenses include personnel and occupancy expenses, external contract manufacturing costs for the scale-up and pre-approval manufacturing of drug used in research and our clinical trials, and costs for drug supplied to our collaborators. Process sciences and manufacturing expenses also include quality control and assurance activities, and storage and shipment of our product candidates. Expenses in 2018 were comparable to 2017. The increase in 2017 as compared to 2016 primarily reflected increased drug supplied to Takeda and, to a lesser extent, increases in staffing and other costs to support our pipeline.

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 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, personnel, facilities and other indirect costs not directly charged to development programs.

				Percentage change		5 years ended
(dollars in thousands)	2018	2017	2016	2018/2017	2017/2016	December 31, 2018
ADCETRIS (brentuximab vedotin)	$40,435	$79,343	$73,623	(49)%	8 %	$ 297,839
Enfortumab vedotin	24,943	20,834	5,607	20 %	272 %	56,102
Tucatinib	40,739	—	—	N/A	N/A	40,739
Tisotumab vedotin	22,253	6,022	—	270 %	N/A	28,275
Ladiratuzumab vedotin	24,523	18,483	4,721	33 %	292 %	52,815
SGN-CD33A (vadastuximab talirine)	3,150	34,151	49,387	(91)%	(31)%	109,828
Other clinical stage programs	22,783	37,083	26,135	(39)%	42 %	148,873
Total third-party costs for clinical stage programs	178,826	195,916	159,473	(9)%	23 %	734,471
Other costs and overhead	386,483	260,784	219,835	48 %	19 %	1,192,118
Total research and development	$565,309	$456,700	$379,308	24 %	20 %	$ 1,926,589

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

Third-party costs for ADCETRIS decreased in 2018 as compared to 2017 primarily due to a decrease in drug supplied to Takeda, as well as a decrease in clinical trial activities. Third-party costs for ADCETRIS increased in 2017 as compared to 2016 primarily due to an increase in drug supplied to Takeda and, to a lesser extent, third-party clinical trial costs as we evaluated the use of ADCETRIS in other lines of therapy. The cost of drug supplied to Takeda is charged to research and development expense. We are reimbursed for the drug, which is included in collaboration and license agreement revenues.

Third-party costs for enfortumab vedotin increased in 2018 and 2017 as compared to prior years primarily due to increases in clinical trial costs primarily related to the ongoing EV-201 and EV-301 clinical trials for patients with metastatic urothelial cancer.

Third-party costs for tucatinib increased due to the acquisition of Cascadian, under which we acquired global rights to tucatinib in March 2018. Tucatinib is currently being evaluated in a phase 2 pivotal trial called HER2CLIMB for patients with HER2 positive metastatic breast cancer who have been previously treated with HER2-targeted agents, including patients with or without brain metastases.

Third-party costs for tisotumab vedotin increased in 2018 and 2017 as compared to prior years due to our exercise of the co-development option in September 2017, and subsequent initiation of the innovaTV phase 2 clinical trials.

Third-party costs for ladiratuzumab vedotin increased in 2018 and 2017 as compared to prior years primarily due to increases in clinical trial and companion diagnostic costs related to the progression of this program and the initiation

of additional clinical trials in 2017.

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Third-party costs for SGN-CD33A decreased in 2018 and 2017 as compared to prior years due to the discontinuation of our phase 3 CASCADE and other SGN-CD33A clinical trials in 2017. We subsequently discontinued our SGN-CD33A program.

Third-party costs for our other clinical stage programs were related to multiple earlier-stage development programs and were relatively consistent across 2018, 2017 and 2016.

Other costs and overhead include third-party costs of our preclinical programs and costs associated with personnel and facilities. These costs increased in 2018 and 2017 as compared to prior years due to increased development activities to expand our product pipeline, including increases in staffing levels and the expansion of our facilities to accommodate our growth. The activity in 2018 also included $35.0 million of upfront in-licensing payments.

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. Likewise, in order to expand labeled indications of use, we are required to conduct additional extensive clinical trials. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including:

- the number of patients required in our clinical trials;
- the length of time required to enroll trial participants;
- the number and location of sites included in the trials;
- the costs of producing supplies of the product candidates needed for clinical trials and regulatory submissions;
- the safety and efficacy profile of the product candidate;
- the use of clinical research organizations to assist with the management of the trials; and
- the costs and timing of, and the ability to secure, regulatory approvals.

We anticipate that our total research and development expenses in 2019 will increase compared to 2018 primarily due to higher costs for the development of our product candidates, primarily enfortumab vedotin, tucatinib, tisotumab vedotin, and ladiratuzumab vedotin. Certain ADCETRIS development activities, including some clinical studies, will be conducted by Takeda, the costs of which are not reflected in our research and development expenses. Because of these and other factors, expenses will fluctuate based upon many factors, including the degree of collaborative activities, timing of manufacturing campaigns, numbers of patients enrolled in our clinical trials and the outcome of each clinical trial event.

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 the uncertainties discussed above, 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 ADCETRIS in any additional approved indications or of any of our product candidates.

Selling, general and administrative

(dollars in thousands)	2018	2017	2016	Percentage change 2018/2017	Percentage change 2017/2016
Selling, general and administrative	$261,096	$167,233	$139,247	56%	20 %

Selling, general and administrative expenses increased in 2018 and 2017 as compared to prior years primarily due to higher costs for staffing and infrastructure to support our continued growth. In 2018, this included staffing and promotional activities in connection with the launches of ADCETRIS in the frontline Hodgkin lymphoma and frontline PTCL indications.

We anticipate that selling, general and administrative expenses will increase in 2019 as compared to 2018 as we continue our commercial activities in support of the commercialization of ADCETRIS, as well as our support of general operations.

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Investment and other income, net

				Percentage change	
(dollars in thousands)	2018	2017	2016	2018/2017	2017/2016
Gain on equity securities	$7,336	$33,777	$—	(78)%	N/A
Investment income, net	6,316	3,137	2,614	N/A	20 %
Total investment and other income, net	$13,652	$36,914	$2,614	(63)%	N/A

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

Gains on equity securities primarily related to our common stock holdings in Immunomedics that we acquired as part of a former strategic relationship. Investment and other income, net also includes other non-operating income and loss, such as realized gains and losses on debt securities, and amounts earned on our investments in U.S. Treasury securities. In 2017, gains and losses on equity securities also included activity related to an Immunomedics warrant derivative prior to the warrant's exercise by us in December 2017.

We adopted “ASU 2016-01, Financial Instruments: Overall” on January 1, 2018, which required 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. Comparative information has not been adjusted and continues to be reported under previous accounting standards.

The gain on equity securities in 2018 was driven by a $7.3 million net gain from changes in the fair value of our equity securities, which included the impact of selling a portion of our Immunomedics common stock holding. The gain on equity securities in 2017 was driven by the increase in the fair value of the Immunomedics warrant derivative.

Investment income reflects amounts earned on our investments in U.S. Treasury securities. Investment income increased in 2018 and 2017 compared to prior years due to a higher effective yield of our portfolio.

Income taxes

				Percentage change	
(dollars in thousands)	2018	2017	2016	2018/2017	2017/2016
Income tax benefit	$23,653	$33,357	$—	(29)%	N/A

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, which was offset by an income tax provision for the same amount in other comprehensive income in stockholders’ equity.

