SEATTLE GENETICS INC /WA
Form 10-K
February 27, 2015
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# Form 10-K

**(Mark One)**

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

**For the fiscal year ended December 31, 2014**

**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 x 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 x

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 x NO ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 x 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, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

| | |
|---|---|
| Large accelerated filer x | Accelerated filer ¨ |
| Non-accelerated filer ¨ (Do not check if smaller reporting company) | Smaller reporting company ¨ |

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ¨ NO x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $3,828,736,451 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 23,245,672 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 124,318,682 shares of the registrant s Common Stock issued and outstanding as of February 23, 2015.

**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 2015 Annual Meeting of Stockholders.

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**SEATTLE GENETICS, INC.**

**FORM 10-K**

**FOR THE YEAR ENDED DECEMBER 31, 2014**

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**PART I**

***This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as may, might, will, should, expect, plan, anticipate, project, believe, estimate, predict, potential, intend or continue, the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. 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 under the heading Item 1A Risk Factors. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.***

**Item 1. Business**

**Overview**

Seattle Genetics is a biotechnology company focused on the development and commercialization of targeted therapies for the treatment of cancer. Our marketed product ADCETRIS®, or brentuximab vedotin, is an antibody-drug conjugate, or ADC, comprising an anti-CD30 monoclonal antibody attached by a protease-cleavable linker to a microtubule disrupting agent, monomethyl auristatin E (MMAE), utilizing our proprietary technology. ADCETRIS received accelerated approval in the United States in August 2011, conditional marketing authorization in the European Union in October 2012 and approval with conditions in Canada in February 2013 for patients with relapsed Hodgkin lymphoma or relapsed systemic anaplastic large cell lymphoma, or sALCL. We are collaborating with Takeda Pharmaceutical Company Limited, or Takeda, to develop and commercialize ADCETRIS on a global basis. Under this collaboration, Seattle Genetics retains commercial rights for ADCETRIS in the United States and its territories and in Canada, and Takeda has commercial rights in the rest of the world. ADCETRIS is now approved in 50 countries, including those described above, as well as Japan, Australia, Switzerland, South Korea, Singapore and Mexico, and Takeda continues to pursue marketing authorizations in multiple other countries. Beyond our current labeled indications, we and Takeda have a broad development strategy for ADCETRIS evaluating its potential application in earlier lines of therapy for patients with Hodgkin lymphoma or mature T-cell lymphoma, or MTCL, including sALCL and in other CD30-positive malignancies.

On September 29, 2014, we and Takeda announced positive top line data from our AETHERA trial, a randomized, double-blind, placebo-controlled phase 3 clinical trial that evaluated ADCETRIS versus placebo in 329 patients with Hodgkin lymphoma at risk of relapse following autologous stem cell transplant, or ASCT. The AETHERA trial met its primary endpoint with ADCETRIS treatment resulting in a statistically significant improvement in progression-free survival, or PFS, versus placebo, as assessed by an independent central review committee (hazard ratio=0.57; p-value=0.001). At the December 2014 American Society of Hematology, or ASH, annual meeting, we announced the median PFS per independent review facility was 43 months for patients who received ADCETRIS versus 24 months for patients who received placebo. A pre-specified interim analysis of overall survival, a secondary endpoint in the trial, showed no statistically significant difference between the treatment arms. Patients on both study arms with progression of Hodgkin lymphoma may have received a variety of subsequent therapies. In the placebo arm, 72 of 85 patients (85 percent) receiving subsequent therapy were

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treated with single agent ADCETRIS. Notably, in the ADCETRIS arm, only eight of 51 patients (16 percent) receiving subsequent therapy were treated with ADCETRIS following relapse. A further analysis of overall survival is planned in 2016. The safety profile of ADCETRIS in the AETHERA trial was generally consistent with the existing prescribing information. The AETHERA trial was not conducted under a Special Protocol Assessment, or SPA, agreement from the U.S. Food and Drug Administration, or FDA, and has not been designated as a confirmatory trial to convert either accelerated approval or conditional marketing authorization to regular approval; however, this trial provides drug safety data analyses that fulfills one of our post-approval requirements with both the FDA and the European Medicines Agency, or EMA. ADCETRIS is not currently approved in the AETHERA treatment setting. Based upon the positive PFS outcome of the AETHERA trial, we recently submitted a supplemental Biologics License Application, or sBLA, to the FDA to seek approval for a new indication in the AETHERA treatment setting.

We and Takeda are conducting three additional phase 3 clinical trials of ADCETRIS, one in relapsed cutaneous T-cell lymphoma, or CTCL, called the ALCANZA trial, one in frontline advanced classical Hodgkin lymphoma, called the ECHELON-1 trial, and one in frontline MTCL, called the ECHELON-2 trial. We have entered into SPA agreements with the FDA for the ALCANZA, ECHELON-1 and ECHELON-2 trials and we also received scientific advice from the EMA with respect to these trials. An SPA is an agreement with the FDA regarding the design of the clinical trial, including size and clinical endpoints, to support an efficacy claim in a Biologics License Application, or BLA, submission to the FDA if the trial achieves its primary endpoints. The ECHELON-1 and ECHELON-2 trials would fulfill post-approval commitment obligations for ADCETRIS regarding drug efficacy, and positive results from either trial would form the basis for a submission to potentially convert the approval of ADCETRIS in the United States from accelerated approval to regular approval in its currently approved indications. The primary endpoint in the ECHELON-1 and ECHELON-2 trials is PFS per independent review facility assessment in patients treated with ADCETRIS compared to that achieved with therapy in the control arm. Given PFS trends in our phase 1 data combining ADCETRIS with standard chemotherapy regimens and the positive PFS outcome in the AETHERA trial, we and Takeda are evaluating the potential that event rates may be slower than expected in both the ECHELON-1 and ECHELON-2 trials and are in discussions with appropriate regulatory agencies on proposed trial modifications. Depending on the modifications, if any, agreed upon with the appropriate regulatory agencies, our ability to successfully complete these trials on a timely basis could be adversely affected. In this regard, earlier analysis or other trial modifications of either or both of the ECHELON-1 and ECHELON-2 trials could potentially make demonstrating a statistically significant improvement in PFS in these trials more difficult. The primary endpoint in the ALCANZA trial is overall response rate lasting at least four months in patients treated with ADCETRIS compared to that achieved with therapy in the control arm.

In addition to ADCETRIS, our pipeline includes six clinical-stage ADC programs consisting of SGN-CD33A, SGN-CD19A, SGN-LIV1A, SGN-CD70A, ASG-22ME, and ASG-15ME, and SEA-CD40, which is based on our sugar-engineered antibody, or SEA, technology. In addition, we have multiple preclinical and research-stage programs that employ our proprietary technologies. We also 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; Pfizer, Inc., or Pfizer; PSMA Development Company LLC, a subsidiary of Progenics Pharmaceuticals Inc., or Progenics; and Takeda; as well as ADC co-development agreements with Agensys, Inc., an affiliate of Astellas Pharma, Inc., or Agensys; Genmab A/S, or Genmab; and Oxford BioTherapeutics Ltd., or OBT.

**Our Antibody-Drug Conjugate (ADC) Technologies**

ADCETRIS and our pipeline of clinical-stage monoclonal antibody-based product candidates 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

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then results in the desired activity, specific killing of the target cell. A key component of our ADCs is the linker that attaches the cell-killing agent to the monoclonal antibody, which is 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 ADCs use proprietary auristatins, which are microtubule disrupting agents, or pyrrolobenzodiazepine, or PBD, dimers, which are DNA cross-linkers, as cell-killing agents. The PBD dimer cell killing agent is stably linked to an antibody using our proprietary, site-specific conjugation technology, resulting in uniform drug-loading of two PBD dimers per antibody. We call this engineered antibody an EC-mAb. 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. ADCETRIS, SGN-CD33A, SGN-CD19A, SGN-LIV1A, SGN-CD70A, ASG-22ME, and ASG-15ME all utilize our proprietary, auristatin-based or PBD-based ADC technology, and this technology is also the basis of our corporate 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**

We have also developed our proprietary SEA technology, which is a method to selectively reduce fucose incorporation in monoclonal antibodies, which we believe 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 is 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-CD40 is a clinical-stage non-fucosylated monoclonal antibody developed using SEA technology. Enhanced binding to effector cells results in crosslinking and activation of CD40 signaling in immune cells. We hypothesize that this increased stimulation of the patient s own immune cells may result in meaningful antitumor activity. We are developing SEA-CD40 as a novel immuno-oncology agent and recently announced initiation of a phase 1 clinical trial of SEA-CD40 for solid tumors.

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. For unconjugated antibodies, we seek intrinsic antitumor activity through direct signaling and/or effector functions and lowered risk of adverse events or immune response. 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 and could also increase toxicity.

**Our Strategy**

Our strategy is to become a leading developer and marketer of targeted therapies for cancer. Key elements of our strategy are to:

*Successfully Execute ADCETRIS Commercial Plan.* An important near-term objective is to continue to execute our ADCETRIS commercial plan by maintaining or increasing market penetration and continuing to drive duration of therapy, consistent with the current ADCETRIS label. We continue to

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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. In addition, as of January 31, 2015, ADCETRIS had received marketing authorizations in relapsed Hodgkin lymphoma and sALCL by regulatory authorities in 50 countries, and we are continuing to support Takeda s efforts to obtain regulatory approvals and conduct commercial launches in many other countries worldwide.

*Expand the Therapeutic Potential of ADCETRIS.* We believe ADCETRIS may have applications in earlier lines of therapy for Hodgkin lymphoma and MTCL and in other types of CD30-positive cancers. In September 2014, we and Takeda announced positive data from our phase 3 AETHERA trial that evaluated ADCETRIS versus placebo, in 329 patients with Hodgkin lymphoma at risk of relapse following ASCT. Based upon the positive PFS outcome of the AETHERA trial, we recently submitted an sBLA to the FDA to seek approval for a new indication in the AETHERA treatment setting. We have reported encouraging data and we also have ongoing clinical trials evaluating ADCETRIS in earlier lines of therapy for Hodgkin lymphoma (the ECHELON-1 trial), MTCL (the ECHELON-2 trial), and in other types of CD30-positive lymphoma such as CTCL (the ALCANZA trial), peripheral T-cell lymphoma and some types of B-cell lymphomas including diffuse large B-cell lymphoma, or DLBCL. Clinical trials are also being conducted by us and as investigator sponsored trials in different CD30-positive indications, including CTCL, salvage therapy for patients with Hodgkin lymphoma prior to autologous hematopoietic cell transplant, novel combinations of ADCETRIS plus other anticancer agents, graft versus host disease and other areas of medical and scientific interest.

*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, particularly SGN-CD33A, SGN-CD19A, SGN-LIV1A, SGN-CD70A, SEA-CD40, ASG-22ME, and ASG-15ME, as well as multiple preclinical programs and research-stage programs that employ our proprietary technologies. In addition, we have ADC co-development agreements with Genmab and OBT that provide us with future ADC product opportunities.

*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, including SGN-CD33A, SGN-CD19A, SGN-LIV1A, SGN-CD70A, ASG-22ME, and ASG-15ME and multiple preclinical and research-stage programs that employ our proprietary technologies. We also license our ADC technology to biotechnology and pharmaceutical companies to generate near-term collaboration revenues and funding, as well as potential future milestones and royalties. Presently, we have active ADC collaborations with AbbVie, Bayer, Celldex, Genentech, GSK, Takeda, Pfizer and Progenics, as well as ADC co-development agreements with Agensys, Genmab and OBT. These ADC collaboration and co-development agreements have generated over $300 million as of December 31, 2014 through a combination of upfront payments, research support, and other fees, milestone payments and equity purchases.

*Support Future Growth of our Pipeline through Internal Research Efforts and Strategic In-Licensing.* We have internal research programs directed toward 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 in-license from biotechnology and pharmaceutical companies and academic institutions. We have license agreements with Bristol-Myers Squibb Corporation, or BMS, and the University of Miami, among others, which provide us with access to technology used in our commercial and development programs. We also have active research collaborations with other biotechnology companies and academic institutions to help advance our technology.

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*Enter into Strategic Product Collaborations to Generate Capital and Supplement our Internal Resources.* We enter into collaborations to broaden and accelerate clinical trial development and potential commercialization of our product candidates. Collaborations can generate significant capital, supplement our own internal expertise in key areas such as manufacturing, regulatory affairs and clinical development, and provide us with access to our collaborators marketing, sales and distribution capabilities in specific territories. When establishing strategic collaborations, we seek beneficial financial terms and endeavor to retain significant product rights, including seeking to retain product rights in the United States and Europe.

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**ADCETRIS and Product Candidate Development Pipeline**

The following table summarizes our ADCETRIS and product candidate development pipeline:

| Name of Product or Product Candidate | Description | Commercial Rights | Status |
|---|---|---|---|
| ADCETRIS® | Anti-CD30 ADC | Seattle Genetics in United States and Canada; Takeda in rest of world | ADCETRIS received accelerated approval in the United States in 2011, conditional marketing authorization in the European Union in 2012, approval with conditions in Canada in 2013 and marketing authorization in Japan in 2014, among other countries, for patients with relapsed Hodgkin lymphoma or relapsed sALCL. As of January 31, 2015, ADCETRIS had received marketing authorizations in relapsed Hodgkin lymphoma or relapsed sALCL by regulatory authorities in 50 countries. |
| | | | AETHERA phase 3 randomized trial ongoing for patients with Hodgkin lymphoma at risk of relapse following ASCT. Based upon the positive PFS outcome of the AETHERA trial, we recently submitted an sBLA to the FDA to seek approval for a new indication in the AETHERA treatment setting. |
| | | | ECHELON-1 phase 3 randomized frontline trial ongoing for patients with advanced classical Hodgkin lymphoma comparing Adriamycin, vinblastine, bleomycin and dacarbazine, or ABVD, versus AVD plus ADCETRIS. |
| | | | ECHELON-2 phase 3 randomized frontline trial ongoing for patients with CD30-positive MTCL, including sALCL, comparing cyclophosphamide, doxorubicin (hydroxydaunorubicin), Oncovin (vincristine) and prednisone, or CHOP, versus CHP plus ADCETRIS. |
| | | | ALCANZA phase 3 randomized trial ongoing for relapsed CD30-positive CTCL patients, comparing ADCETRIS versus investigator s choice of methotrexate or bexarotene. |
| | | | Phase 2 trial ongoing for patients with relapsed or refractory CD30-positive non-Hodgkin lymphomas, including DLBCL, peripheral T-cell lymphoma and other less common lymphoma subtypes (but excluding sALCL). |

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| Name of Product or Product Candidate | Description | Commercial Rights | Status |
|---|---|---|---|
| | | | Phase 2 trial ongoing for patients age 60 or older with newly diagnosed Hodgkin lymphoma evaluating ADCETRIS as a frontline monotherapy. In addition, the trial was subsequently amended to include the administration of ADCETRIS in combination with bendamustine or dacarbazine. |
| | | | Phase 1/2 second-line trial ongoing for patients with relapsed Hodgkin lymphoma evaluating ADCETRIS in combination with bendamustine. |
| | | | Phase 2 frontline trial ongoing for patients with DLBCL evaluating ADCETRIS in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone, or R-CHOP. The trial was subsequently amended to include evaluation of ADCETRIS in combination with cyclophosphamide, doxorubicin, and prednisone in CD30-positive patients with DLBCL. |
| SGN-CD33A | Anti-CD33 ADC | Seattle Genetics | Phase 1 trial ongoing for patients with acute myeloid leukemia, or AML. This trial includes single-agent as well as combination with hypomethylating agents. |
| | | | Phase 1b trial ongoing for patients with newly diagnosed AML evaluating SGN-CD33A administered in combination with frontline standard of care regimens for induction (cytarabine and daunorubicin) and/or consolidation therapy (cytarabine). In addition, the study will evaluate single-agent SGN-CD33A as a maintenance regimen. |
| SGN-CD19A | Anti-CD19 ADC | Seattle Genetics | Two phase 1 trials ongoing for relapsed or refractory B-cell non-Hodgkin lymphomas and relapsed or refractory B-cell acute lymphoblastic leukemia. |
| SGN-LIV1A | Anti-LIV1 ADC | Seattle Genetics | Phase 1 trial ongoing for patients with LIV-1-positive metastatic breast cancer. |
| SGN-CD70A | Anti-CD70 ADC | Seattle Genetics | Phase 1 trial ongoing for patients with CD70-positive non-Hodgkin lymphoma or metastatic renal cell carcinoma. |
| SEA-CD40 | Anti-CD40 SEA empowered antibody | Seattle Genetics | Phase 1 trial ongoing for patients with CD40-positive solid tumors. |

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| Name of Product or Product Candidate | Description | Commercial Rights | Status |
|---|---|---|---|
| ASG-22ME | Anti-Nectin-4 ADC | 50:50 co-development and commercialization with Agensys | Phase 1 trial ongoing for Nectin-4-positive solid tumors. |
| ASG-15ME | Anti-SLITRK6 ADC | 50:50 co-development and commercialization with Agensys | Phase 1 trial ongoing for patients with bladder cancer. |

***ADCETRIS***

ADCETRIS is an ADC comprising an anti-CD30 monoclonal antibody attached by a protease-cleavable linker to a proprietary microtubule disrupting agent, monomethyl auristatin E (MMAE). ADCETRIS employs a linker system that is designed to be stable in the bloodstream and to release MMAE upon internalization into CD30-positive 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 retain

commercial rights in the United States and Canada. Takeda has exclusive rights to commercialize ADCETRIS in the rest of the world. ADCETRIS has received regulatory approvals as follows:

United States. In August 2011, the FDA granted accelerated approval of ADCETRIS in two indications: (1) the treatment of patients with Hodgkin lymphoma after failure of ASCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates and (2) the treatment of patients with sALCL, after failure of at least one prior multi-agent chemotherapy regimen. The indications for ADCETRIS are approved under accelerated approval based on overall response rate. An improvement in patient-reported outcomes or survival has not been established. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Canada. In February 2013, Health Canada issued a Notice of Compliance with conditions, authorizing marketing of ADCETRIS for two lymphoma indications: (1) the treatment of patients with Hodgkin lymphoma after failure of ASCT or after failure of at least two multi-agent chemotherapy regimens in patients who are not ASCT candidates, and (2) the treatment of patients with sALCL after failure of at least one multi-agent chemotherapy regimen. The indications for ADCETRIS were authorized based on promising response rates demonstrated in single-arm trials. No data demonstrate increased survival with ADCETRIS.

European Union. In October 2012, the European Commission granted conditional marketing authorization of ADCETRIS for the treatment of adult patients with relapsed or refractory CD30-positive Hodgkin lymphoma: (1) following ASCT, or (2) following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option. In addition, ADCETRIS was indicated for the treatment of adult patients with relapsed or refractory sALCL.

Worldwide. As of January 31, 2015, ADCETRIS had received marketing authorization in relapsed Hodgkin lymphoma and relapsed sALCL by regulatory authorities in 50 countries.

In addition, we and Takeda recently announced positive data from our AETHERA trial, a randomized, double-blind, placebo-controlled phase 3 clinical trial that evaluated ADCETRIS versus placebo, in 329 patients with Hodgkin lymphoma at risk of relapse following ASCT. Based upon the positive PFS outcome of the AETHERA trial, we recently submitted an sBLA to the FDA to seek approval for a new indication in the AETHERA treatment setting. The AETHERA trial met its primary endpoint with ADCETRIS treatment resulting in a statistically significant improvement in PFS versus placebo, as assessed by an independent central review

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committee (hazard ratio=0.57; p-value=0.001). The most common adverse events in the ADCETRIS arm were peripheral sensory neuropathy (56 percent), neutropenia (35 percent), upper respiratory tract infection (26 percent), fatigue (24 percent) and peripheral motor neuropathy (23 percent). The most common adverse events in the placebo arm were upper respiratory tract infection (23 percent), fatigue (18 percent) peripheral sensory neuropathy (16 percent), cough (16 percent) and neutropenia (12 percent). Eighty-five percent of patients with peripheral neuropathy on the ADCETRIS arm had resolution or improvement in symptoms with a median time to improvement of 23.4 weeks. Grade 3 or higher adverse events in the ADCETRIS arm included neutropenia, peripheral sensory neuropathy, peripheral motor neuropathy, nausea, fatigue and diarrhea. Grade 3 or higher adverse events in the placebo arm included neutropenia, fatigue, peripheral motor neuropathy, diarrhea and peripheral sensory neuropathy. No Grade 4 peripheral neuropathy events occurred. One death occurred within 30 days of ADCETRIS treatment from treatment-related acute respiratory distress syndrome, or ARDS, associated with pneumonitis. One death occurred on the ADCETRIS arm at Day 40 from ARDS following an episode of treatment-related acute pancreatitis, which had resolved at the time of death.

*Required ADCETRIS Post-approval Clinical Studies*

ADCETRIS was granted approval in two indications under the FDA s accelerated approval regulations, which allows the FDA to approve products for cancer or other serious or life-threatening illnesses based on surrogate endpoints or on a clinical endpoint other than survival or irreversible morbidity. Under the FDA s accelerated approval regulations, we are subject to certain post-approval requirements pursuant to which we are conducting additional confirmatory phase 3 trials to verify and describe the clinical benefit of ADCETRIS. In addition, we are subject to extensive ongoing obligations and continued regulatory review from the FDA and other applicable regulatory agencies, such as continued adverse event reporting requirements and the requirement to have our promotional materials pre-cleared by the FDA. Successful completion of either of these two trials could result in conversion to regular approval for both indications:

- An ongoing phase 3 randomized trial comparing ADCETRIS in combination with AVD versus ABVD as frontline therapy in advanced classical Hodgkin lymphoma patients, called the ECHELON-1 trial. The primary endpoint is PFS per independent review facility assessment, with overall survival as a key secondary endpoint.

- An ongoing phase 3 randomized, double-blind clinical trial comparing ADCETRIS in combination with CHP versus CHOP as frontline therapy in patients with CD30-positive MTCL, including sALCL, called the ECHELON-2 trial. The primary endpoint is PFS per independent review facility assessment, with overall survival as a key secondary endpoint.

Both of these studies are described in greater detail below under Clinical Development Plan . Failure to complete these required post-approval studies or adhere to the timelines set by the FDA could result in penalties, including fines or withdrawal of ADCETRIS from the market, unless we are able to demonstrate good cause for not completing the studies or adhering to the timelines. The FDA may also initiate proceedings to withdraw approval if these post-approval studies fail to verify the clinical benefit of ADCETRIS. Further, the FDA may require us to further strengthen the warnings and precautions section of the ADCETRIS package insert. Post-approval clinical studies similar to those required by the FDA are required in many other countries, including in Canada and the European Union. The requirements of these post-approval clinical studies vary from country to country and may in some cases involve testing in addition to the post-approval studies required by the FDA.

*Market Opportunities*

According to the American Cancer Society, more than 9,000 cases of Hodgkin lymphoma are expected to be diagnosed in the United States during 2015, and an estimated 1,150 people will die of the disease. Approximately 1,700 additional patients per year in the United States are diagnosed with sALCL, a type of MTCL lymphoma that expresses the CD30 antigen. The use of combination chemotherapy as frontline therapy for malignant lymphomas has resulted in high remission rates; however, these frontline chemotherapy regimens have substantial associated toxicities and a significant number of lymphoma patients relapse and require additional

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treatments including other chemotherapy regimens and ASCT. In addition to lymphoma, CD30 is also expressed in leukemia, multiple myeloma and some solid tumors, which may provide additional market opportunities in the future. CD30 is also expressed at increased levels in many autoimmune diseases, which could provide a non-cancer area for future development. For the reasons discussed in Item 1A Risk Factors , we may not be able to obtain regulatory approvals to market ADCETRIS for frontline Hodgkin lymphoma or MTCL, or otherwise expand its labeled indications of use.

*Clinical Development Plan*

In collaboration with Takeda, we are pursuing a broad development strategy that includes clinical trials of ADCETRIS both as a single agent and in combination with standard therapies for CD30-positive cancers. These ongoing clinical trials include:

*Phase 3 Frontline Hodgkin Lymphoma*. In November 2012, we and Takeda announced a randomized, open-label, phase 3 trial investigating ADCETRIS plus AVD versus ABVD as frontline therapy in patients with advanced classical Hodgkin lymphoma, or the ECHELON-1 trial. The primary endpoint is modified PFS per independent review facility assessment. Secondary endpoints include overall survival, complete remission rate and safety. The multi-center trial is being conducted in North America, Europe, Latin America and Asia. The study is planned to enroll approximately 1,040 eligible patients (approximately 520 patients per treatment arm) who have histologically-confirmed diagnosis of Stage III or IV classical Hodgkin lymphoma who have not been previously treated with systemic chemotherapy or radiotherapy. The trial is being conducted under a SPA agreement with the FDA and also received scientific advice from the EMA. We are required to conduct this trial as part of our ADCETRIS post-marketing requirement, and the trial is designed to be confirmatory in the United States and Canada. At the December 2012 ASH meeting, we announced interim results from a phase 1 dose-escalation combination trial in frontline Hodgkin lymphoma that evaluated ADCETRIS combined with ABVD or combined with AVD. Among the 25 evaluable patients in the ADCETRIS plus AVD cohorts, 24 patients who completed frontline therapy on study achieved a complete remission. At the 2014 ASH meeting, we announced that in the ADCETRIS plus AVD arm, three-year overall survival was 100 percent and three-year failure-free survival was 92 percent. In the ADCETRIS plus ABVD arm, three-year overall survival was 92 percent and three-year failure-free survival was 79 percent. Grade 3 or higher adverse events occurring in more than one patient overall noted in the ABVD and AVD cohorts, respectively, were neutropenia (80 percent, 77 percent), anemia (20 percent, 12 percent), febrile neutropenia (20 percent, 8 percent) and pulmonary toxicity (24 percent, 0 percent). Based on safety data from this phase 1 trial we determined that ADCETRIS should not be combined with bleomycin, one of the drugs in ABVD chemotherapy, due to increased incidence of pulmonary toxicity in the combination arm of the trial. As a result, we added a contraindication warning relating to the concomitant use of ADCETRIS and bleomycin due to pulmonary toxicity. One patient experienced a Grade 3 peripheral neuropathy event. Data from this phase 1 trial supported initiation of the ECHELON-1 trial.

*Phase 3 Frontline Mature T-Cell Lymphoma.* In January 2013, we and Takeda initiated a global randomized, double-blind, placebo-controlled multi-center phase 3 clinical trial evaluating ADCETRIS in combination with CHP versus CHOP for the treatment of newly diagnosed CD30-positive MTCL patients, including patients with sALCL and other types of peripheral T-cell lymphomas, or the ECHELON-2 trial. The primary endpoint is PFS per independent review facility assessment. Secondary endpoints include overall survival, complete remission rate and safety. The trial is being conducted in North America, Europe and Asia and is planned to enroll approximately 300 patients. A molecular companion diagnostic test is being used in this trial to identify eligible patients based on CD30-expression. We are developing a companion diagnostic under a collaboration agreement with Ventana and Takeda. The trial is being conducted under a SPA agreement with the FDA and also received scientific advice from the EMA. We are required to conduct this trial as part of our ADCETRIS post-marketing requirement, and the trial is designed to be confirmatory in the United States and Canada. At the September 2014 European Society for Medical Oncology meeting, we announced updated results from a phase 1 dose-escalation combination trial to evaluate ADCETRIS plus chemotherapy for sALCL, which was subsequently amended to include patients with any CD30-positive MTCL. Interim data were reported from

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26 patients who received the combination regimen of ADCETRIS plus CHP. The median age of patients was 56 years. Nineteen patients had sALCL, including 16 patients (62 percent) with anaplastic lymphoma kinase (ALK) negative disease, typically associated with a poor prognosis and median PFS of approximately 18 months with a five-year overall survival of less than 50 percent. Seven patients had a diagnosis of other types of peripheral T-cell lymphoma, or PTCL. The estimated two-year PFS rate was 54 percent, with no patients receiving a consolidative stem cell transplant. As of the date of the presentation there had been no progression events since the previous presentation at the ASH annual meeting in December 2013. The estimated two-year overall survival rate was 80 percent. The most common treatment-emergent adverse events of any grade occurring in more than 40 percent of patients were peripheral sensory neuropathy, nausea, fatigue, hair loss, diarrhea and shortness of breath. Data from this trial supported initiation of the ECHELON-2 trial. In addition, we previously reported that ADCETRIS was added to the National Comprehensive Cancer Network, or NCCN, guidelines for the treatment of relapsed CD30-positive PTCL.