Liquidity and capital resources

	December 31,		
(dollars in thousands)	2018	2017	2016
Cash, cash equivalents and investments	$459,866	$413,171	$618,974
Working capital	428,523	409,932	586,132
Stockholders’ equity	1,273,943	677,569	634,087

	Years ended December 31,		
(dollars in thousands)	2018	2017	2016
Cash provided by (used in):			
Operating activities	$(203,536)	$(118,900)	$(96,971)
Investing activities	(592,630)	129,861	68,193
Financing activities	713,407	41,311	35,196

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

The changes in net cash from investing activities reflected differences between the proceeds received from sale and maturity of our investments and amounts reinvested, which included $91.9 million received for the sale of a portion of our Immunomedics common stock holdings in 2018 and $55.1 million paid for the Immunomedics common stock holdings in 2017. Net cash from investing activities also reflected payments for the purchases of property and equipment for all years presented, the Cascadian Acquisition in 2018, and the acquisition of a manufacturing facility in 2017. We paid $614.1 million (or $598.2 million net of the cash acquired) for the Cascadian Acquisition in March 2018. We paid $41.7 million for the acquisition of a biologics manufacturing facility in October 2017.

The changes in net cash from financing activities included proceeds from stock option exercises and our employee stock purchase plan for all years presented, and for 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 ADCETRIS, 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, 2018, we had $410.7 million held in cash or 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 from sales of ADCETRIS 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, support our development, manufacturing and clinical trial activities for ADCETRIS and our other pipeline programs, as well as commercialize ADCETRIS and prepare to potentially commercialize additional product candidates. 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. We also anticipate continuing to commit substantial capital resources to development and commercialization activities related to enfortumab vedotin, tucatinib, and tisotumab vedotin. Our commitment of resources to the continuing development, regulatory and commercialization activities for ADCETRIS, the research, continued development and manufacturing of our product candidates and the anticipated expansion of our pipeline and operations will likely require us to raise substantial amounts of 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. Moreover, in the event of a termination of the ADCETRIS collaboration agreement with Takeda, we would not receive development cost sharing payments or milestone payments or royalties for the development or sale of ADCETRIS in Takeda’s territory, and we would be required to fund all ADCETRIS development and commercial activities, which could lead to a need for us to raise additional capital. In addition, 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. 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 funding 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.

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Commitments

The following table reflects our future minimum contractual commitments as of December 31, 2018:

(dollars in thousands)	Total	2019	2020	2021	2022	2023	Thereafter
Operating leases	$89,912	$10,332	$11,863	$12,770	$12,288	$12,142	$ 30,517
Supply and other agreements	243,078	92,105	30,689	31,091	24,033	21,720	43,440
Total	$332,990	$102,437	$42,552	$43,861	$36,321	$33,862	$ 73,957

We have entered into leases for our office and laboratory facilities expiring in 2019 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. In addition, we entered into various operating leases for building space in 2018, with lease commencement dates of 2019. Future obligations related to those leases are included in the table above but no rent expense has been recognized in 2018.

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, as well as payments by us upon the achievement of development and regulatory milestones. Some of our licensing agreements obligate us to pay royalties from the low single digit to mid-teens based on net sales of products utilizing licensed technology. Such royalties 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 $1.8 billion in total potential future milestone payments to Pieris, Unum and other 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)	2018	2017
Short-term investments	$332,486	$252,226
Long-term investments	49,194	—
Total	$381,680	$252,226

We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of $2.0 million in the fair value of our investments as of December 31, 2018. In addition, a hypothetical decrease of 10% in the effective yield of our investments would reduce our expected investment income by $0.9 million over the next twelve months based on our investment balance at December 31, 2018.

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Equity Price Risk

As of December 31, 2018, we held shares of Immunomedics common stock and shares of Unum common stock. The fair values of the common stock fluctuate based on changes in the stock prices of Immunomedics and Unum. These holdings were acquired in connection with strategic transactions.

Upon our adoption of the Accounting Standards Update entitled “ASU 2016-01, Financial Instruments: Overall” on January 1, 2018, we recorded changes in the fair value of equity securities in net income or loss. To the extent that we continue to hold equity securities, our operating results may fluctuate significantly. Based on our shares of Immunomedics and Unum common stock held as of December 31, 2018, a hypothetical decrease of 10% in the prices of Immunomedics and Unum common stock would reduce the fair values of the investments and, accordingly, our net income by approximately $11.4 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, 2018, 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.

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Item 8. Financial Statements and Supplementary Data

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Report of Independent Registered Public Accounting Firm
To the Board of Directors and Stockholders of
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, 2018 and 2017, 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, 2018, 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 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, 2018 based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Change in Accounting Principles

As discussed in Note 2 to the consolidated financial statements, the Company has changed 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.

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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.

/s/ PricewaterhouseCoopers LLP
Seattle, Washington
February 7, 2019
We have served as the Company's auditor since 1998.

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

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$78,186	$160,945
Short-term investments	332,486	252,226
Accounts receivable, net	146,281	84,774
Inventories	53,239	59,978
Prepaid expenses and other current assets	43,403	19,138
Total current assets	653,595	577,061
Property and equipment, net	103,820	103,756
Long-term investments	49,194	—
In-process research and development	300,000	—
Goodwill	274,671	—
Other non-current assets	122,049	197,132
Total assets	$1,503,329	$877,949
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$44,179	$27,373
Accrued liabilities	147,293	105,299
Current portion of deferred revenue	33,600	34,457
Total current liabilities	225,072	167,129
Long-term liabilities:		
Deferred revenue, less current portion	—	30,618
Other long-term liabilities	4,314	2,633
Total long-term liabilities	4,314	33,251
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; 160,262 shares issued and outstanding at December 31, 2018 and 144,395 shares issued and outstanding at December 31, 2017	160	144
Additional paid-in capital	2,598,411	1,806,159
Accumulated other comprehensive income (loss)	(40)	63,836
Accumulated deficit	(1,324,588)	(1,192,570)
Total stockholders' equity	1,273,943	677,569
Total liabilities and stockholders' equity	$1,503,329	$877,949

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

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

	Years ended December 31,		
	2018	2017	2016
Revenues:			
Net product sales	$476,903	$307,562	$265,766
Collaboration and license agreement revenues	94,357	108,632	84,926
Royalty revenues	83,440	66,056	67,455
Total revenues	654,700	482,250	418,147
Costs and expenses:			
Cost of sales	66,085	34,768	28,168
Cost of royalty revenues	22,208	19,350	14,149
Research and development	565,309	456,700	379,308
Selling, general and administrative	261,096	167,233	139,247
Total costs and expenses	914,698	678,051	560,872
Loss from operations	(259,998)	(195,801)	(142,725)
Investment and other income, net	13,652	36,914	2,614
Loss before income taxes	(246,346)	(158,887)	(140,111)
Income tax benefit	23,653	33,357	—
Net loss	$(222,693)	$(125,530)	$(140,111)
Net loss per share - basic and diluted	$(1.41)	$(0.88)	$(1.00)
Shares used in computation of per share amounts - basic and diluted	157,655	143,174	140,746
Comprehensive loss:			
Net loss	$(222,693)	$(125,530)	$(140,111)
Other comprehensive income:			
Unrealized gain on securities available-for-sale net of tax provision of $0, $33,357, and $0, respectively	293	63,888	616
Foreign currency translation gain (loss)	(50)	11	4
Total other comprehensive income	243	63,899	620
Comprehensive loss	$(222,450)	$(61,631)	$(139,491)

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

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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, 2015	139,674	$ 140	$1,613,383	$ (683)	$(926,929)	$685,911
Net loss	—	—	—	—	(140,111)	(140,111)
Other comprehensive income	—	—	—	620	—	620
Issuance of common stock for employee stock purchase plan	203	—	5,686	—	—	5,686
Stock option exercises	1,778	1	29,509	—	—	29,510
Restricted stock vested during the period, net	538	1	(1)	—	—	—
Share-based compensation	—	—	52,471	—	—	52,471
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

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

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

	Years ended December 31,		
	2018	2017	2016
Operating activities:			
Net loss	$(222,693)	$(125,530)	$(140,111)
Adjustments to reconcile net loss to net cash used by operating activities			
Share-based compensation	78,861	63,802	52,471
Depreciation and amortization	26,032	24,269	18,034
Amortization of premiums, accretion of discounts and (gains) losses on debt securities	(2,530)	497	4,746
Gain on equity securities	(7,336)	(33,777)	—
Income tax benefit on unrealized loss on available-for-sale securities	—	(33,357)	—
Deferred income taxes	(23,653)	—	—
Other long-term liabilities	1,681	(154)	(882)
Changes in operating assets and liabilities:			
Accounts receivable, net	(45,233)	(22,846)	(8,998)
Inventories	6,739	8,146	(11,161)
Prepaid expenses and other assets	(14,567)	(2,170)	(4,378)
Accounts payable and accrued liabilities	33,076	19,098	29,939
Deferred revenue	(33,913)	(16,878)	(36,631)
Net cash used by operating activities	(203,536)	(118,900)	(96,971)
Investing activities:			
Purchases of securities	(512,334)	(513,016)	(603,772)
Proceeds from maturities of securities	398,722	653,200	699,800
Proceeds from sales of securities	140,352	60,056	—
Purchases of property and equipment	(21,219)	(28,722)	(27,835)
Acquisition of manufacturing facility	—	(41,657)	—
Acquisition of Cascadian Therapeutics, Inc., net of cash acquired	(598,151)	—	—
Net cash provided (used) by investing activities	(592,630)	129,861	68,193
Financing activities:			
Net proceeds from issuance of common stock	658,242	—	—
Proceeds from exercise of stock options and employee stock purchase plan	55,165	41,311	35,196
Net cash provided by financing activities	713,407	41,311	35,196
Net increase (decrease) in cash and cash equivalents	(82,759)	52,272	6,418
Cash and cash equivalents at beginning of year	160,945	108,673	102,255
Cash and cash equivalents at end of year	$78,186	$160,945	$108,673

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

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Seattle Genetics, Inc.
Notes to 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. 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,” “us,” or the “Company”). The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. All significant intercompany transactions and balances have been eliminated. 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 also have subsidiaries in Australia, Canada, Ireland, Luxembourg, Switzerland, and the United Kingdom.

Use of estimates

The preparation of financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts in the 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 between accounts payable and accrued liabilities on our consolidated balance sheet to conform to current year presentation. These reclassifications had no effect on our total current liabilities 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 investing activities

We had $4.6 million and $1.0 million of accrued capital expenditures as of December 31, 2018 and 2017, 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.

As further described in Note 5, we exercised a warrant to purchase additional shares of common stock in Immunomedics, Inc., or Immunomedics, in 2017. The fair value of the warrant derivative on the exercise date represented a non-cash investing activity and, accordingly, has not been included in the consolidated statement of cash flows.

Investments

We hold certain equity securities that we acquired in connection with strategic agreements, which are reported at estimated fair value. We adopted Accounting Standards Update, or ASU, “ASU 2016-01, Financial Instruments:

Overall" as of 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 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, comparative information has not been adjusted and continues to be reported under previous accounting standards. The implementation of this standard increases 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, 2018 or 2017.

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.

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 product, ADCETRIS, are capitalized into inventory. ADCETRIS 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 ADCETRIS. In the event that we identify excess, obsolete or unsalable inventory, its value is written down to net realizable value.

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Seattle Genetics, Inc.
Notes to Consolidated Financial Statements (Continued)

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. Concessions received by us in connection with leases, including tenant improvement allowances and prorated rent, are included in deferred rent and other long-term liabilities and recognized as a reduction in rent expense over the term of the applicable lease.

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 periods in which the costs are incurred and included in loss from operations in the consolidated financial statements. The results of operations of the acquired business are included in the consolidated financial statements from the acquisition date.

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Seattle Genetics, Inc.
Notes to Consolidated Financial Statements (Continued)

Other non-current assets

Other non-current assets included:

- Equity securities of $113.8 million and $188.4 million as of December 31, 2018 and 2017, respectively. See Note 5 for additional information. As of December 31, 2017, we also held a cost method investment for our $5.0 million non-controlling investment in Unum Therapeutics, Inc., or Unum, which was a privately-held company. We purchased this investment in connection with a strategic collaboration as disclosed in Note 12. In 2018, Unum concluded an initial public offering, at which point our investment became a marketable equity security recorded at fair value, and is disclosed as such in Note 5 as of December 31, 2018.
- Intangible assets resulting from milestone payments that became due upon the approval of ADCETRIS related to certain in-licensed technology. Intangible assets are amortized to cost of sales over the estimated life of the related licenses, which range from six to ten years. The components of net intangible assets are summarized as follows (in thousands):

	December 31,	
	2018	2017
Intangible assets	$5,650	$5,650
Less: accumulated amortization	(5,610)	(4,886)
Total	$40	$764

Amortization expense on intangible assets resulting from milestone payments was $0.7 million for the year ended December 31, 2018, and $0.8 million for each of the years ended December 31, 2017 and 2016, respectively. Intangible assets will be fully amortized in 2019.

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, 2018 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 Accounting Standards Codification Topic 606—Revenue from Contracts with Customers, or Topic 606, on January 1, 2018, resulting in a change to our accounting policy for revenue recognition. We used the modified retrospective method and recognized the cumulative effect of initially applying Topic 606 as an adjustment to decrease the opening accumulated deficit at January 1, 2018. Accordingly, 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 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 pharmaceutical distributors in the U.S. and Canada. Customers order ADCETRIS through these distributors, and we typically ship product directly to the customer. The delivery of ADCETRIS to the end-user site represents a single performance obligation for these transactions. 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 from ADCETRIS.

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 ADCETRIS. 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 our experience to-date. We have also completed a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of ADCETRIS. 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 ADCETRIS. 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 ADCETRIS 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 with pharmaceutical and biotechnology and companies. Our proprietary ADC technology for linking cytotoxic agents to monoclonal antibodies is the basis for many of these collaboration and license agreements, including the ADC collaborations that we have entered into in the ordinary course of business, under which we granted our collaborators research and commercial licenses to our technology and typically provide technology transfer services, technical advice, supplies and services for a period of time.

Our collaboration and license agreements include contractual milestones. Generally, the milestone events coincide with the progression of the collaborators' product candidates. These consist of development milestones (such as designation of a product candidate or initiation of preclinical studies and the initiation of phase 1, phase 2, or phase 3 clinical trials), regulatory milestones (such as the filing of regulatory applications for marketing approval), and commercialization milestones (such as first commercial sale in a particular market and product sales in excess of a pre-specified threshold). Our ADC collaborators are solely responsible for the development of their product candidates, and the achievement of milestones in any of the categories identified above is based solely on the collaborators' efforts. Since we do not take a substantive role or control the research, development or commercialization of any products generated by our ADC collaborators, we are not able to reasonably estimate when, if at all, any milestone payments or royalties may be payable to us by our ADC collaborators. As such, the milestone payments associated with our ADC collaborations 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.

ADC collaborations 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 significant future

reversal and, therefore, should be included in the transaction price at the inception of the contract. 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 ADC collaborations, 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 our current ADC collaborations is not distinct from the perspective of our collaborators at the time of initial transfer, since we 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 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 our current ADC collaborations as evaluated at contract inception were not distinct and represented a single performance obligation. 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 as revenue 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 sales volume. 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. Both of these amounts are recognized in the period in which the related sales by Takeda occur.