*Phase 3 Cutaneous T-Cell Lymphoma.* In May 2012, we and Takeda initiated a phase 3 trial of ADCETRIS for relapsed CD30-positive CTCL patients, or the ALCANZA trial. The ALCANZA trial is a randomized, open-label, phase 3 trial of ADCETRIS versus investigator s choice of methotrexate or bexarotene in patients with CD30-positive CTCL, including those with primary cutaneous anaplastic large cell lymphoma, or pcALCL, or mycosis fungoides, or MF. The primary endpoint of the study is overall response rate, lasting at least four months. The key secondary endpoints are complete response rate, PFS and burden of symptoms. Approximately 124 patients are expected to be enrolled in the pivotal trial. The ALCANZA trial is being conducted under an SPA agreement with the FDA and also received EMA scientific advice. Results from two investigator-sponsored phase 2 trials of ADCETRIS in patients with CD30-positive CTCL were presented at the 2012 and 2013 ASH meetings. Of the aggregate 68 evaluable CD30-positive CTCL patients reported by these two studies, 49 patients treated with ADCETRIS achieved an objective response. The most common adverse events were peripheral neuropathy, fatigue, decreased appetite, rash and nausea. ADCETRIS was recently added to NCCN guidelines for systemic frontline or later treatment of CTCL or mycosis fungoides.

*Relapsed or Refractory CD30-Positive Non-Hodgkin Lymphoma, including DLBCL and other B-cell Lymphomas*. In August 2011, we initiated a phase 2 trial for patients with relapsed or refractory CD30-positive non-Hodgkin lymphomas, including DLBCL, peripheral T-cell lymphoma and other less common lymphoma subtypes, but excluding sALCL. The primary endpoint of this trial is to determine the antitumor activity of ADCETRIS in different lymphomas as measured by objective response rate. In addition, the trial will assess safety and characterize the relationship of CD30 expression with potential antitumor activity. Interim data were reported at the December 2013 ASH meeting from 50 patients with relapsed DLBCL. Of these patients, 42 percent achieved an objective response, including 16 percent complete remissions and 26 percent partial remissions. At the time of data analysis, the median duration of response for DLBCL was 5.8 months. For DLBCL patients who achieved a complete remission, the median duration of response was 11.5 months. Objective responses were observed across a broad range of CD30 expression, from DLBCL patients with undetectable CD30 by standard immunohistochemistry testing to those with CD30 expression up to 90 percent. The most common treatment-emergent adverse events of any grade in patients with DLBCL and other B-cell lymphomas occurring in more than 25 percent of all patients enrolled were fatigue (49 percent), neutropenia (40 percent), nausea (38 percent), diarrhea (37 percent) and fever (29 percent). The most common Grade 3 treatment-emergent adverse events in patients with DLBCL and other B-cell lymphomas were neutropenia and anemia. The only Grade 4 treatment-emergent event was neutropenia. Serious adverse events considered related to treatment and occurring in more than one patient were pneumonia (three patients), anemia, febrile neutropenia, neutropenia and thrombocytopenia (two patients each). Enrollment of this trial is now closed. Based on the results of this trial, we recently announced plans to initiate a randomized phase 2 trial during 2015 for patients with CD30-positive DLBCL who have relapsed following autologous stem cell transplant or who are ineligible for transplant. This planned trial will randomize patients to receive Rituxan and bendamustine with or without ADCETRIS. ADCETRIS was recently added to NCCN guidelines for patients with second-line or beyond CD30-positive DLBCL.

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*Frontline Therapy for Hodgkin Lymphoma Patients Age 60 and Over*. In October 2012, we initiated a phase 2 clinical trial evaluating ADCETRIS monotherapy as a frontline therapy for patients age 60 or older with newly diagnosed Hodgkin lymphoma. The trial was subsequently amended to include the administration of ADCETRIS in combination with bendamustine or dacarbazine. The phase 2 single-arm, open-label clinical trial will evaluate the efficacy and tolerability of ADCETRIS in patients age 60 or older with Hodgkin lymphoma. The primary endpoint of the trial is the objective response rate, with key secondary endpoints of safety and tolerability, duration of response, complete remission rate and PFS. At the December 2014 ASH Meeting, we presented interim data from this study. Of 27 evaluable patients in the single-agent ADCETRIS arm, 25 patients (93 percent) had an objective response, including 19 patients (70 percent) with a complete remission and six patients (22 percent) with a partial remission. Two patients (seven percent) had stable disease. Of 14 evaluable patients in the ADCETRIS and dacarbazine combination arm, 13 patients (93 percent) had an objective response, including four patients (29 percent) with a complete remission and nine patients (64 percent) with a partial remission. All evaluable patients in both arms achieved tumor reduction. Fifteen of 18 patients in the ADCETRIS and dacarbazine combination arm were still on treatment at the time of the analysis. In the single-agent ADCETRIS arm, the most common adverse events of any grade occurring in 20 percent or more of patients were peripheral sensory neuropathy, fatigue, nausea, swelling, diarrhea, decreased appetite and constipation. The only Grade 3 adverse events occurring in more than one patient were peripheral sensory neuropathy (seven patients) and peripheral motor neuropathy and rash (two patients each). In the ADCETRIS and dacarbazine combination arm, the most common Grade 1 and 2 adverse events were peripheral sensory neuropathy and nausea (33 percent each); diarrhea and constipation (28 percent each); fatigue, hair loss, joint pain and headache (22 percent each). Grade 3 or serious adverse events occurring in one patient each were colitis and vomiting, hypotension and hyperglycemia. The study is expected to enroll up to 70 patients at multiple centers in the United States and is currently enrolling patients to evaluate the combination of ADCETRIS and bendamustine.

*Second-line Therapy for Relapsed or Refractory Hodgkin Lymphoma Patients*. In June 2013, we initiated a phase 1/2 single-arm, open-label clinical trial to evaluate the efficacy and tolerability of ADCETRIS in combination with bendamustine in Hodgkin lymphoma patients after first relapse. The multi-phase study is divided into two cohorts to determine the recommended dose and tolerability of ADCETRIS in combination with bendamustine and to assess the complete remission rate associated with combination use. Bendamustine is an alkylating agent used in the treatment of chronic lymphocytic leukemias and lymphomas. Patients are eligible to receive up to six cycles of ADCETRIS in combination with bendamustine followed by additional single-agent ADCETRIS for a total of 16 cycles. As a part of the trial design, after patients receive ADCETRIS plus bendamustine combination therapy, they have the option to pause therapy to receive an ASCT and then resume treatment with single-agent ADCETRIS as consolidation. At the December 2014 ASH Meeting, we presented interim data of 48 patients evaluable for response. Of the evaluable patients, 46 patients (96 percent) had an objective response, including 40 patients (83 percent) with a complete remission and six patients (13 percent) with a partial remission. One patient had stable disease and one patient had progressive disease. The majority of complete remissions (34 of 40 patients) were achieved after two cycles of combination therapy. Median duration of response, PFS and overall survival had not yet been reached. No adverse impact on stem cell mobilization or engraftment was observed. Thirty-two patients had received an ASCT as of the date of the oral presentation. The most common adverse events from combination treatment were infusion-related reactions, or IRRs, which were seen in approximately 50 percent of patients. Approximately 20 percent of IRRs were Grade 3 or higher. The majority of IRRs occurred within 24 hours of the second cycle of combination treatment and were considered related to both therapies. Symptoms associated with IRRs were dyspnea (15 percent), chills (13 percent) and flushing (13 percent). The trial protocol was amended to require premedication with corticosteroids and antihistamines, which decreased the severity of IRRs. Enrollment of this trial is now closed.

*Frontline Therapy for DLBCL Patients*. In August 2013, we initiated a phase 2 study of ADCETRIS in combination with R-CHOP as frontline therapy in patients with DLBCL. Patients were randomized to receive standard dose R-CHOP with either 1.2 milligrams per kilogram (mg/kg) or 1.8 mg/kg of ADCETRIS every three weeks. This study is evaluating the safety and antitumor activity of adding ADCETRIS to standard frontline therapy for DLBCL. At the December 2014 meeting, interim data were reported from 47 patients with a median

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age of 67 years. Nearly all patients (95 percent) had stage III/IV disease at the time of diagnosis and were considered either high-risk (38 percent) or high-intermediate risk (62 percent). Of 22 patients in both arms evaluable for response, 21 patients (95 percent) had an objective response, including 17 patients (77 percent) with a complete remission and four patients (18 percent) with a partial remission. One patient had progressive disease. Antitumor activity was not significantly different between the two ADCETRIS dosage arms. In the arm with the recommended dose of 1.2 mg/kg of ADCETRIS plus RCHOP, all 13 evaluable patients had an objective response, including eight patients (80 percent) with a complete remission and two patients (20 percent) with a partial remission. Preliminary data suggest a higher complete remission rate in CD30-positive patients (greater than 90 percent) versus CD30-undetectable DLBCL patients. Across both treatment arms, 100 percent of patients achieved tumor reduction. ADCETRIS administered at 1.2 mg/kg in combination with RCHOP had a similar safety profile to that expected from RCHOP alone in this patient population. The most common adverse events occurring in more than 25 percent of patients of any grade in the RCHOP plus 1.2 mg/kg of ADCETRIS arm were nausea (38 percent), fatigue and diarrhea (33 percent each), anemia (30 percent), peripheral sensory neuropathy and febrile neutropenia (29 percent each). The most common Grade 3 or 4 adverse events in the RCHOP plus 1.2 mg/kg of ADCETRIS arm were neutropenia, febrile neutropenia, anemia, weight loss and insomnia. The study has been amended to include a new cohort of CD30-positive frontline DLBCL patients to be treated with ADCETRIS (1.8 mg/kg) and CHP. The study is expected to enroll up to 75 patients at multiple centers in the United States.

*Secondline Therapy for Hodgkin and B-cell and T-cell non-Hodgkin lymphoma Patients*. In January 2015, we and BMS announced a clinical trial collaboration agreement to evaluate the investigational combination of ADCETRIS and BMS immunotherapy nivolumab (OPDIVO) in two planned phase 1/2 clinical trials. Nivolumab is a human programmed death receptor-1, or PD-1, blocking antibody that binds to the PD-1 receptor expressed on activated T-cells. The first trial will evaluate the combination of ADCETRIS and nivolumab as a potential treatment option for patients with relapsed or refractory Hodgkin lymphoma and the second trial will focus on patients with relapsed or refractory B-cell and T-cell non-Hodgkin lymphomas, including DLBCL. The studies are expected to begin in 2015.

*Investigator-Sponsored Studies.* As of December 31, 2014, there were two completed investigator-sponsored trials, 21 ongoing investigator-sponsored trials and three ongoing cooperative group trials of ADCETRIS in the U.S. In addition, we and Takeda are reviewing proposals from multiple clinical investigators and cooperative groups in the United States, Canada and Europe about potential clinical trials of ADCETRIS. The investigator-sponsored trials to date include the use of ADCETRIS in a number of malignant hematologic indications such as CTCL, DLBCL, untreated limited stage Hodgkin lymphoma, salvage therapy for patients with Hodgkin lymphoma prior to autologous hematopoietic stem cell transplantation and graft versus host disease. There are also numerous other investigator-sponsored trials for the use of ADCETRIS in other CD30-positive and select CD30-undetectable settings, and in solid tumors such as mesothelioma and testicular germ cell tumors. One cooperative group trial is currently evaluating ADCETRIS with immuno-oncology compounds in Hodgkin lymphoma, and we expect additional studies might evaluate ADCETRIS in novel combination regimens.

***SGN-CD33A***

SGN-CD33A is an ADC composed of an anti-CD33 monoclonal antibody linked to a potent PBD dimer using our proprietary ADC technology, and is a product candidate for the treatment of AML. SGN-CD33A targets CD33, a protein that is expressed on most AML cells. SGN-CD33A employs our newest proprietary ADC technology. This technology is comprised of a PBD dimer, which is a potent cell-killing agent that works by a different mechanism than auristatins, linked to an engineered antibody called EC-mAb, resulting in uniform drug-loading of two PBD dimers per antibody.

In July 2013 we initiated a phase 1, open-label, multi-center, dose-escalation clinical trial of SGN-CD33A. The primary endpoints of the study are the estimation of the maximum tolerated dose and evaluation of the safety of SGN-CD33A. In addition, the trial will evaluate anti-leukemia activity, pharmacokinetics, PFS and overall

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survival in patients with CD33-positive AML. The dose escalation portion of the study is designed to evaluate SGN-CD33A administered every three weeks and will enroll up to approximately 90 patients at multiple centers in the United States. Patients who achieve a complete remission are eligible to continue to receive SGN-CD33A at a lower, maintenance dose given every three weeks. Dose escalation cohorts that show evidence of anti-leukemia activity may be expanded to allow for a more comprehensive evaluation of safety and clinical activity. At the December 2014 ASH meeting, we reported interim data from 56 evaluable AML patients with a median age of 75 years and predominantly intermediate or adverse cytogenetic risk. Of the 56 patients, 43 percent had received intensive therapy and 57 percent had declined intensive therapy. More than 50 percent of patients had evidence of underlying myelodysplasia. Of the 52 evaluable patients treated across all dose levels, the best clinical response by investigator included 11 patients (21 percent) with a complete remission or complete remission with incomplete recovery, or CR/CRi. An additional 12 patients (23 percent) achieved a morphologic leukemia free state. Data suggest an emerging dose-response relationship with rapid and marked decreases in bone marrow blasts. Of the 17 response-evaluable patients treated at 40 micrograms per kilogram (mcg/kg), five patients (29 percent) achieved a CR/CRi. At last follow-up, 12 of 18 patients (67 percent) treated at this dose level remained alive. Ten patients treated at this dose level were elderly and had declined intensive therapy, of which four patients (40 percent) achieved CR/CRi. Among patients treated at the 40 mcg/kg dose level or higher, 77 percent (17 of 22) had a 50 percent or more reduction in bone marrow blasts. For CR/CRi patients, median time to neutrophil count recovery was 6.7 weeks and median time to platelet count recovery was 12 weeks. The most common treatment-related adverse events of any grade occurring in 15 percent or more of patients were febrile neutropenia (32 percent), fatigue (20 percent) and low blood platelet count (16 percent). The most common post-baseline Grade 3 or 4 laboratory abnormalities were low blood neutrophil count (98 percent), low blood leukocyte count (97 percent) and low blood platelet count (87 percent). The 30-day mortality rate was two percent, with no treatment-related deaths occurring during the first thirty days. As of the date of the presentation, the maximum tolerated dose had not been reached and dose exploration is continuing, including combination cohorts with hypomethylating agents.