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 $26.6 million, $13.8 million, and $12.9 million in advertising expenses during 2018, 2017, and 2016, 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, are not federally insured. We have accounts receivable from the sale of ADCETRIS 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 ADCETRIS 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 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,		
	2018	2017	2016
Distributor A	28 %	23 %	22 %
Distributor B	22 %	19 %	19 %
Distributor C	20 %	18 %	17 %
Takeda	21 %	29 %	27 %

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

	December 31,	
	2018	2017
Distributor A	32%	32 %
Distributor B	21%	26 %
Distributor C	23%	29 %
Takeda	20%	<10%

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. While primarily one source of supply is utilized for certain components of ADCETRIS 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

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differences are expected to reverse. We have provided a full 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 ("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 Accounting Standards Codification 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 ADCETRIS sales and royalties and from collaboration and license agreements. ADCETRIS is our only product available for sale and is 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 ADCETRIS 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 ADCETRIS in an effort to continue to expand ADCETRIS' labeled indications of use, and there can be no assurance that we and/or Takeda will obtain and maintain the necessary regulatory approvals to market ADCETRIS 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 (in thousands):

	Years ended December 31,		
	2018	2017	2016
Stock options and RSUs	13,439	13,592	12,987

Recent accounting pronouncements not yet adopted

In February 2016, the Financial Accounting Standards Board, or FASB, issued "ASU 2016-02, Leases." The standard requires entities to recognize in the consolidated balance sheet a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. We will adopt the standard on January 1, 2019 using the modified retrospective method in the year of adoption, and electing certain transition practical expedients. We are in the process of evaluating the impact of this standard and expect it to primarily relate to our operating leases for office and laboratory space noted in "Part I. Item 2. Properties" of this Annual Report on Form 10-K, for which we will record a lease liability and corresponding right-of-use asset upon adoption. We do not expect the adoption of this standard to impact retained earnings on January 1, 2019. We have also entered into additional facility leases that will commence in 2019 that will be accounted for under ASU 2016-02. Future undiscounted obligations related to our facility leases in effect as of December 31, 2018, as well as those facility leases entered into prior to December 31, 2018, but contain lease commencement dates after January 1, 2019, are included in the table of future obligations disclosed Note 14.

In June 2016, FASB issued "ASU 2016-13, Financial Instruments: Credit Losses." 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, with early adoption permitted. We are currently evaluating the guidance to determine the potential 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, with early adoption permitted. We are currently evaluating the guidance to determine the potential 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 Topic 808, Collaborative Arrangements, and Topic 606,

Revenue from Contracts with Customers. Currently, 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 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, with early adoption permitted. We are currently evaluating the guidance 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 Topic 606 applying the modified retrospective method to all contracts that were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 were presented under Topic 606, while prior period amounts were not adjusted and reported under the accounting standards in effect for the prior periods. We recorded the following cumulative effect as of January 1, 2018, itemized here (in thousands) and further described below:

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

Topic 606 does not generally change the practice under which we recognize revenue from net product sales of ADCETRIS.

Impact to collaboration and license agreement revenues

The achievement of development milestones under our collaborations will be recorded during the period their achievement becomes most likely, which may result in earlier recognition as compared to previous accounting principles. Each of our current ADC collaborations contain a single performance obligation under Topic 606.

The Takeda ADCETRIS collaboration is the only ongoing collaboration that was significantly impacted by the adoption of 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 include 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, are 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, are 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 one marketed product, ADCETRIS. Substantially all of our product revenues are 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 (in thousands):

	Years ended December 31,		
	2018	2017	2016
Takeda	$58,605	$74,872	$44,384
AbbVie	13,000	23,260	25,676
Genmab	7,000	—	—
GSK	6,000	—	—
Other	9,752	10,500	14,866
Collaboration and license agreement revenues	$94,357	$108,632	$84,926

Contract balances and performance obligations

Contract assets consist of unbilled receivables related to the Takeda ADCETRIS collaboration and were $12.7 million and zero as of January 1, 2018 and December 31, 2018, respectively. These were recorded in prepaid expenses and other current assets on the consolidated balance sheet. The decrease from January 1, 2018 to December 31, 2018 was primarily due to reimbursement for drug supplied against the 2018 production forecast during the year ended December 31, 2018.

Contract liabilities consist of deferred revenue primarily related to our remaining performance obligations under the Takeda ADCETRIS collaboration and are presented as line items on the consolidated balance sheet. Deferred revenue will be recognized as the remaining performance obligations are satisfied through November 2019.

We recognized collaboration and license agreement revenues of $34.5 million during the year ended December 31, 2018 that were included in the deferred revenue balance as of January 1, 2018. For the year ended December 31, 2018, collaboration and license agreement revenues from Takeda also included substantially all of a $10.0 million regulatory milestone.

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Seattle Genetics, Inc.
Notes to Consolidated Financial Statements (Continued)

Impacts to December 31, 2018 consolidated financial statements (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. Acquisition of Cascadian

In March 2018, we acquired all issued and outstanding shares of Cascadian Therapeutics Inc., or 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, or the Cascadian Acquisition, expanded our late-stage pipeline, providing global rights to tucatinib, an investigational oral tyrosine kinase inhibitor, or TKI, that is currently being evaluated in a pivotal phase 2 trial called HER2CLIMB for patients with HER2 positive metastatic breast cancer who have been previously treated with HER2-targeted agents, including patients with or without brain metastases.

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 (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 initial amount allocated to goodwill presented in the previous quarterly unaudited condensed consolidated financial statements in 2018 was preliminary, since the acquisition accounting was not yet finalized as it related to income taxes.

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Seattle Genetics, Inc.
Notes to Consolidated Financial Statements (Continued)

In the fourth quarter of 2018, we recorded a $23.7 million increase to goodwill and a corresponding deferred tax liability related to the intangible assets acquired upon finalization of various analyses for pre-acquisition tax periods. See Note 11 for additional information on the impact of this adjustment to incomes taxes.

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 (in thousands, except for per share information):

	Years Ended December 31,	
	2018	2017
Revenues	$654,700	$482,250
Net loss	(251,626)	(212,364)
Net loss per share - basic and diluted	(1.58)	(1.36)

5. Fair Value

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

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly.

Level 3: Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

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

The fair value hierarchy of the Company’s assets carried at fair value and measured on a recurring basis was as follows (in thousands):

	Fair value measurement using:			
	Quoted prices in active markets for identical assets (Level 1)	Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
December 31, 2018				
Short-term investments—debt securities	$332,486	$—	$—	$332,486
Long-term investments—debt securities	49,194	—	—	49,194
Other non-current assets—equity securities	113,812	—	—	113,812
Total	$495,492	$—	$—	$495,492

December 31, 2017				
Short-term investments—debt securities	$252,226	$	—$	—$252,226
Other non-current assets—equity securities	188,358	—	—	188,358
Total	$440,584	$	—$	—$440,584

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Seattle Genetics, Inc.
Notes to Consolidated Financial Statements (Continued)

Our debt securities consisted of the following (in thousands):

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
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
December 31, 2017				
U.S. Treasury securities	$252,511	$ —	$ (285)	$252,226
Contractual maturities (at date of purchase):				
Due in one year or less	$151,903			$151,842
Due in one to two years	100,608			100,384
Total	$252,511			$252,226

Our equity securities consisted of holdings in common stock of Immunomedics and Unum, each holding purchased in connection with strategic collaborations with the respective company. The collaboration agreement with Immunomedics was terminated in 2017.

Immunomedics stock purchase agreement: In February 2017, we paid Immunomedics $14.7 million for 3.0 million shares of Immunomedics common stock and a warrant to purchase an additional 8.7 million shares of Immunomedics common stock at an exercise price of $4.90 per share. The consideration was primarily allocated to the common stock based on the relative fair values as of the purchase date. The shares of common stock were classified as available-for-sale securities and carried at estimated fair value.

In September 2017, Immunomedics registered the resale of the shares of its common stock underlying the warrant under the Securities Act of 1933, as amended, and as a result, the warrant met the definition of a derivative as of that date and was recorded at fair value. We recorded a non-cash net gain of $33.8 million in investment and other income, net, primarily resulting from the change in the fair value of the warrant derivative, during 2017. This amount approximated the fair value of the warrant derivative upon exercise in December 2017, when we exercised the warrant in its entirety for cash of $42.4 million and received 8.7 million shares of Immunomedics common stock upon exercise. The shares of common stock that are held by us as a result of the warrant exercise, similar to the shares purchased in February 2017, were classified as available-for-sale securities and carried at estimated fair value.

6. Investment and Other Income, Net

Investment and other income, net consisted of the following (in thousands):

	Years ended December 31,		
	2018	2017	2016
Gain on equity securities	$7,336	$33,777	$—
Investment income, net	6,316	3,137	2,614
Total investment and other income, net	$13,652	$36,914	$2,614

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 5. As disclosed in Note 2, we adopted “ASU 2016-01, Financial Instruments: Overall” on January 1, 2018, which required 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. Comparative information has not been adjusted and continues to be reported under previous accounting standards.

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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.

7. Inventories

Inventories were comprised of ADCETRIS and consisted of the following (in thousands):

	December 31,	
	2018	2017
Raw materials	$43,986	$52,398
Finished goods	9,253	7,580
Total	$53,239	$59,978

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

8. Property and equipment

Property and equipment consisted of the following (in thousands):

	December 31,	
	2018	2017
Leasehold improvements	$101,743	$86,778
Laboratory and manufacturing equipment	62,947	57,800
Building	23,341	23,448
Computers, software and office equipment	25,159	20,928
Furniture and fixtures	7,043	6,627
Land	4,771	4,771
	225,004	200,352
Less: accumulated depreciation and amortization	(121,184)	(96,596)
Total	$103,820	$103,756

Depreciation and amortization expenses on property and equipment totaled $25.3 million, $23.5 million, and $17.3 million for the years ended December 31, 2018, 2017, and 2016, respectively. Leasehold improvements included $18.5 million and $3.5 million of construction in process at December 31, 2018 and 2017, respectively.

9. Manufacturing facility acquisition

Under a series of agreements among Bristol Myers Squibb Company, or BMS, and its landlord, we completed the acquisition of a biologics manufacturing facility and certain related equipment and improvements located in Bothell, Washington in October 2017. The purchase price was paid for in cash. The acquisition of the manufacturing facility and the related assets were accounted for as a business combination using the acquisition method. The results of operations of the manufacturing facility and the estimated fair values of the assets acquired and liability assumed have been included in our consolidated financial statements as of the closing date of the acquisition. Acquisition-related costs were not significant.

We also entered into a clinical manufacturing services agreement in October 2017 with BMS, under which we agreed to manufacture certain BMS clinical product candidates in accordance with prescribed production schedules and quantities. These activities concluded as of March 31, 2018. We recorded revenue under the clinical manufacturing services agreement within collaboration and license agreement revenues. This revenue was not significant during the years ended December 31, 2018 and 2017.

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Seattle Genetics, Inc.
Notes to Consolidated Financial Statements (Continued)

The purchase price was allocated to the assets acquired and liability assumed based on their estimated fair values as follows (in thousands):

Building	$23,448
Land	4,771
Other property and equipment	14,538
Current portion of deferred revenue	(1,100)
Total purchase price	$41,657

Pro forma results of operations have not been presented because the effects of this acquisition were not significant to our consolidated results of operations.

10. Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2018	2017
Employee compensation and benefits	$49,788	$38,469
Clinical trial and related costs	38,692	26,514
Contract manufacturing	9,215	8,910
Gross-to-net deductions and third-party royalties	32,908	20,980
Professional services and other	16,690	10,426
Total	$147,293	$105,299

11. Income taxes

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

	December 31,		
	2018	2017	2016
U.S.	$(226,626)	$(71,698)	$(66,215)
Foreign	(19,720)	(87,189)	(73,896)
Total	$(246,346)	$(158,887)	$(140,111)

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

	Years ended December 31,		
	2018	2017	2016
Statutory federal income tax rate	(21.0)%	(35.0)%	(35.0)%
Tax credits	(6.0)	(11.0)	(25.0)
Foreign rate differential	(8.0)	14.0	16.0
State income taxes and other	(3.0)	(1.0)	1.0
Valuation allowance	44.0	(55.0)	40.0
Stock compensation	(4.0)	(5.0)	3.0
Worthless stock deduction	(12.0)	—	—
Impact of the Act	—	72.0	—
Effective tax rate, before impact in other comprehensive income	(10.0)	(21.0)	0.0
Impact in other comprehensive income	—	21.0	—
Effective tax rate, after impact in other comprehensive income	(10.0)%	0.0 %	0.0 %

In connection with the 2018 Cascadian Acquisition, we recognized a deferred tax liability of $23.7 million on acquired intangible assets. 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 US tax rate of 35% in 2017 to 21% in 2018, and an increase in pre-tax earnings from our operations in Switzerland. At December 31, 2018, 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 (in thousands):

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$283,888	$158,951
Foreign net operating loss carryforwards	12,766	2,651
Tax credit carryforwards	175,702	148,027
Deferred revenue	2,553	13,779
Share-based compensation	29,354	26,454
Capitalized research and development	1,362	17,150
Depreciation and amortization	8,456	7,606
Other	20,627	15,178
Total deferred tax assets	534,708	389,796
Less: valuation allowance	(477,834)	(364,538)
Total deferred tax assets, net of valuation allowance	56,874	25,258
Deferred tax liability:		
Intangibles and amortization	(48,819)	—
Realized and unrealized gain on available-for-sale securities	(8,055)	(25,258)
Net deferred tax assets (liability)	$—	$—

Our deferred tax assets primarily consist of net operating loss, or NOL, carryforwards, tax credit carryforwards, share-based compensation, capitalized research and development expense and deferred revenue. 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, 2018, we had gross federal NOL carryforwards of $1.2 billion, of which $184.8 million may be carried forward indefinitely and $1.0 billion of which expire from 2019 to 2038 if not utilized, gross state NOL carryforwards of $450.8 million, gross foreign NOL carryforwards of $143.2 million and tax credit carryforwards of $196.4 million expiring from 2019 to 2038.

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, 2017 and believe that it is likely that utilization of its NOLs would not be limited under Section 382 as of December 31, 2017. 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 $113.3 million in 2018, decreased by $16.8 million in 2017, and increased by $59.2 million in 2016, which was mostly related to the changes in our deferred tax asset balances. The 2018 increase in the valuation allowance of $143.3 million related to the current year loss, tax credits and other activity, offset by $23.7 million decrease for release of valuation allowance related to the deferred tax assets and liabilities acquired in the Cascadian acquisition, 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 (in thousands):

	Years ended December 31,		
	2018	2017	2016
Balance at January 1	$18,172	$16,023	$—
Increase (decrease) related to prior year tax positions	108	(1,292)	12,631
Increase related to current year tax positions	2,426	3,441	3,392
Balance at December 31	$20,706	$18,172	$16,023

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 2018 remain subject to future examination for federal income taxes.

12. Collaboration and license agreements

We have entered into various collaboration and license agreements with pharmaceutical and biotechnology companies. Revenues recognized under these agreements are disclosed in Note 3 under the “Disaggregation of total revenues” heading.