In December 2014, we initiated a phase 1b clinical trial of SGN-CD33A in combination with standard of care chemotherapy, including cytarabine and daunorubicin, for patients with newly diagnosed AML. The trial will also evaluate SGN-CD33A in the consolidation setting for AML, both in combination with cytarabine and as a single-agent maintenance regimen. The study is a phase 1b, open-label, multi-center, dose-escalation clinical trial designed to evaluate SGN-CD33A administered in combination with frontline standard of care regimens for induction (cytarabine and daunorubicin) and/or consolidation (cytarabine). In addition, the study will evaluate single-agent SGN-CD33A as a maintenance regimen. The primary endpoints are determination of the maximum tolerated dose and safety profile of SGN-CD33A in these settings. In addition, the trial will evaluate anti-leukemic activity, pharmacokinetics, PFS and overall survival. The phase 1b trial will enroll approximately 90 patients at multiple centers in the United States.

***SGN-CD19A***

SGN-CD19A is an ADC composed of an anti-CD19 monoclonal antibody linked to a potent auristatin compound using our proprietary ADC technology, and is a product candidate for the treatment of hematologic malignancies. CD19 is a B-cell antigen that is expressed in non-Hodgkin lymphoma, chronic lymphocytic leukemia and acute lymphoblastic leukemia, or ALL. We have previously reported preclinical data demonstrating that SGN-CD19A binds to target cells with high affinity, internalizes and induces potent cancer-cell-killing activity and durable tumor regressions at low doses in multiple cancer models. In February 2013 we announced the initiation of two phase 1, open-label, dose-escalation clinical trials of SGN-CD19A. The first trial is enrolling adult and pediatric patients with relapsed or refractory B-cell ALL, as well as patients with Burkitt lymphoma or leukemia or B-cell lymphoblastic lymphoma. The dose escalation portion of the study is designed to evaluate both weekly and every three week schedules and the entire trial is expected to enroll approximately 100 patients at multiple centers in the United States. The second trial is enrolling patients with relapsed or refractory aggressive B-cell non-Hodgkin lymphomas, including DLBCL and mantle cell lymphoma. The dose escalation portion of the trial is evaluating SGN-CD19A administered every three weeks and the entire trial is

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expected to enroll approximately 75 patients at multiple centers in the United States. The primary endpoints for both trials are to estimate the maximum tolerated dose and to evaluate the safety of SGN-CD19A. In addition, the trials are evaluating antitumor activity, pharmacokinetics, PFS and overall survival.

At the December 2014 ASH annual meeting, we announced interim data from 52 patients with relapsed or refractory NHL, including 45 patients with DLBCL, three patients with grade 3 follicular lymphoma and four patients with mantle cell lymphoma. Of the 52 patients, 30 patients (58 percent) were refractory to their last therapy and 22 patients (42 percent) were relapsed. Fourteen patients (27 percent) had received a prior autologous stem cell transplant. The median age of patients was 65 years. Of the 51 patients evaluable for response, 18 patients (35 percent) achieved an objective response, including 10 patients (20 percent) with a complete remission and eight patients (16 percent) with a partial remission. Thirteen patients (25 percent) achieved stable disease and 20 patients (39 percent) had disease progression. Antitumor activity appeared to be higher in relapsed patients. Of the 22 relapsed patients, 12 patients (55 percent) achieved an objective response, including seven patients (32 percent) with a complete remission and five patients (23 percent) with a partial remission. Six patients (27 percent) achieved stable disease and four patients (18 percent) had disease progression. The most common adverse events of any grade occurring in more than 25 percent of patients were blurred vision (60 percent), dry eye (46 percent), fatigue (38 percent), constipation (33 percent) and keratopathy (31 percent). Most ocular symptoms were Grade 1/2. The majority of patients with Grade 3 or 4 ocular symptoms and/or corneal findings experienced improvement and/or resolution at last follow-up. Ocular symptoms and corneal findings were managed with steroid eye drop treatment and dose modifications. Based on these results, we recently announced plans to initiate a randomized phase 2 trial evaluating SGN-CD19A in combination with R-ICE chemotherapy for second-line DLBCL during 2015.

In addition, at the December 2014 ASH annual meeting, we announced interim data from 51 adult patients with relapsed or refractory B-lineage ALL and highly aggressive lymphoma, including B-cell lymphoblastic lymphoma, or LBL, and Burkitt lymphoma. The median age of adult patients was 43 years and the median number of prior systemic therapies was two, with 14 patients (27 percent) having received a prior allogeneic stem cell transplant. At the time of data analysis, dose escalation is ongoing. Safety analysis included data from 51 patients, including 18 patients treated every three weeks and 33 patients treated weekly. Of the 14 ALL and LBL adult patients evaluable for response treated every three weeks, five patients (36 percent) achieved an objective response, including four patients (29 percent) with a complete remission and one patient (seven percent) with a partial remission. Eight patients (57 percent) achieved stable disease and one patient (seven percent) had disease progression. Of the 29 ALL and LBL adult patients evaluable for response treated with weekly dosing, six patients (20 percent) achieved an objective response, including five patients (17 percent) with a complete remission and one patient (three percent) with a partial remission. Ten patients (34 percent) achieved disease stabilization and 13 patients (45 percent) had disease progression. The most common adverse events of any grade occurring in 25 percent or more of adult patients treated every three weeks (18 patients) and weekly (33 patients), respectively, were fever (56 and 55 percent), chills (33 and 56 percent), fatigue (33 and 55 percent), headache and nausea (28 and 55 percent), blurred vision (39 and 36 percent), vomiting (28 and 42 percent) and febrile neutropenia (28 and 33 percent). Symptoms related to keratopathy were reported in 27 patients. All symptoms were Grade 1/2; no Grade 3 symptoms were reported. The most common symptoms were blurred vision, dry eye and photophobia. Grade 3 or 4 keratopathy was reported in 10 patients and the majority had experienced improvement and/or resolution at last follow-up. Ocular symptoms and corneal findings were managed with steroid eye drop treatment and dose modifications. Prophylactic eye drops were instituted early in the trial and appear to reduce the severity of corneal events in the weekly treatment schedule.

***SGN-LIV1A***

SGN-LIV1A is an ADC composed of an anti-LIV-1 monoclonal antibody linked to a potent auristatin compound using our proprietary ADC technology, and is a product candidate for the treatment of LIV-1-positive metastatic breast cancer. In October 2013 we initiated a phase 1, open-label, dose-escalation clinical trial to evaluate the safety and antitumor activity of SGN-LIV1A in patients with LIV-1-positive metastatic breast

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cancer. The trial is enrolling patients with triple negative disease who have previously been treated with at least two prior cytotoxic regimens in the metastatic setting, or patients with ER-positive and/or PR-positive and HER2-negative disease who have previously been treated with at least two prior cytotoxic regimens in the metastatic setting, and at least three prior hormonal therapies. The primary endpoint of the trial is safety, with key secondary endpoints of objective response, duration of response and PFS. The study is expected to enroll up to 70 patients at multiple centers in the United States.

***SGN-70A***

SGN-CD70A is an ADC composed of an anti-CD70 EC-mAb linked to a potent PBD dimer using our proprietary ADC technology, and is a product candidate for the treatment of CD70-positive renal cell carcinoma and non-Hodgkin lymphoma. In August 2014, we announced the initiation of a phase 1, open-label, multi-center, dose-escalation clinical trial evaluating SGN-CD70A for CD70-positive relapsed or refractory non-Hodgkin lymphoma and metastatic renal cell carcinoma. The primary endpoints are to estimate the maximum tolerated dose and to evaluate the safety of SGN-CD70A. In addition, the trial will evaluate the antitumor activity and pharmacokinetics in patients with CD70-positive metastatic renal cell carcinoma or relapsed or refractory non-Hodgkin lymphoma, including mantle cell lymphoma and diffuse large B-cell lymphoma. The study is designed to evaluate SGN-CD70A administered every three weeks and will enroll approximately 95 patients at multiple centers in the United States.

***SEA-CD40***

SEA-CD40 utilizes our novel SEA technology to produce a non-fucosylated antibody targeting CD40. It builds on our extensive experience targeting CD40. We recently initiated a phase 1, open label, multi center, dose escalation trial of SEA-CD40 in multiple solid tumors.

***ASG-22ME***

ASG-22ME 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 bladder, breast, lung and pancreatic cancers. We are developing ASG-22ME as a product candidate for the treatment of solid tumors under our co-development collaboration with Agensys. Based on the results of a prior phase 1 clinical trial of ASG-22ME, we initiated a new trial in 2014 to evaluate the safety, tolerability, pharmacokinetic profile and antitumor activity of ASG-22ME when given on Days 1, 8 and 15 of a 28 day cycle. The maximum tolerated dose has not yet been established in this trial and dose escalation is continuing.

***ASG-15ME***

ASG-15ME is an ADC composed of an anti- SLITRK6 monoclonal antibody linked to a potent auristatin compound using our proprietary ADC technology. SLITRK6 is a novel target expressed in bladder and lung cancer. We are developing ASG-15ME as a product candidate for the treatment of bladder cancer under our co-development collaboration with Agensys. A phase 1 clinical trial of ASG-15ME for the treatment of bladder cancer was initiated in October 2013. This trial is evaluating the safety, tolerability, pharmacokinetic profile and antitumor activity of escalating doses of ASG-15ME given on Days 1, 8, and 15 of a 28 day cycle. The maximum tolerated dose has not yet been established in this trial and dose escalation is continuing.

**Research Programs**

In addition to our pipeline of product candidates and antibody-based 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 and PBDs that we currently use in our ADC technology and new classes of cell-killing agents.

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*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 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 Genmab and OBT.

*Antibody Engineering.* We have substantial internal expertise in antibody engineering, both for antibody humanization and defucosylation, 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.

**Research and Development Expense**

Since inception, we have devoted a significant amount of resources to develop ADCETRIS, our product candidates and our antibody-based technologies. For the years ended December 31, 2014, 2013, and 2012, we recorded $230.7 million, $218.6 million, and $170.3 million, respectively, in research and development expenses.

**Corporate Collaborations**

We enter into collaborations with biotechnology and pharmaceutical 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 license our ADC technology to collaborators to be developed with their own antibodies. These ADC 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 ADC product candidates.

***Takeda ADCETRIS Collaboration***

In December 2009, we entered into a collaboration agreement with Takeda to develop and commercialize ADCETRIS, under which Seattle Genetics retains commercial rights in the United States and its territories and in Canada, and Takeda and its Takeda affiliates have commercial rights in the rest of the world. As of December 31, 2014, we had received an upfront payment of $60 million and had achieved milestone payments totaling $50 million related to regulatory and commercial progress by Takeda. We are entitled to receive additional progress- and sales-dependent milestone payments of up to $185 million based on Takeda s achievement of significant events under the collaboration in addition to tiered royalties with percentages starting in the mid-teens and escalating 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. Takeda is

funding half of joint worldwide development costs under the collaboration, excluding costs solely related to development in Japan, which Takeda is solely responsible for funding. Although we are funding half of joint worldwide development costs, 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

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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.

***Agensys Co-Development Collaboration***

In January 2007, we entered into an agreement with Agensys to jointly research, develop and commercialize ADCs for the treatment of cancer. The collaboration encompasses combinations of our ADC technology with fully-human antibodies developed by Agensys to proprietary cancer targets. Under this collaboration, Agensys is conducting research and development aimed at identifying ADC product candidates for multiple designated antigens as well as clinical trials on various ADC product candidates.

The co-development provisions of the collaboration agreement included an initial co-development product candidate, ASG-5ME, and provided us with two options to co-develop additional product candidates. We have exercised all of our co-development options and are currently co-developing ASG-22ME and ASG-15ME. Development of ASG-5ME has been discontinued. We and Agensys are co-funding all development and commercialization costs for both ASG-22ME and ASG-15ME, and will share equally in any profits for these product candidates. Based on the results of a prior phase 1 clinical trial of ASG-22ME, we initiated a new trial in 2014 to evaluate the safety, tolerability, pharmacokinetic profile and antitumor activity of ASG-22ME when given on Days 1, 8 and 15 of a 28 day cycle. The maximum tolerated dose has not yet been established in this trial and dose escalation is continuing. A phase 1 clinical trial of ASG-15ME for the treatment of bladder cancer was initiated in October 2013.

Agensys has the right to develop and commercialize the other ADC product candidates on its own, subject to paying us annual maintenance fees, milestones, royalties and support fees for research and development services and material provided under the collaboration agreement. We are entitled to receive progress- and sales-dependent milestone payments of up to approximately $96 million based on Agensys achievement of significant events under the collaboration in addition to mid-single digit royalties on net sales of any of these other ADC product candidates by Agensys. Either party may opt out of co-development and profit-sharing in return for receiving milestones and royalties from the continuing party. Either party may terminate the collaboration agreement if the other party becomes insolvent or the other party materially breaches the agreement and such breach remains uncured. Subject to certain restrictions, either party may terminate the collaboration agreement for any reason upon prior written notice to the other party. The collaboration agreement can also be terminated by mutual written consent of the parties. If neither party exercises its option to terminate the collaboration agreement, then the agreement will automatically terminate on the later of: (a) the expiration of all payment obligations pursuant to the collaboration agreement, or (b) the day upon which we and Agensys cease to develop and commercialize products under the agreement.

***Genmab Co-Development Collaboration***

In September 2010, we entered into an ADC research collaboration agreement with Genmab. Under the agreement, Genmab has rights to utilize our ADC technology with its HuMax-TF antibody targeting the Tissue Factor, or TF, antigen, which is expressed on numerous types of solid tumors. Under this agreement, we received an upfront payment and have the right to exercise a co-development option for any resulting ADC products at the end of phase 1 clinical development. Genmab is responsible for research, manufacturing, preclinical development and phase 1 clinical trials of ADCs under the collaboration. We receive research support payments for any assistance provided to Genmab. If we opt into the anti-TF ADC product at the end of phase 1, we and Genmab would co-develop and share all future costs and profits for the product on a 50:50 basis. If we do not opt in, then Genmab would pay us fees, milestones and mid-single digit royalties on worldwide net sales of the product.

In September 2014, we and Genmab announced that we had entered into an additional ADC collaboration. Under the terms of the additional agreement, Genmab paid us an upfront fee of $11 million for exclusive rights to utilize our auristatin-based ADC technology with Genmab s HuMax®-AXL, an antibody targeting AXL, which is

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expressed on multiple types of solid cancers. We are also entitled to receive more than $200 million in potential milestone payments and mid-to-high single digit royalties on worldwide net sales of any resulting products. In addition, prior to Genmab s initiation of a phase 3 study for any resulting products, we have the right to exercise an option to increase the royalties to double digits in exchange for a reduction of the milestone payments owed by Genmab. Irrespective of any exercise of option, Genmab remains in full control of development and commercialization.

***ADC Collaborations***

We have active collaborations with eight companies to allow them to use our proprietary ADC technology with their monoclonal antibodies. Under our ADC collaborations, which we enter into in the ordinary course of business, we receive or are entitled to receive upfront cash payments, progress-dependent milestones and single digit royalties on net sales of products incorporating our ADC technology, as well as annual maintenance fees and support fees for research and development services and materials provided under the agreements. Our ADC collaborators are responsible for development, manufacturing and commercialization of any ADC product candidates that result from the collaborations and are solely responsible for the achievement of any of the potential milestones under these collaborations.

Our current ADC collaborations are at various stages of clinical and preclinical development We do not expect to receive material revenues from our current ADC collaboration agreements unless and until a product that incorporates our ADC technology enters late-stage clinical development and receives marketing approval from the FDA when the milestone payments, royalties or other rights and benefits become more substantial. Below is a table setting forth our active ADC collaborations and current development status:

***OBT Co-Development Collaboration***

In September 2011, we entered into a strategic collaboration with OBT to jointly discover novel ADCs for the treatment of cancer. Under the collaboration, OBT is generating panels of monoclonal antibodies against novel tumor-specific antigens identified using its proprietary Oxford Genome Anatomy Project (OGAP$^{(R)}$) database. The antibodies generated by OBT are then screened for activity using our ADC technology. The resulting ADCs may be selected by each company for further development and commercialization. Under the

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terms of the multi-year, multi-product agreement, we and OBT each have an equal number of alternating options to select programs from among the preclinical ADCs identified for exclusive, worldwide development and commercialization. Each company will receive progress-dependent milestone payments and royalties on net sales of any resulting ADCs developed by the other party.

***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.* In March 1998, we obtained rights to some of our technologies and product candidates, portions of which are exclusive, through a license agreement with Bristol-Myers Squibb. Through this license, we secured rights to use various targeting technologies, including chemical linkers covered by patents owned by Bristol-Myers Squibb. 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 technology covered by patents licensed from Bristol-Myers Squibb.

*University of Miami.* 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 are required to pay annual maintenance fees, progress-dependent milestone payments and royalties in the low single digits on net sales of products, including ADCETRIS, incorporating technology licensed from the University of Miami.

**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, ASG-22ME, and ASG-15ME, 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 combinations, 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. 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.

For ADCETRIS and our related ADC technology, including certain methods of treatment using ADCETRIS, our nineteen issued patents will expire between 2015 and 2031 in the United States and Europe. Of these nineteen issued patents, we own rights to eighteen patents and have exclusively licensed rights to one patent. For SGN-CD33A and our related ADC technology, our five issued patents will expire between 2027 and 2030 in the United States and Europe, and additional patent applications are pending that, if issued, could increase the patent term to 2033 for certain methods of treatment using SGN-CD33A. Of these five patents, we own rights to two patents and have exclusively licensed rights to three patents. For SGN-CD19A and our related ADC technology, our seventeen issued patents will expire between 2024 and 2029 in the United

States and Europe. Of these seventeen issued patents, we own rights to all seventeen patents. For SGN-LIV1A and our related ADC technology, our thirteen issued patents will expire between 2015 and 2026 and additional patent

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applications are pending that, if issued, could increase the patent term to 2031 for SGN-LIV1A and for certain methods of treatment using SGN-LIV1A. Of these thirteen patents, we own rights to ten patents and have exclusively licensed rights to three patents. For SGN-70A and our related ADC technology, our eighteen issued patents will expire between 2024 and 2030 in the United States and Europe and additional patent applications are pending that, if issued, could increase the patent term to 2031 for SGN-70A and for certain methods of treatment using SGN-70A. Of these eighteen patents, we own rights to fifteen patents and have exclusively licensed rights to three patents. For SEA-CD40 and our related SEA technology, our 22 issued patents will expire between 2020 and 2030. Of these 22 patents, we exclusively own rights to twelve patents and have exclusively licensed rights to ten patents. For ASG-22ME and our related ADC technology, our fourteen issued patents will expire between 2015 and 2031. Of these fourteen patents, we exclusively own rights to ten patents, have exclusively licensed rights to one patent, and have non-exclusive rights to three patents. For ASG-15ME and our related ADC technology, including certain methods of treatment using ASG-15ME, our eleven issued patents will expire between 2015 and 2027 in the United States and Europe and additional patent applications are pending that, if issued, could increase the patent term to 2033. Of these eleven patents, we exclusively own rights to ten patents and have exclusively licensed rights to one patent. In some cases, our U.S. patents may be eligible for patent term extension, and our European patents may be eligible for supplemental protection in one or more countries. The length of any such extension would vary by country.

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. Our patents have been and may in the future be challenged by third parties in post-issuance administrative proceedings or in litigation as invalid or unenforceable under U.S. or foreign laws, or they may be infringed by third parties. As a result, we are from time to time involved in the defense and enforcement of our patent or other intellectual property rights in a court of law, U.S. Patent and Trademark Office inter partes review or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding 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. A number of pharmaceutical and biotechnology companies, universities and research institutions may have filed patent applications or may have been granted patents that cover technologies similar to the technologies owned, optioned by 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 enforceability in order to continue commercializing ADCETRIS or to commercialize 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.

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 patent efforts. 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 propriety information and inventions assignment agreement

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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 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 annually with a report on development;
- 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 either a New Drug Application, or NDA, or a BLA, 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
- 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

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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 not result in FDA authorization 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 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. Since we received accelerated approval for ADCETRIS from the FDA, we are subject to certain post-approval requirements pursuant to which we are conducting additional confirmatory phase 3 trials to verify and describe the clinical benefit of ADCETRIS in its two approved indications. 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 an NDA or BLA, 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, similar to one the FDA convened for ADCETRIS. The FDA is not obligated to follow the Advisory Committee s recommendation. The submission of an NDA or BLA 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. Accelerated approval of ADCETRIS additionally requires the pre-submission of marketing materials to the FDA for the product until such time as the accelerated approval requirements have been terminated. Once 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

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ADCETRIS, including phase 4 clinical trials, and surveillance programs to monitor the safety of ADCETRIS, and the FDA has the power to prevent or limit further marketing of ADCETRIS 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 483 and Warning Letters that could cause us to modify certain activities. A Form 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 guidances. Failure to adequately and promptly correct the observations(s) can result in further regulatory enforcement action. In addition to Form 483 notices and Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, not approve our products, require us to recall a product from distribution or withdraw approval of the BLA or NDA for that product. Failure to comply with ongoing regulatory obligations can result in delay of approval or Warning Letters, product seizures, criminal penalties, and withdrawal of approved products, among other enforcement remedies.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet, and off-label promotion. While physicians may prescribe for off label uses, manufacturers may only promote 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.

***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 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 that required for FDA approval.

***Healthcare Regulation***

Federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, are also applicable to our business. If we fail to comply with those laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected. The laws 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.

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The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item, or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term remuneration has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated. Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively PPACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, PPACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

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

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new 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 its implementing regulations, imposes certain requirements 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.

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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 were required to submit reports on aggregate payment data to the government for the first reporting period by June 30, 2014, and were required to report detailed payment data for the first reporting period and submit legal attestation to the completeness and accuracy of such data by September 29, 2014.

Many states have similar statutes or regulations to the above federal laws that may be broader in scope than the aforementioned federal laws and apply regardless of payor, and many of which differ from each other in significant ways and may not have the same effect, further complicate 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, 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.

***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. A pharmaceutical product or procedure may not be reimbursed by third party payors based on a number of factors, such as a determination that it is experimental, not medically necessary, or not appropriate for a particular patient.

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 will be made on a plan by plan basis. One payor s determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. These third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments 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 revenue and results. If

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third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans 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 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. 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 private entities that are eligible for government pricing under the Public Health Services Act. Participation in these programs requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations. The terms of these procurement contracts 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.

In some foreign jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. 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.

***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 expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to biopharmaceutical products, PPACA is expected to, among other things, expand and increase 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 has not yet occurred.

Many provisions of PPACA may 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, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required PHS discount to increase.

PPACA and/or certain of its provisions may be modified or eliminated by future legislation or litigation. Many of the details regarding the implementation of PPACA are yet to be determined, and at this time, it remains unclear the full effect that PPACA will have on our business.

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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 of 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 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 new 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.

**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 cancer and autoimmune disease therapy. 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 currently no FDA-approved drugs other than ADCETRIS for the treatment of relapsed Hodgkin lymphoma or specifically indicated for relapsed sALCL; however, Celgene s Istodax and Spectrum Pharmaceuticals Folotyn are both approved for relapsed or refractory peripheral T-cell lymphoma. Compelling data have been presented involving several developing technologies, including antibody therapies that target PD-1 and CAR modified T-cell therapies, which may compete with ADCETRIS in the future. For example, the FDA recently granted breakthrough therapy designation for BMS s investigational PD-1 antibody therapy to treat patients with Hodgkin lymphoma after failure of ASCT and ADCETRIS therapy. In addition, we are aware of multiple investigational agents that are currently being studied, including Pfizer s crizotinib and Takeda s alistertib, Pharmacyclics ibrutinib, and Gilead s idelalisib, which, if successful, may compete with ADCETRIS in the future. Further, there are many competing approaches used in the treatment of patients in ADCETRIS two approved indications, including ASCT, combination chemotherapy, clinical trials with experimental agents and single agent regimens.

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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;
- 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.

We are aware of other companies that have technologies that may be competitive with ours, including AstraZeneca, Bristol-Myers Squibb, ImmunoGen and Pfizer, all of which have ADC technology. Pfizer is conducting a phase 3 trial of an anti-CD22 ADC for B-cell malignancies that may compete with our or our collaborators product candidates. 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 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. For example, we believe Bristol-Myers Squibb has anti-CD30 and anti-CD70 antibody programs, and Amgen, Wyeth and Xencor have anti-CD19 programs that may be competitive with ADCETRIS or our product candidates. In addition, our ADC collaborators may develop compounds utilizing our technology that may compete with product candidates that we are developing. Many other pharmaceutical and biotechnology companies are developing and/or marketing therapies for the same types of cancer and autoimmune diseases that our product candidates are designed and being developed to treat. For example, we believe that companies including Amgen, Bayer, Biogen IDEC, Bristol-Myers Squibb, Celgene, Eisai, Genentech, GSK, Gilead, ImmunoGen, Infinity, Merck, Novartis, Pfizer, Pharmacyclics, Sanofi-Aventis, Spectrum Pharmaceuticals, Takeda, Teva and Xencor are developing and/or marketing products or technologies that may compete with ours.

**Manufacturing**

We do not currently have the internal ability to manufacture the drug products that we sell or need to conduct our clinical trials, and we therefore 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 Sigma Aldrich Fine Chemicals, or SAFC, for clinical and commercial supplies. We have multiple contract manufacturers for conjugating the drug linker to the antibody and producing the ADCETRIS product. For our ADC product candidates, multiple contract manufacturers, including AbbVie and SAFC, perform antibody and drug-linker manufacturing and several other contract manufacturers perform conjugation of the drug-linker to the antibody and fill/finish of the drug product. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including shipping and storage of ADCETRIS and our product candidates.

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We established our commercial scale supply chain for ADCETRIS prior to commercial launch. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce, vial and store sufficient quantities of ADCETRIS for use in our clinical trials and for commercial sale. In addition, we depend on outside vendors for the supply of raw materials used to produce ADCETRIS. For our pipeline programs, we believe that our existing supplies of drug product and our contract manufacturing relationships will be sufficient to accommodate clinical trials through phase 3. However, we may need to obtain additional manufacturing arrangements or increase our own manufacturing capability to meet our future commercial needs, both of which could require significant capital investment. In addition, we have committed to provide Takeda with their needs of certain parts of the ADCETRIS supply chain for a limited period of time, which may require us to arrange for additional manufacturing supply. We may also enter into collaborations with pharmaceutical or larger biotechnology companies to enhance the manufacturing capabilities for our product candidates.

*AbbVie Biotechnology*. In February 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 was made effective as of February 23, 2004 and will continue until the completion of the tenth contract year following commercial launch of ADCETRIS with automatic 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.

*SAFC*. In December 2010, we entered into a commercial supply agreement with SAFC to manufacture commercial quantities of drug linker that is a component of ADCETRIS. The agreement generally provides for the supply by SAFC 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 was made effective as of December 1, 2010 and will continue until the completion of the tenth contract year following commercial launch of ADCETRIS with automatic 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.

**Commercial Operations and Information About Geographic Areas**

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 the 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. ADCETRIS was granted conditional marketing authorization in the European Union in October 2012 for patients with relapsed Hodgkin lymphoma or relapsed sALCL. We and Takeda have received marketing authorizations by regulatory authorities in 50 countries, including those described above, as well as Japan, Australia, Switzerland, South Korea and Singapore, 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 AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation each accounted for 10% or

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more of our total revenue in 2014 and 2013, respectively. Our net product sales of ADCETRIS for the years ended December 31, 2014, 2013, and 2012 were $178.2 million, $144.7 million, and $138.2 million, respectively. Revenues generated outside the United States as determined by customer location were less than 10% of total revenues for the years ended December 31, 2014, 2013, and 2012. All of our long-lived assets are located in the United States.

**Employees**

As of December 31, 2014, we had 657 employees. Of these employees, 457 were engaged in or support research, development and clinical activities, 102 were in administrative and business related positions, and 98 were in sales and marketing. Each of our employees has signed confidentiality and inventions assignment agreements and none are covered by a collective bargaining agreement. We have never experienced employment-related work stoppages and consider our employee relations to be good.