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, and/or challenges to patents which are subject to the related agreement. Each agreement is discussed in more detail in the following sections.

Takeda

The Takeda ADCETRIS collaboration provides for the global co-development of ADCETRIS and the commercialization of ADCETRIS by Takeda in its territory. We retained 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. Additionally, the companies equally co-fund the cost of selected development activities conducted under the collaboration, with the exception of Japan where Takeda is solely responsible for development costs. Costs associated with co-development activities are included in research and development expense.

As disclosed in Note 3 under the heading,“Impact to collaboration and license agreement revenues,” 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, are recognized 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, where royalties are based on a percentage of Takeda’s net sales of ADCETRIS in its licensed territories ranging from

the mid-teens to the mid-twenties based on sales volume, 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

We have an agreement with Agensys, which subsequently became an affiliate of Astellas, to research, develop and commercialize ADCs for the treatment of several types of cancer. The collaboration encompasses combinations of our ADC technology with antibodies developed by Astellas. We and Astellas are co-funding all development costs for enfortumab vedotin. Costs associated with co-development activities are included in research and development expense and amounted to $54.9 million, $36.3 million, and $15.0 million for the years ended December 31, 2018, 2017, and 2016, respectively.

In October 2018, we and Astellas entered into a joint commercialization agreement to govern the global commercialization of enfortumab vedotin, if approved for commercial sale:

- In the U.S., we and Astellas will jointly promote enfortumab vedotin. We will record sales of enfortumab vedotin in the U.S. and be responsible for all U.S. distribution activities. The companies will share equally in costs incurred, and any profits realized, in the U.S.
- Outside the U.S., we will commercialize and record product revenues of enfortumab vedotin in all countries in North and South America, and Astellas will commercialize in rest of the world, including Europe, Asia, Australia and Africa. The agreement is intended to provide that we and Astellas will effectively share equally 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 cost and profit share for both parties.

Either party may opt out of co-development and profit-sharing in return for receiving milestones and royalties from the continuing party.

Genmab

We have an agreement with Genmab to develop and commercialize ADCs for the treatment of several types of cancer, under which we exercised a co-development option for tisotumab vedotin in August 2017. We and Genmab will share all costs and potential future 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 $33.8 million and $6.8 million for the years ended December 31, 2018 and 2017, respectively.

We will be responsible for tisotumab vedotin commercialization activities in the U.S., Canada, and Mexico, while 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.

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Either party may opt out of co-development and profit-sharing in return for receiving milestones and royalties from the continuing party.

Unum

We have an agreement with Unum to develop and commercialize novel antibody-coupled T-cell receptor, or ACTR, therapies for cancer. We and Unum are developing two ACTR product candidates combining Unum’s ACTR technology with our antibodies. Unum is conducting research and clinical development activities through phase 1 clinical trials, and we are providing funding for these activities. The agreement calls for us and Unum to co-develop and jointly fund programs after phase 1 clinical trials unless either company opts out. Costs associated with these co-development activities are included in research and development expense and amounted to $6.2 million, $8.5 million, and $5.3 million for the years ended December 31, 2018, 2017, and 2016, respectively.

We and Unum would co-commercialize any co-developed product candidates and share any profits equally in the U.S. We have exclusive commercial rights outside of the U.S., potentially owing Unum a royalty that is a high single digit to mid-teens percentage of ex-U.S. sales.

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The potential future licensing and progress-dependent milestone payments to Unum under the collaboration may total up to $400.0 million for the ACTR programs, payment of which is triggered by the achievement of development, regulatory and commercial milestones. In addition and as disclosed in Note 5, we made an equity investment in Unum under the terms of this agreement at the time of its execution.

Other collaboration agreements

We have other active ADC collaborations with a number of companies to allow them to use our proprietary ADC technology. Under these collaborations, which we have entered into in the ordinary course of business, we have granted research and commercial licenses to use our technology in conjunction with the collaborator's technology. We also have agreed to conduct limited development activities and to provide other materials, supplies and services to our ADC collaborators during the performance obligation period of the collaboration. We receive upfront cash payments, progress- and sales-dependent milestones for the achievement by our collaborators 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 ADC collaborators 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.

In February 2018, we executed an agreement with Pieris to develop novel potential treatments of cancer based on bispecifics incorporating our proprietary antibodies and Pieris' proprietary technology designed to stimulate an antibody-directed immune response against solid tumors and blood cancers. Pieris is conducting preclinical research, and we are providing funding for these activities. Following this research phase, we will have the option to select up to three product candidates for further development. We would develop the product candidates independently, subject to a limited opt in right by Pieris. Under that opt in right, we and Pieris would co-develop and co-commercialize one of the product candidates and share equally in costs and profits associated with that co-developed product candidate. Pieris would be responsible for commercialization in the U.S., and we would be responsible for commercialization in all other territories. For any commercialized product candidates that we developed independently, we would owe Pieris royalties in the mid-single to low-double digits. Under the terms of the agreement, we paid Pieris a $30.0 million upfront fee in 2018, which was recorded in research and development expenses. The potential future licensing and progress-dependent milestone payments to Pieris under the collaboration for the three product candidates total up to $1.2 billion based on the achievement of development, regulatory and commercial milestones.

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 are obligated to make future minimum payments under operating leases for building space used for general office and research and development purposes. The leases expire between 2019 through 2029 and include options to renew at the then fair market rental for the facilities. The lease agreements typically contain scheduled rent increases and provide for tenant improvement allowances. Assuming we do not exercise any extensions, future minimum lease payments under all non-cancelable operating leases are set forth below.

In addition, we have certain non-cancelable obligations under other agreements, including supply agreements relating to the manufacture of ADCETRIS and our product candidates which contain annual minimum purchase commitments

and other firm commitments when a binding forecast is provided.

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Notes to Consolidated Financial Statements (Continued)

As of December 31, 2018, our future obligations related to building leases and supply and other agreements are as follows (in thousands):

	Building Leases	Supply and Other Agreements
Years ending December 31,		
2019	$10,332	$92,105
2020	11,863	30,689
2021	12,770	31,091
2022	12,288	24,033
2023	12,142	21,720
Thereafter	30,517	43,440
Total	$89,912	$243,078

Rent expense attributable to non-cancelable operating leases totaled approximately $8.7 million, $6.6 million, and $5.6 million for the years ended December 31, 2018, 2017, and 2016, respectively. We entered into various operating leases for building space in 2018, with lease commencement dates in 2019. Future obligations related to those leases are included in the table above but no rent expense has been recognized in 2018.

Non-cancelable obligations under other agreements do not include payments that are contingent upon achievement of certain progress-dependent milestones, as well as the payment of 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.

Contingencies. On March 29, 2017, a stockholder derivative lawsuit, or the Stockholder Derivative Action, was filed in Washington Superior Court for the County of Snohomish, or the Snohomish County Superior Court. The complaint named as defendants certain of our current and former executives and members of our board of directors. We were named as a nominal defendant. The Stockholder Derivative Action was largely based on a January 2017 securities class action suit, or the CD33A Class Action, that was filed in the United States District Court for the Western District of Washington and which alleged material misrepresentations and omissions in public statements regarding our business, operational and compliance policies, as well as violations of Sections 10(b) and 20(b) of the Securities Exchange Act. Following the dismissal with prejudice of the CD33A Class Action, on August 30, 2018, the plaintiffs in the Stockholder Derivative Action filed an amended complaint. This complaint alleged that the defendants breached their fiduciary duties by making or failing to correct certain allegedly improper public statements regarding our former SGN-CD33A program and by wasting our assets by allowing certain SGN-CD33A trials to continue. On October 4, 2018, we filed a motion to dismiss the amended complaint for failure to plead demand futility. On November 15, 2018, the plaintiffs voluntarily dismissed their complaint with prejudice as to plaintiffs.

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 the Cascadian Acquisition. We filed our answer to this complaint on March 28, 2018. As a result of this lawsuit, we may incur litigation and indemnification 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. 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.

At December 31, 2018, shares of common stock reserved for future issuance are as follows (in thousands):

Stock options and RSUs outstanding	13,795
Shares available for future grant under the 2007 Equity Incentive Plan	6,776
Employee stock purchase plan shares available for future issuance	383
Total	20,954

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 May 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, 2018, 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 granted with time-based vesting requirements or, in connection with our LTIPs, vesting upon achievement of pre-determined regulatory milestones.

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 beginning of the vesting period and thereafter ratably each month over the following thirty-six months. Generally, RSUs granted to employees prior to August 2018 vest 100% on the third anniversary of the beginning of the vesting period, and subsequent grants 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 options and RSUs granted in connection with our LTIPs varies by plan but generally includes a portion that vests upon achievement of pre-determined regulatory milestones and a portion that vests based upon 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 $78.9 million, $63.8 million, and $52.5 million for the years ended December 31, 2018, 2017, and 2016, 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 full valuation allowance to offset all of the potential tax benefits associated with its deferred tax assets. During 2018, 2017, and 2016, $1.0 million, $1.3 million, and $1.0 million of share-based compensation expense was included in production overhead used in the determination of inventory cost, respectively.

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Notes to Consolidated Financial Statements (Continued)

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,		
	2018	2017	2016	2018	2017	2016
Risk-free interest rate	2.8%	1.8%	1.3%	1.67%	0.76%	0.35%
Expected lives in years	5.6	5.7	6.5	0.5	0.5	0.5
Expected dividends	0%	0%	0%	0%	0%	0%
Expected volatility	42%	42%	44%	36%	46%	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, 2017	11,510,161	$ 34.32		
Granted	1,645,938	$ 71.83		
Exercised	(1,799,791)	$ 25.54		
Forfeited/expired	(481,196)	$ 43.77		
Balance at December 31, 2018	10,875,112	$ 41.03	6.11	$ 196,916
Expected to vest	10,490,591	$ 40.44	6.01	$ 194,027
Options exercisable	6,729,510	$ 32.55	4.59	$ 163,278

The weighted average grant-date fair values of options granted with exercise prices equal to market were $30.77, $20.34, and $18.20 for the years ended December 31, 2018, 2017, and 2016, 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, 2018. The aggregate intrinsic value of options exercised was $73.3 million during 2018, $52.9 million during 2017, and $61.4 million during 2016, determined as of the date of option exercise. As of December 31, 2018, there was approximately $49.5 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 1.42 years. We utilize newly issued shares to satisfy option exercises.

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Notes to Consolidated Financial Statements (Continued)

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, 2017	2,191,350	$ 45.46
Granted	1,339,322	$ 70.78
Vested	(591,872)	$ 40.52
Forfeited	(258,559)	$ 46.45
Non-vested at December 31, 2018	2,680,241	$ 59.11

The weighted average grant-date fair values of RSUs granted were $70.78, $50.12, and $44.72 for the years ended December 31, 2018, 2017, and 2016, respectively. The total fair value of RSUs that vested during 2018, 2017, and 2016 (measured on the date of vesting) was $42.4 million, $27.5 million, and $23.3 million, respectively. As of December 31, 2018, there was approximately $86.3 million of total unrecognized compensation cost related to non-vested RSU awards that will be recognized as expense over a weighted-average period of 1.61 years. We utilize newly issued shares for RSUs that vest.

LTIP equity activity

We have various LTIPs related to certain development goals of our product candidates, which contain performance-based equity compensation. During 2018, an LTIP milestone was achieved related to the U.S. 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.

Pursuant to one of the other LTIPs, RSUs were granted to eligible participants in November 2018. If the pre-determined regulatory milestone is achieved, the underlying shares will vest, and a second tranche of RSUs will be granted subject to a time-based vesting requirement. 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, 2017	—	$ —
Granted	242,328	$ 58.14
Vested	—	$ —
Forfeited	(2,511)	$ 58.14
Non-vested at December 31, 2018	239,817	$ 58.14

As of December 31, 2018, the estimated unrecognized compensation cost related to all LTIPs was $63.5 million.

Employee Stock Purchase Plan

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

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 $7.7 million in 2018, $5.7 million in 2017, and $4.7 million in 2016.

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Seattle Genetics, Inc.
Notes to Consolidated Financial Statements (Continued)

18. Quarterly financial data (unaudited)

The unaudited quarterly financial information should be read in conjunction with the 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 (in thousands, except per share data):

	Three months ended			
	March 31,	June 30,	September 30,	December 31,
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)
2017				
Total revenues	$109,131	$108,223	$ 135,291	$ 129,605
Net income (loss)	$(59,990)	$(56,360)	$ 50,021	$ (59,201)
Net income (loss) per share - basic	$(0.42)	$(0.39)	$ 0.35	$ (0.41)
Net income (loss) per share - diluted	$(0.42)	$(0.39)	$ 0.34	$ (0.41)

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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.

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, 2018 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, 2018.

The effectiveness of our internal control over financial reporting as of December 31, 2018 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included in Item 8 in this Annual Report on Form 10-K.

Item 9B. Other Information

Amendment to Senior Executive Bonus Plan

To reflect market practice among peer companies and further align pay with performance, the Compensation Committee of our Board of Directors, or the Compensation Committee, amended our Senior Executive Annual Bonus Plan, or the Plan, on February 4, 2019 to (i) increase the maximum Company and individual performance percentages from 150% to 200% in the event that the Company or the individual exceeds expected goals or performance for any Plan year and (ii) provide that if a participant's individual performance percentage for any Plan year is less than 100%, then regardless of the actual Company performance percentage, in calculating such participant's final bonus payout, the Company performance percentage will be capped at the participant's individual performance percentage. All other material terms of the Plan remain unchanged. Under the Plan, which is administered by the Compensation Committee, executives at the Vice President level or higher are eligible to receive an annual performance-based cash bonus for each calendar year based on the achievement of specified Company goals and, as applicable, an assessment of individual performance. The above description of the amendments to the Plan is only a brief summary of such amendments, does not purport to be complete, and is qualified in its entirety by reference to the Plan, as amended, which is filed as Exhibit 10.69 to this Annual Report on Form 10-K.

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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 2018 fiscal year pursuant to Regulation 14A for our 2019 Annual Meeting of Stockholders, or the 2019 Proxy Statement, and the information to be included in the 2019 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 2019 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—Certain Other Corporate Governance Matters—Code of Ethics” appearing in the 2019 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 “Section 16(a) Beneficial Ownership Reporting Compliance” appearing in the 2019 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 2019 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 2019 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 2019 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 2019 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” appearing in the 2019 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. 2—Ratification of Appointment of Independent Registered Public Accounting Firm” appearing in the 2019 Proxy Statement. Such information is incorporated herein by reference.