**Corporate Information**

We were incorporated in Delaware on July 15, 1997. Our principal executive offices are located at 21823 30$^{th}$ Drive SE, Bothell, Washington 98021. Our telephone number is (425) 527-4000. Seattle Genetics® and  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 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 Securities and Exchange Commission. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this Annual Report on Form 10-K.

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**Item 1A. Risk Factors**

You should carefully consider the following risk factors, in addition to the other information contained in this annual report on Form 10-K, including our consolidated financial statements and related notes. If any of the events described in the following risk factors occurs, our business, operating results and financial condition could be seriously harmed.

This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10-K.

**Risks Related to Our Business**

***Our 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 expand its labeled indications of use, our ability to generate significant revenue or achieve profitability will be adversely affected.***

ADCETRIS ® (brentuximab vedotin) received accelerated approval in the United States in August 2011 and approval with conditions in Canada in February 2013 for patients with relapsed Hodgkin lymphoma or relapsed systemic anaplastic large cell lymphoma, or sALCL. ADCETRIS is our only product approved for marketing and our ability to generate revenue from product sales and achieve profitability is substantially dependent on our continued ability to effectively commercialize ADCETRIS for the treatment of patients in its two approved indications and our ability 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 not be able to obtain and maintain regulatory approvals to market ADCETRIS for any additional indications, including for frontline Hodgkin lymphoma or mature T-cell lymphoma, or MTCL, or otherwise expand its labeled indications of use;
- as a result of proposed trial modifications to the ECHELON-1 and ECHELON-2 trials, our ability to successfully complete these trials on a timely basis could be adversely affected, which in turn could adversely affect our ability to expand ADCETRIS labeled indications of use;
- the market penetration rate of ADCETRIS may be lower, or the duration of therapy in patients in ADCETRIS approved indications may be shorter, than our projections;
- results from our required post-approval studies may fail to verify the clinical benefit of ADCETRIS in some or all of its approved indications, which could result in the withdrawal of ADCETRIS from the market;
- 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 required post-approval studies such as our ECHELON-1, ECHELON-2 or AETHERA clinical trials, or as the result of adverse events observed in these or other studies, including in investigator-sponsored studies;

we may not be able to establish or demonstrate in the medical community the safety and efficacy of ADCETRIS and its potential advantages over and side effects compared to existing and future therapeutics;

physicians may be reluctant to prescribe ADCETRIS until results from our required post-approval studies are available or other long term efficacy and safety data exists;

the estimated incidence rate of new patients in ADCETRIS approved indications may be lower than our projections;

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there may be adverse results or events reported in any of the clinical trials that we and/or Takeda are conducting or may in the future conduct for ADCETRIS;

new competitive therapies may be approved for marketing by regulatory authorities in ADCETRIS labeled indications;

we may be unable to continue to effectively market, sell and distribute ADCETRIS;

ADCETRIS may receive adverse reimbursement and coverage policies from government and private payers such as Medicare, Medicaid, insurance companies, health maintenance organizations and other plan administrators or may be subject to pricing pressures enacted by industry organizations;

the relative price of ADCETRIS may be higher than alternative treatment options;

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 December 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 European Commission for patients with relapsed Hodgkin lymphoma or relapsed sALCL, and has since obtained marketing approvals for ADCETRIS in many other countries. Conditional marketing authorization by the European Commission includes obligations to provide additional clinical data at a later stage to confirm the positive benefit-risk balance. Although Takeda received conditional marketing authorization from the European Commission and other countries, 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 its territory.

We believe that the level of our ongoing ADCETRIS sales in the United States is largely attributable to the incidence flow of patients eligible for treatment with ADCETRIS. We also believe that the incidence rate of new patients in ADCETRIS approved indications is relatively low, particularly when compared to many other oncology indications. For these and other reasons, we expect that meaningful future ADCETRIS sales growth, if any, will depend primarily on our ability to expand ADCETRIS labeled indications of use. Accordingly, we are exploring the use of ADCETRIS as a single agent and in combination therapy regimens earlier in the treatment of Hodgkin lymphoma and MTCL, including sALCL, and in a range of CD30-positive hematologic malignancies, including relapsed cutaneous T-cell lymphoma, or CTCL. This will continue to require additional time and investment in clinical trials 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. 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 molecular 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. However, Ventana may not be able to successfully develop a molecular companion diagnostic that may be required by regulatory authorities to support regulatory approval of ADCETRIS in other CD30-positive malignancies in a timely manner or at all. 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 have periodically increased the price of

ADCETRIS, most recently in July 2014. We cannot assure you that price increases we have taken or may take in the future have not already negatively affected, or will not in the future negatively affect, ADCETRIS sales volumes.

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***Our operating results are unpredictable 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. We have only been commercializing ADCETRIS since August 2011 and 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. Such guidance is based on assumptions that may be incorrect or that may change from quarter to quarter. Sales of ADCETRIS have in the past 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 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 and the duration of therapy for patients receiving ADCETRIS;
- 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 payers;
- 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, including but not limited to an increase in our cost of sales as a percentage of sales in future periods as product manufactured prior to FDA approval, and therefore fully expensed, is consumed;
- 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 activities involving ADCETRIS and our product candidates; and
- expenditures we will or may incur to conduct required post-approval studies for ADCETRIS and acquire or develop additional technologies, product candidates and products.

In addition, from time to time, we enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments, 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 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, 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.

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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, 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.

***Reports of adverse events or safety concerns involving ADCETRIS could delay or prevent us from obtaining or maintaining regulatory approval, or could negatively impact sales of ADCETRIS.***

Reports of adverse events or safety concerns involving ADCETRIS could interrupt, delay or halt clinical trials of ADCETRIS, including the ongoing FDA-required ADCETRIS post-approval confirmatory studies as well as the post-approval confirmatory studies that Takeda is required to conduct as a condition to the conditional marketing authorization of ADCETRIS by the European Commission. For example, during 2013 concerns regarding pancreatitis caused an investigator conducting an independent study to temporarily halt enrollment in a trial to amend the eligibility criteria and monitoring for the trial. Subsequently, we have revised our prescribing information to add pancreatitis as a known adverse event. In addition, reports of adverse events or safety concerns involving ADCETRIS could result in regulatory authorities 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. There are no assurances that patients receiving ADCETRIS will not experience serious adverse events in the future.

Adverse events may also negatively impact the sales of ADCETRIS. We may also be required to further update the ADCETRIS package insert based on reports of adverse events or safety concerns or implement a Risk Evaluation and Mitigation Strategy, 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, we have revised the prescribing information for ADCETRIS to add pancreatitis, impaired hepatic function and impaired renal function as known adverse events as well as to include 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. In addition, we are currently in discussion with the FDA to update the prescribing information with respect to patients who may experience pulmonary toxicity. 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.

***Even though we have obtained approval to market ADCETRIS in two indications, we are subject to ongoing regulatory obligations and review, including post-approval requirements that could result in the withdrawal of ADCETRIS from the market if such requirements are not met.***

ADCETRIS was approved for treating patients in two indications under accelerated approval regulations in the U.S. and approval with conditions in Canada, which allow for approval of products for cancer or other serious or life threatening illnesses based on a surrogate endpoint or on a clinical endpoint other than survival or irreversible morbidity. Under these types of approvals, we are subject to certain post-approval requirements pursuant to which we are conducting additional confirmatory and safety phase 3 trials to verify and describe the clinical benefit of ADCETRIS in its two approved indications. Our failure to complete these required post-approval studies, or to confirm a clinical benefit during these post-approval studies, could result in the withdrawal of approval of ADCETRIS, which would seriously harm our business. In addition, we are subject to extensive ongoing obligations and continued regulatory review from applicable regulatory agencies, such as continued adverse event reporting requirements and the requirement to have 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 ability to commercialize ADCETRIS in the United States, Canada or potentially other jurisdictions. Similarly, the conditional marketing authorization of ADCETRIS for two indications by the European Commission includes obligations to provide additional clinical data at a later stage to confirm the results of the two pivotal studies. Takeda s failure to provide these additional clinical data or to confirm the results of the pivotal studies, could result in the European Commission withdrawing approval of ADCETRIS in

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the European Union, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Takeda in the European Union and could adversely affect our results of operations.

Under the FDA s accelerated approval regulations, the labeling, packaging, adverse event reporting, storage, advertising and promotion for ADCETRIS are subject to extensive regulatory requirements all of which may result in significant expense and limit our ability to commercialize ADCETRIS. 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. 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 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 filed by us or Takeda;
- refusals to permit drugs to be imported into or exported from the United States;
- restrictions on operations, including costly new manufacturing requirements; and
- product recalls or seizures.

The policies of the FDA and other regulatory agencies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of ADCETRIS in other 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.

***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. 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

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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. 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 and the availability of alternative or new treatments. In addition, many of our future and ongoing ADCETRIS clinical trials are being or will be coordinated with Takeda, which may delay the commencement or affect the continuation or completion of these trials. We have experienced enrollment-related delays in certain of our current and previous clinical trials and will likely experience similar delays in our future trials, particularly as we attempt to enroll larger numbers of patients required for phase 3 studies of ADCETRIS that we are required to conduct, and are currently conducting, to satisfy the FDA s post-approval requirements. 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 and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under cGMP and other requirements in foreign countries, and may require large numbers of test patients. We, the FDA or other foreign governmental agencies could delay, suspend, halt or modify our clinical trials of ADCETRIS or any of our product candidates, as well as any related special protocol assessment, or SPA, agreements, for numerous reasons, including:

- ADCETRIS or the applicable product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- deficiencies in the conduct of the clinical trial, including failure to conduct the clinical trial in accordance with regulatory requirements, GCP or clinical protocols;
- 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 to produce or obtain sufficient quantities of ADCETRIS or the applicable product candidate to complete the trials;
- our inability 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 to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;

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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 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; or

our inability 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.

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies, which often occur in later-stage clinical trials. For example, it is currently unknown if ADCETRIS may be safely and effectively combined with human programmed death receptor-1, or PD-1, inhibitors, including nivolumab. As a further example, during 2011 we announced that, based on a phase 1 trial combining ADCETRIS with ABVD chemotherapy, ADCETRIS should not be combined with bleomycin, one of the drugs in ABVD chemotherapy, due to increased incidence of pulmonary toxicity in the combination arm of the trial. As a result, we added a contraindication warning relating to the concomitant use of ADCETRIS and bleomycin due to pulmonary toxicity. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive clinical trial results could negatively affect our ability to market ADCETRIS or expand into other indications. For example, although we reported positive top line data from our AETHERA trial, regulatory agencies, including the FDA, or their advisors, may disagree with our interpretations of data from the AETHERA trial and may not approve the expansion of ADCETRIS labeled indications of use based on the results of the AETHERA trial or any other of our clinical trials. Further, given the phase 1 data combining ADCETRIS with standard chemotherapy regimens and the positive progression-free survival, or PFS, outcome in the AETHERA trial, we and Takeda are evaluating the potential that event rates may be slower than expected in both the ECHELON-1 and ECHELON-2 trials and are in discussions with regulatory agencies in both the U.S. and Europe regarding proposed trial modifications. We cannot currently predict the scope or impact of any such trial modifications, if any, or whether the FDA may opt to rescind the related SPA Agreements if we are unable to reach agreement with the FDA regarding such trial modifications. Depending on the modifications, if any, agreed upon with the appropriate regulatory agencies, our ability to successfully complete these trials on a timely basis could be adversely affected. In this regard, earlier analysis or other trial modifications of either or both of the ECHELON-1 and ECHELON-2 trials could potentially make demonstrating a statistically significant improvement in PFS in these trials more difficult. Adverse medical events, including patient fatalities that may be attributable to ADCETRIS during a clinical trial, could cause a trial to be redone or terminated. Further, some of our clinical trials may be 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.

***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.***

With respect to ADCETRIS, there are currently no FDA-approved drugs other than ADCETRIS for the treatment of relapsed Hodgkin lymphoma or specifically indicated for relapsed sALCL; however, Celgene s Istodax and Spectrum Pharmaceuticals Folotyn are both approved for relapsed or refractory peripheral T-cell lymphoma. Compelling data have been presented involving several developing technologies, including antibody therapies that target PD-1 and CAR modified T-cell therapies, that may compete with ADCETRIS in the future. For example, the FDA recently granted breakthrough therapy designation for Bristol-Myers Squibb s investigational PD-1 antibody therapy to treat patients with Hodgkin lymphoma after failure of ASCT and ADCETRIS therapy. In addition, we are aware of multiple investigational agents that are currently being studied, including Pfizer s crizotinib, Takeda s alistertib, Pharmacyclics ibrutinib, and Gilead s idelalisib, which, if successful, may compete with ADCETRIS in the future. In addition, there are many existing approaches used in the treatment of patients in ADCETRIS two approved indications, including ASCT, combination chemotherapy, clinical trials with experimental agents and single agent regimens, which represent competition for ADCETRIS.

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The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. We are aware of many pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antibody therapy or that are otherwise developing various approaches to cancer and autoimmune disease therapy. Some of these competitors have successfully commercialized antibody products or are developing or testing product candidates that do or may in the future compete directly with our product candidates. For example, we believe that companies including Amgen, Bayer, Biogen IDEC, Bristol-Myers Squibb, Celgene, Eisai, Genentech, GSK, Gilead, ImmunoGen, Infinity, Merck, Novartis, Pfizer, Pharmacyclics, Sanofi-Aventis, Spectrum Pharmaceuticals, Takeda, Teva and Xencor are developing and/or marketing products or technologies that may compete with ours, and some of these companies, including AstraZeneca, Bristol-Myers Squibb, ImmunoGen and Pfizer, have ADC technology. Other potential competitors include large, fully integrated pharmaceutical companies and more established biotechnology companies that have significant resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals and marketing. Also, academic institutions, government agencies and other public and private research organizations conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing. It is possible that these competitors will succeed in developing technologies that are more effective than ADCETRIS or our product candidates or that would render our technology obsolete or noncompetitive. We anticipate that we will face increased competition in the future as new companies enter our market and scientific developments surrounding other cancer therapies continue to accelerate.

***We are subject to various state and federal healthcare related laws and regulations that may impact our business and could subject us to significant fines and penalties.***

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, HIPAA/HITECH, the federal civil monetary penalties statute, and the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively PPACA. These laws may impact, among other things, the sales, marketing and education programs for ADCETRIS.

The federal Anti-Kickback Statute prohibits persons 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. 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 prohibit, among other things, persons or entities from knowingly filing, or causing to be filed, 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 government in fines or settlement. The filing of qui tam actions has caused a number of

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pharmaceutical, medical device and other healthcare companies to have to defend a civil False Claims Act action. When an entity is determined to have violated the civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new 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.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, governs the conduct of certain electronic healthcare transactions and protects 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 require certain manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests.

There may be foreign and state law equivalents of these laws, such as anti-kickback, false claims, and data privacy and security laws, to which we may be subject. 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 or marketing expenditures. Many of these state laws differ from each other in significant ways, thus complicating compliance efforts.

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 FDA and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. 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.

In order to comply with these laws, we have implemented a comprehensive 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

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various laws and regulations seriously and our compliance program is designed to prevent the violation of these laws and regulations, if we are found to be in violation of any of the laws and regulations described above or other applicable state and federal healthcare fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and/or the curtailment or restructuring of our operations, any of which could have a material adverse effect on our business and results of operations. 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.

***We have a history of net losses. We expect to continue to incur net losses and may not achieve 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 required post-approval and other clinical trials of, and seeking additional regulatory approvals for, ADCETRIS as well as commercializing ADCETRIS for the treatment of patients in its two approved indications. In addition, we expect to make substantial expenditures to further develop and potentially commercialize our product candidates. Accordingly, we expect to continue to incur net losses and may not achieve profitability for some time, if at all. Although we now 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 operating and commercialization history makes our future operating results difficult to predict. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

***If we or our collaborators are not able to obtain or maintain required regulatory approvals, we or our collaborators will not be able to commercialize 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 earlier in the treatment of Hodgkin lymphoma and MTCL and in other CD30-positive malignancies, including CTCL, 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. For example, both the FDA and its Oncologic Drugs Advisory Committee, which provides the FDA with independent expert advice and recommendations, have expressed concerns about whether the AETHERA trial could support label expansion. The AETHERA trial was not conducted under a SPA agreement with the FDA and, accordingly, we have not reached any agreement with the FDA regarding either the design or the clinical endpoints of the trial. Based upon the positive PFS outcome of the AETHERA trial, we recently

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submitted a supplemental Biologics License Application, or sBLA, to the FDA to seek approval for a new indication in the AETHERA treatment setting. However, the FDA may disagree with our interpretations of the data from the AETHERA trial and/or may otherwise determine not to approve the planned sBLA in a timely manner or at all. Moreover, even though three of our phase 3 clinical trials of ADCETRIS that we are conducting with Takeda are being conducted under SPA agreements with the FDA, this is not a guarantee or indication of approval, and we cannot be certain that the design of, or data collected from, any of our current or potential future clinical trials that are being conducted under SPAs with the FDA will be sufficient to support FDA approval. Further, a SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement is entered into become evident, other new scientific concerns regarding product safety or efficacy arise, new drugs are approved in the same indication, or if we have failed to comply with the agreed upon trial protocols. In addition, a SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of a SPA agreement and the data and results from the applicable clinical trial. Regulatory agencies also may approve a product candidate for fewer indications than requested or may grant approval subject to the performance of post-approval studies or risk evaluation and mitigation strategies 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 additional indications.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols and/or related SPA agreements to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors ADCETRIS could take a significantly longer time to gain regulatory approval in additional indications than we expect or may never gain regulatory approval, which could delay or eliminate any potential product revenue from sales of ADCETRIS in any additional indications, which could significantly delay or prevent us from achieving profitability.

***In some circumstances we rely on collaborators to assist in the research and development of ADCETRIS and, in other situations, to utilize our ADC technology. If we are not able to locate suitable collaborators or if our collaborators do not perform as expected, it may affect our ability to commercialize ADCETRIS and/or generate revenues through technology licensing.***

We have established and intend to continue to establish 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. We also have ADC collaborations with AbbVie, Bayer, Celldex, GSK, Genentech, Pfizer, Progenics and Takeda, and ADC co-development agreements with Agensys, Genmab, and Oxford BioTherapeutics, or OBT.

Under certain conditions, our collaborators may terminate their agreements with us and discontinue use of our technologies. In addition, we cannot control the amount and timing of resources our collaborators may devote to products incorporating our technology. Moreover, our relationships with our collaborators may divert significant time and effort of our scientific staff and management team and require effective allocation of our resources to multiple internal and collaborative projects. Our collaborators may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborators. Even if our collaborators continue their contributions to the collaborative arrangements, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Our collaborators may fail to perform their obligations under the collaboration agreements or may be slow in performing their obligations. If any of our collaborators terminate or breach our agreements with them, or otherwise fail to complete their obligations in a timely manner, it may have a detrimental effect on our financial position by reducing or eliminating the potential for us to receive technology access and license fees, milestones and royalties, reimbursement of development costs, as well as possibly requiring us to devote additional efforts and incur costs associated with pursuing internal development of product candidates. In particular, if Takeda

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were to terminate the ADCETRIS collaboration, 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. In turn, this could significantly harm our financial position, adversely affect our stock price and require us to incur all the costs of developing and commercializing ADCETRIS, which are now being co-funded by Takeda. Furthermore, if our collaborators do not prioritize and commit substantial resources to programs associated with our product candidates, we may be unable to commercialize our product candidates, which would limit our ability to generate revenue and become profitable. In the future, we may not be able to locate third-party collaborators to develop and market our product candidates and we may lack the capital and resources necessary to develop all our product candidates alone.

***Healthcare law and policy changes, based on recently enacted legislation, may have a material adverse effect on us.***

In March 2010, the PPACA became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among 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 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. In addition, we anticipate that 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 any approved product, which may harm our business. For example, increased discounts, rebates or chargebacks may be mandated by governmental or private insurers or pricing pressures enacted by industry organizations, any of which could significantly affect the revenue generated by sales of our products, including ADCETRIS. Insurers may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. In addition, although ADCETRIS is approved in two indications in the European Union, Japan and other countries, government austerity measures or further healthcare reform measures in other countries could adversely affect demand and pricing for ADCETRIS, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Takeda.

***To date, we have depended on a small number of collaborators for most of our revenue. The loss of any one of these collaborators or our inability to generate sufficient sales revenue could result in a substantial 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 ADCETRIS received regulatory approval in the United States, our revenues will still depend in part on Takeda s ability and willingness to market the approved product outside of the United States and Canada. The loss of our collaborators, especially Takeda, or the failure of our collaborators to perform their obligations under their agreements with us, 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 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.***

We do not currently have the internal ability to manufacture the drug products that we sell or need to conduct our clinical trials, and we therefore 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 Sigma Aldrich Fine Chemicals, or SAFC, for clinical and commercial supplies. We have multiple contract manufacturers for conjugating the drug linker to the antibody and producing the ADCETRIS product. For our ADC product candidates, multiple contract manufacturers, including AbbVie and SAFC, perform antibody and drug-linker manufacturing and several other contract manufacturers perform conjugation of the drug-linker to the antibody and fill/finish of the drug product. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including shipping and storage of ADCETRIS and our product candidates. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce, vial 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 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 could result in the cancellation of shipments, loss of product in the manufacturing process, a shortfall in ADCETRIS supply, or the inability to sell our products in the U.S. or abroad. In addition, we have committed to provide Takeda with their needs of certain parts of the ADCETRIS supply chain for a limited period of time, which may require us to arrange for additional manufacturing supply. Moreover, we 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 commercial and clinical requirements would be adversely affected.

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

ADCETRIS and our SGN-CD33A, SGN-CD19A, SGN-LIV1A, SGN-CD70A, ASG-22ME, and ASG-15ME 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, Agensys, Bayer, Celldex, Genentech, GSK, Takeda, Pfizer and Progenics, and our co-development agreements with Agensys, Genmab, and OBT. 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

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been approved for commercial sale in any jurisdiction. Any failures or setbacks in our ADC development program, including adverse effects resulting from the use of this technology in human clinical trials, 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.

***Our current product candidates are in relatively early stages of development, and it is possible that none of these product candidates will ever become commercial products.***

Our current product candidates are in relatively early stages of development. These product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all. Currently, we have six clinical-stage ADC programs, which consist of SGN-CD33A, SGN-CD19A, SGN-LIV1A, SGN-CD70A, ASG-22ME, and ASG-15ME. If a product candidate fails at any stage of development or we 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, we previously determined to discontinue the development of SGN-75 and we will not receive any return on our investment in that product candidate. Moreover, we still have only limited data from our phase 1 trials of our product candidates. As a result, we 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. Due to the uncertain and time-consuming clinical development and regulatory approval process, we may not successfully develop any of our product candidates and it is possible that none of our current product candidates will ever become commercial products. In addition, we expect that much of our effort and many of our expenditures over the next few years will be devoted to the additional clinical development of and commercialization activities associated with ADCETRIS, which may restrict or delay our ability to develop our clinical and preclinical product candidates.

***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 and support our preclinical development, manufacturing and clinical trial activities, as well as commercialize ADCETRIS and conduct required post-approval, and other clinical studies of ADCETRIS. Although some of these expenditures related to ADCETRIS are expected to be shared with Takeda, and we expect to offset some of these costs with sales proceeds of ADCETRIS, we may need to raise significant amounts of additional capital. In addition, we may require significant additional capital in order to acquire additional technologies, products or companies. We may seek additional funding through public or private financings and we do not know whether additional financing will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If adequate funds are not available to us when we need them, we will 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 rate of progress and cost of the confirmatory post-approval studies that we are required to conduct as a condition to the FDA s accelerated approval 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;

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;

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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, including licenses we may need to commercialize our products;

the terms and timing of any future collaborative, licensing and other arrangements that we may establish;

the potential costs associated with international, state and federal taxes; and

competing technological and market developments.

In addition, changes in our business may occur that would consume available capital resources sooner than we expect. 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.

***We rely on license agreements for certain aspects of ADCETRIS and 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 and our ADC technology. Currently, we have license agreements with Bristol-Myers Squibb and the University of Miami, among others. Some of these license agreements contain diligence and milestone-based termination provisions, in which case our failure to meet any agreed upon 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. Further, we may 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. For example, on March 31, 2014, Arizona State University and related entities, or Arizona State, filed a patent infringement lawsuit against us concerning a U.S. patent that we licensed from Arizona State. An adverse result in this dispute, or current or 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 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 commercialize ADCETRIS 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 the University of Miami and Bristol-Myers Squibb, among others. 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 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

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not contain claims that will permit us to stop competitors from using similar technology. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. For example, the U.S. Supreme Court has recently modified some legal standards applied by the U.S. Patent and Trademark Office 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, 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, and may increase the uncertainties and costs surrounding our patent prosecution and the protection, if any, given by our patents if we attempt to enforce them or if they are challenged in court.

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 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. In this regard, on March 31, 2014, Arizona State filed a patent infringement lawsuit against us concerning a U.S. patent that we licensed from Arizona State. 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. 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.

We are from time to time involved in the defense and enforcement of our patent or other intellectual property rights in a court of law, U.S. Patent and Trademark Office interference or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding in the United States and elsewhere. These proceedings are costly and time consuming. Successful challenges to our patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction and may allow third parties to use our proprietary technologies without a license from us or our collaborators, which may also result in loss of future royalty payments. Furthermore, if such challenges to our rights are not resolved promptly in our favor, our existing business relationships may be jeopardized and we could be delayed or prevented from entering into new collaborations or from commercializing potential products, which could adversely affect our business and results of operations. In addition, we may challenge the patent or other intellectual property rights of third parties and if we are unsuccessful in actions we bring against the rights of such parties, through litigation or otherwise, and it is determined that we infringe the intellectual property rights of such parties, we may be prevented from commercializing potential products in the relevant jurisdiction, or may be required to obtain licenses to those rights or develop or obtain alternative technologies, any of which could harm our business.

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***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. The loss of the services of any one of the principal members of our managerial or scientific staff may prevent us from achieving our business objectives.

In addition, the competition for qualified personnel in the biotechnology field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. In order to commercialize ADCETRIS, we have been required to expand our workforce, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development, sales and marketing. These activities required the addition of new personnel, including sales and marketing management, and the development of additional expertise by existing management personnel. 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.

***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 might be made directly by consumers or healthcare providers or indirectly by pharmaceutical companies, our corporate collaborators or others selling such products. We may experience financial losses in the future due to product liability claims. We have obtained limited general commercial liability insurance coverage for our clinical trials. We expanded our insurance coverage to include the sale of commercial products upon approval of ADCETRIS. 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 liabilities, 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.

***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 the event of an accident or environmental discharge, 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 interrupted, our business could be seriously harmed.***

We conduct most of our business in a limited number of facilities in a single geographical location in Bothell, 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

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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, maintain laboratory, patient 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. If we were to experience a prolonged system disruption in the information technology systems, it could result in the delay of development of our product candidates or the coordination of our sales activities, which could adversely affect our business. In addition, in order to maximize our information technology efficiency, we have physically consolidated our primary corporate data and computer operations. This concentration, however, exposes us to a greater risk of disruption to our internal information technology systems. 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 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, 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 disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these 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.

***We may engage in future acquisitions 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 acquiring complementary products, technologies or businesses. Any potential acquisitions may entail numerous risks, including increased operating expenses and cash requirements, assimilation

of operations and products, retention of key employees, diversion of our management s attention and uncertainties in our ability to maintain key business relationships of the acquired entities. In addition, if we undertake acquisitions, we may issue dilutive

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securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. 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.

***Legislative actions and potential 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. 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.

***Risks Related to Our 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 fourth quarter of 2014, our closing stock price fluctuated between $31.10 and $37.80 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 and clinical activities by us, including the clinical results of any of our current product candidates, or those of our competitors;
- announcements regarding the results of the clinical trials we and/or Takeda are conducting or may in the future conduct for ADCETRIS, including the post-approval confirmatory studies of ADCETRIS that we are required to conduct as a condition to the FDA s grant of accelerated approval for ADCETRIS, Health Canada s Notice of Compliance with conditions, and the conditional marketing authorization of ADCETRIS by the European Commission;
- announcements regarding, or negative publicity concerning, adverse events associated with the use of ADCETRIS;
- issuance of new or changed analysts reports and recommendations regarding us or 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;

termination of or changes in our existing collaborations or licensing arrangements, especially our ADCETRIS collaboration with Takeda or establishment of new collaborations or licensing arrangements;

actions taken by regulatory authorities with respect to our product candidates, our clinical trials or our regulatory filings;

our ability to raise additional capital when we need it 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;

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 stocks in particular, have historically experienced significant volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may 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. Any such litigation 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.