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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		Incorporation By Reference			
Number	Exhibit Description	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	11/25/2015
4.1	Specimen Stock Certificate.	S-1/A	333-50266	4.1	2/8/2001
4.2	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
4.3	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	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
10.2	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
10.3	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
10.4†	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
10.5	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
10.6	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
10.7†	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

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Exhibit Number	Exhibit Description	Incorporation By Reference Form	SEC File No.	Exhibit	Filing Date
10.8	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
10.9	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
10.10†	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
10.11†	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
10.12†	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
10.13†	Office Lease dated May 9, 2011 between Seattle Genetics, Inc. and WCM Highlands II, LLC.	10-Q	000-32405	10.1	8/5/2011
10.14†	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
10.15†	Collaboration and License Agreement dated January 7, 2007 between Seattle Genetics, Inc. and Agensys, Inc.	10-Q	000-32405	10.1	5/8/2007
10.16†	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
10.17†	Collaboration Agreement between Seattle Genetics, Inc. and Millennium Pharmaceuticals, Inc. (a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited) dated December 14, 2009.	10-K	000-32405	10.50	3/12/2010
10.18†	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
10.19†	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
10.20†	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
10.21	Development and Supply Agreement dated February 23, 2004 between Seattle Genetics, Inc. and Abbott Laboratories.	10-K	000-32405	10.15	2/27/2015
10.22†	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
10.23†	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
10.24†	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
10.25†		10-Q	000-32405	10.6	11/4/2011

Fourth Amendment to Development and Supply Agreement dated April 18, 2010 between Seattle Genetics, Inc. and Abbott Laboratories, Inc.	

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Exhibit Number	Exhibit Description	Incorporation By Reference Form	SEC File No.	Exhibit	Filing Date
10.26†	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
10.27†	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
10.28†	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
10.29†	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
10.30†	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
10.31†	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
10.32	Stock Purchase Agreement, dated February 10, 2017 between Seattle Genetics, Inc. and Immunomedics, Inc	10-Q	000-32405	10.4	5/1/2017
10.33	Registration Rights Agreement, dated February 10, 2017 between Seattle Genetics, Inc. and Immunomedics, Inc	10-Q	000-32405	10.5	5/1/2017
10.34	Immunomedics, Inc. Common Stock Purchase Warrant, dated February 16, 2017	10-Q	000-32405	10.6	5/1/2017
10.35	Warrant Agreement, dated February 16, 2017, between Immunomedics, Inc. and Broadridge Corporate Issuer Solutions, Inc., as Warrant Agent	10-Q	000-32405	10.7	5/1/2017
10.36†	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
10.37	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
10.38†	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
10.39	License Agreement between Cascadian Therapeutics, Inc. and Array BioPharma Inc. dated December 11, 2014.	10-Q	000-32405	10.1	4/26/2018
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 1998 Stock Option Plan, effective as of August 5, 2009.	10-Q	000-32405	10.1	8/10/2009
10.42*	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
10.43*	2000 Directors' Stock Option Plan, as amended February 5, 2010.	10-K	000-32405	10.13	3/12/2010
10.44*	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
10.45*		10-K	000-32405	10.35	2/21/2017

Amended and Restated 2000 Employee Stock Purchase Plan, effective May 20, 2011.

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Exhibit Number	Exhibit Description	Incorporation By Reference Form	SEC File No.	Exhibit	Filing Date
10.46*	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
10.47*	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
10.48*	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
10.49*	Form Stock Option Agreement for employees under Seattle Genetics, Inc. 2007 Equity Incentive Plan.	10-K	000-32405	10.44	3/13/2009
10.50*	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
10.51*	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
10.52*	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
10.53*	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*	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	10.3	7/26/2018
10.55*	Form of Stock Unit Grant Notice and Stock Unit Agreement for non-employee directors under the Amended and Restated 2007 Equity Incentive Plan.	10-Q	000-32405	10.4	7/26/2018
10.56*	Form of Stock Option Agreement for Non-US Participants under the Amended and Restated 2007 Equity Incentive Plan.	10-Q	000-32405	10.5	7/26/2018
10.57*	Form of Stock Unit Grant Notice and Stock Unit Agreement for non-US participants under the Amended and Restated 2007 Equity Incentive Plan.	10-Q	000-32405	10.6	7/26/2018
10.58*	Form of Performance-Based Stock Option Agreement for employees under Seattle Genetics, Inc. 2007 Equity Incentive Plan.	10-Q	000-32405	10.7	7/26/2018
10.59*	Form of Time-Based Stock Option Agreement for employees under Seattle Genetics, Inc. 2007 Equity Incentive Plan.	10-Q	000-32405	10.8	7/26/2018
10.60*	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.	10-Q	000-32405	10.9	7/26/2018
10.61*	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.	10-Q	000-32405	10.10	7/26/2018
10.62*	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
10.63*		10-Q	000-32405	10.2	10/26/2018

Amended and Restated Employment Agreement dated October 25, 2018, between Seattle Genetics, Inc. and Todd Simpson.

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Exhibit Number	Exhibit Description	Incorporation By Reference Form	SEC File No.	Exhibit	Filing Date
10.64*	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
10.65*	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
10.66*	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
10.67*	Amended and Restated Employment Agreement dated October 25, 2018, between Seattle Genetics, Inc. and Jean Liu.	10-Q	000-32405	10.60	10/26/2018
10.68*	Seattle Genetics, Inc. Senior Executive Annual Bonus Plan, effective January 1, 2017.	8-K	000-32405	10.1	2/1/2017
10.69*+	Seattle Genetics, Inc. Senior Executive Annual Bonus Plan, effective February 4, 2019.	—	—	—	—
10.70*	Seattle Genetics, Inc. Long Term Incentive Plan for ECHELON-1.	10-Q	000-32405	10.2	7/26/2016
10.71*	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
10.72*	Seattle Genetics, Inc. Long Term Incentive Plan for TV and EV.	10-Q	000-32405	10.4	11/6/2017
10.73*	Form of Stock Unit Grant Notice for Long Term Incentive Plan for TV and EV.	10-Q	000-32405	10.5	11/6/2017
10.74*	Form of Stock Unit Grant Notice for Non-US Participants Long Term Incentive Plan.	10-Q	000-32405	10.6	11/6/2017
10.75*	Seattle Genetics, Inc. Long Term Incentive Plan for Tucatinib.	10-Q	000-32405	10.7	10/26/2018
10.76*	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
10.77*	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
10.78*	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
10.79*	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
10.80*	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

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Exhibit Number	Exhibit Description	Incorporation By Reference Form	SEC File No.	Exhibit	Filing Date
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.INS+	XBRL Instance Document	—	—	—	—
101.SCH+	XBRL Taxonomy Extension Schema Document.	—	—	—	—
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	—
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	—
101.LAB+	XBRL Taxonomy Extension Labels Linkbase Document	—	—	—	—
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	—

+ 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.

* 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

Not applicable.

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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 7, 2019 By: /S/ CLAY B. SIEGALL
Clay B. Siegall
President & Chief Executive Officer
(Principal Executive Officer)

Date: February 7, 2019 By: /S/ TODD E. SIMPSON
Todd E. Simpson
Chief Financial Officer
(Principal Financial and Accounting Officer)

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

Signature	Title	Date
/S/ CLAY B. SIEGALL Clay B. Siegall	Director, President & CEO (Principal Executive Officer)	February 7, 2019
/S/ TODD E. SIMPSON Todd E. Simpson	Chief Financial Officer (Principal Financial and Accounting Officer)	February 7, 2019
/S/ SRINIVAS AKKARAJU Srinivas Akkaraju	Director	February 7, 2019
/S/ FELIX J. BAKER Felix J. Baker	Director	February 7, 2019
/S/ DAVID W. GRYSKA David W. Gryska	Director	February 7, 2019
/S/ MARC E. LIPPMAN Marc E. Lippman	Director	February 7, 2019
/S/ JOHN A. ORWIN John A. Orwin	Director	February 7, 2019
/S/ Alpna Seth		

Alpna Seth	Director	February 7, 2019
/S/ NANCY A. SIMONIAN Nancy A. Simonian	Director	February 7, 2019
/S/ DANIEL G. WELCH Daniel G. Welch	Director	February 7, 2019