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

Our executive officers and directors and holders of greater than five percent of our outstanding voting stock, together with entities that may be deemed affiliates of, or related to, such persons or entities, beneficially owned approximately 64.2 percent of our voting power as of February 23, 2015. As a result, these stockholders, acting together, may be able to control our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. Consequently, this concentration of ownership may have the effect of delaying, deferring or preventing a change in control, including a merger, consolidation, takeover or other business combination involving us or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control, which might affect the market price of our common stock.

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

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

**Item 1B. Unresolved Staff Comments**

None.

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**Item 2. Properties**

Our headquarters are in Bothell, Washington, where we lease four buildings totaling approximately 255,000 square feet of office space that we use for laboratory, discovery, research and development and general and administrative purposes. All of our leases include renewal options.

We believe that our facilities are currently adequate to meet our needs.

**Item 3. Legal Proceedings**

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. 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. While we believe that the pending legal proceedings with which we are currently involved will not have a material adverse effect on our business, financial position or results of operations, management s view of these proceedings may change in the future or we could otherwise become involved in future legal proceedings that could result in a material adverse effect on our business, financial condition and results of operations.

**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**

***Price Range of Our Common Stock***

Our common stock is traded on the NASDAQ Global Select Market under the symbol SGEN. As of February 23, 2015, there were 124,318,682 shares of our common stock outstanding, which were held by approximately 79 holders of record of our common stock. On February 23, 2015, the closing price of our common stock as reported on the NASDAQ Global Select Market was $34.37 per share.

The following table sets forth, for the periods indicated, the reported high and low sales prices per share of our common stock as reported on the NASDAQ Global Market or the NASDAQ Global Select Market, as applicable:

| | High | Low |
|---|---|---|
| **2013** | | |
| First Quarter | $ 36.99 | $ 23.31 |
| Second Quarter | 39.00 | 28.15 |
| Third Quarter | 49.23 | 32.30 |
| Fourth Quarter | 46.48 | 36.79 |
| **2014** | | |
| First Quarter | $ 55.99 | $ 38.35 |
| Second Quarter | 47.67 | 32.35 |
| Third Quarter | 44.95 | 33.65 |
| Fourth Quarter | 40.35 | 30.50 |
| **2015** | | |
| First Quarter (through February 23, 2015) | $ 35.99 | $ 30.05 |

***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, 2014. In addition, we did not repurchase any of our equity securities during the fourth quarter of 2014.

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***Stock Performance Graph***

We show below the cumulative total return to our stockholders during the period from December 31, 2009 through December 31, 2014 in comparison to the cumulative return on the NASDAQ Pharmaceutical Index, the NASDAQ Composite Index and the NASDAQ Biotechnology Index during that same period. The results assume that $100 was invested on December 31, 2009 in our common stock and each of the indexes listed above, including reinvestment of dividends, if any.

| | Years ended | | | | | |
|---|---|---|---|---|---|---|
| | 12/09 | 12/10 | 12/11 | 12/12 | 12/13 | 12/14 |
| **Seattle Genetics, Inc.** | **100.00** | **147.15** | **164.52** | **228.05** | **392.62** | **316.24** |
| **NASDAQ Composite** | **100.00** | **117.61** | **118.70** | **139.00** | **196.83** | **223.74** |
| **NASDAQ Pharmaceutical** | **100.00** | **104.24** | **117.69** | **161.80** | **271.53** | **349.75** |
| **NASDAQ Biotechnology** | **100.00** | **106.73** | **122.40** | **166.72** | **286.55** | **379.71** |

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

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**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, 2014, 2013, and 2012 and Consolidated Balance Sheet data as of December 31, 2014 and 2013 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, 2011 and 2010 and Consolidated Balance Sheet data as of December 31, 2012, 2011 and 2010 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, | | | | |
|---|---|---|---|---|---|
| | 2014 | 2013 | 2012 | 2011 | 2010 |
| | (in thousands, except for per share amounts) | | | | |
| **Consolidated Statements of Comprehensive Loss Data:** | | | | | |
| Revenues: | | | | | |
| Net product sales | $ 178,198 | $ 144,665 | $ 138,200 | $ 43,241 | $ 0 |
| Collaboration and license agreement revenues | 68,556 | 106,781 | 67,547 | 51,537 | 107,470 |
| Royalty revenues | 40,004 | 17,818 | 5,065 | 0 | 0 |
| Total revenues | 286,758 | 269,264 | 210,812 | 94,778 | 107,470 |
| Costs and expenses: | | | | | |
| Cost of sales | 17,513 | 13,759 | 11,546 | 3,115 | 0 |
| Cost of royalty revenues | 11,545 | 7,385 | 1,923 | 0 | 0 |
| Research and development | 230,743 | 218,627 | 170,297 | 163,396 | 146,410 |
| Selling, general and administrative | 104,320 | 92,354 | 84,300 | 72,659 | 29,258 |
| Loss from operations | (77,363) | (62,861) | (57,254) | (144,392) | (68,198) |
| Investment and other income (loss), net | 1,222 | 341 | 3,472 | (7,638) | 1,933 |
| Net loss | $ (76,141) | $ (62,520) | $ (53,782) | $ (152,030) | $ (66,265) |
| Net loss per share basic and diluted | $ (0.62) | $ (0.51) | $ (0.46) | $ (1.34) | $ (0.66) |
| Shares used in computation of net loss per share basic and diluted | 123,408 | 121,575 | 117,851 | 113,098 | 101,055 |

| | December 31, | | | | |
|---|---|---|---|---|---|
| | 2014 | 2013 | 2012 | 2011 | 2010 |
| | (in thousands) | | | | |
| **Consolidated Balance Sheet Data:** | | | | | |
| Cash, cash equivalents and short-term investments | $ 313,413 | $ 374,267 | $ 364,258 | $ 330,696 | $ 294,840 |
| Working capital | 282,093 | 338,058 | 340,283 | 308,441 | 249,295 |
| Total assets | 458,965 | 483,898 | 471,422 | 425,216 | 329,936 |
| Stockholders equity | 210,834 | 230,185 | 226,148 | 218,849 | 161,518 |

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**Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations**

**Forward-Looking Statements**

*The following discussion of our financial condition and results of operations contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as may, might, will, should, expect, plan, anticipate, project, believe, estimate, predict, potential, intend or continue, the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading Item 1A Risk Factors. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.*

**Overview**

Seattle Genetics is a biotechnology company focused on the development and commercialization of targeted therapies for the treatment of cancer. Our marketed product ADCETRIS®, or brentuximab vedotin, is an antibody-drug conjugate, or ADC, comprising an anti-CD30 monoclonal antibody attached by a protease-cleavable linker to a microtubule disrupting agent, monomethyl auristatin E (MMAE), utilizing our proprietary technology. ADCETRIS received accelerated approval in the United States in August 2011, conditional marketing authorization in the European Union in October 2012 and approval with conditions in Canada in February 2013 for patients with relapsed Hodgkin lymphoma or relapsed systemic anaplastic large cell lymphoma, or sALCL. We are collaborating with Takeda Pharmaceutical Company Limited, or Takeda, to develop and commercialize ADCETRIS on a global basis. Under this collaboration, Seattle Genetics retains commercial rights for ADCETRIS in the United States and its territories and in Canada, and Takeda has commercial rights in the rest of the world. ADCETRIS is now approved in 50 countries, including those described above, as well as Japan, Australia, Switzerland, South Korea, Singapore and Mexico, and Takeda continues to pursue marketing authorizations in multiple other countries. Beyond our current labeled indications, we and Takeda have a broad development strategy for ADCETRIS evaluating its potential application in earlier lines of therapy for patients with Hodgkin lymphoma or mature T-cell lymphoma, or MTCL, including sALCL and in other CD30-positive malignancies.

On September 29, 2014, we and Takeda announced positive top line data from our AETHERA trial, a randomized, double-blind, placebo-controlled phase 3 clinical trial that evaluated ADCETRIS versus placebo in 329 patients with Hodgkin lymphoma at risk of relapse following autologous stem cell transplant, or ASCT. The AETHERA trial met its primary endpoint with ADCETRIS treatment resulting in a statistically significant improvement in progression-free survival, or PFS, versus placebo, as assessed by an independent central review committee (hazard ratio=0.57; p-value=0.001). At the December 2014 American Society of Hematology, or ASH, annual meeting, we announced the median PFS per independent review facility was 43 months for patients who received ADCETRIS versus 24 months for patients who received placebo. A pre-specified interim analysis of overall survival, a secondary endpoint in the trial, showed no statistically significant difference between the treatment arms. Patients on both study arms with progression of Hodgkin lymphoma may have received a variety of subsequent therapies. In the placebo arm, 72 of 85 patients (85 percent) receiving subsequent therapy were treated with single agent ADCETRIS. Notably, in the ADCETRIS arm, only eight of 51 patients (16 percent)

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receiving subsequent therapy were treated with ADCETRIS following relapse. A further analysis of overall survival is planned in 2016. The safety profile of ADCETRIS in the AETHERA trial was generally consistent with the existing prescribing information. The AETHERA trial was not conducted under a Special Protocol Assessment, or SPA, agreement from the U.S. Food and Drug Administration, or FDA, and has not been designated as a confirmatory trial to convert either accelerated approval or conditional marketing authorization to regular approval; however, this trial provides drug safety data analyses that fulfills one of our post-approval requirements with both the FDA and the European Medicines Agency, or EMA. ADCETRIS is not currently approved in the AETHERA treatment setting. Based upon the positive PFS outcome of the AETHERA trial, we recently submitted a supplemental Biologics License Application, or sBLA, to the FDA to seek approval for a new indication in the AETHERA treatment setting.

We and Takeda are conducting three additional phase 3 clinical trials of ADCETRIS, one in relapsed cutaneous T-cell lymphoma, or CTCL, called the ALCANZA trial, one in frontline advanced classical Hodgkin lymphoma, called the ECHELON-1 trial, and one in frontline MTCL, called the ECHELON-2 trial. We have entered into SPA agreements with the FDA for the ALCANZA, ECHELON-1 and ECHELON-2 trials and we also received scientific advice from the EMA with respect to these trials. An SPA is an agreement with the FDA regarding the design of the clinical trial, including size and clinical endpoints, to support an efficacy claim in a Biologics License Application, or BLA, submission to the FDA if the trial achieves its primary endpoints. The ECHELON-1 and ECHELON-2 trials would fulfill post-approval commitment obligations for ADCETRIS regarding drug efficacy, and positive results from either trial would form the basis for a submission to potentially convert the approval of ADCETRIS in the United States from accelerated approval to regular approval in its currently approved indications. The primary endpoint in the ECHELON-1 and ECHELON-2 trials is PFS per independent review facility assessment in patients treated with ADCETRIS compared to that achieved with therapy in the control arm. Given PFS trends in our phase 1 data combining ADCETRIS with standard chemotherapy regimens and the positive PFS outcome in the AETHERA trial, we and Takeda are evaluating the potential that event rates may be slower than expected in both the ECHELON-1 and ECHELON-2 trials and are in discussions with appropriate regulatory agencies on proposed trial modifications. Depending on the modifications, if any, agreed upon with the appropriate regulatory agencies, our ability to successfully complete these trials on a timely basis could be adversely affected. In this regard, earlier analysis or other trial modifications of either or both of the ECHELON-1 and ECHELON-2 trials could potentially make demonstrating a statistically significant improvement in PFS in these trials more difficult. The primary endpoint in the ALCANZA trial is overall response rate lasting at least four months in patients treated with ADCETRIS compared to that achieved with therapy in the control arm.

In addition to ADCETRIS, our pipeline includes six clinical-stage ADC programs consisting of SGN-CD33A, SGN-CD19A, SGN-LIV1A, SGN-CD70A, ASG-22ME, and ASG-15ME, and SEA-CD40, which is based on our sugar-engineered antibody, or SEA, technology. In addition, we have multiple preclinical and research-stage programs that employ our proprietary technologies. We also 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; Pfizer, Inc., or Pfizer; PSMA Development Company LLC, a subsidiary of Progenics Pharmaceuticals Inc., or Progenics; and Takeda; as well as ADC co-development agreements with Agensys, Inc., an affiliate of Astellas Pharma, Inc., or Agensys; Genmab A/S, or Genmab; and Oxford BioTherapeutics Ltd., or OBT.

Our ongoing research, development and commercial activities will require substantial amounts of capital and may not ultimately be successful. Our product candidates are in relatively early stages of development. These product candidates will require significant further development, financial resources and personnel to pursue and obtain regulatory approval and develop into commercially viable products, if at all. Accordingly, over the next several years, we expect that we will incur substantial expenses, primarily as a result of activities related to the commercialization and continued development of ADCETRIS. We will also continue to invest in research, development and manufacturing of our product candidates. Our commitment of resources to the continuing

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development, regulatory and commercialization activities for ADCETRIS and the research, continued development and manufacturing of our product candidates may require us to raise substantial amounts of additional capital and our operating expenses will fluctuate as a result of such activities. In addition, we may incur significant milestone payment obligations as our product candidates progress through clinical trials towards potential commercialization.

Although we recognize revenue from ADCETRIS product sales in the United States and Canada, we have only been commercializing ADCETRIS since August 2011 and our future ADCETRIS product sales will be difficult to accurately predict from period to period. 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, including the incidence rate of new patients in ADCETRIS approved indications, customer ordering patterns, the overall level of demand for ADCETRIS, the duration of therapy for patients receiving ADCETRIS, and the extent to which coverage and reimbursement for ADCETRIS is available from government and other third-party payers, particularly in an increasingly challenging environment due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the U.S. and worldwide. We believe that the level of our ongoing ADCETRIS sales in the United States is largely attributable to the incidence flow of patients eligible for treatment with ADCETRIS, which could vary significantly from period to period. Moreover, we believe that the incidence rate in ADCETRIS approved indications is relatively low, particularly when compared to many other oncology indications. For these and other reasons, we expect that meaningful future ADCETRIS sales growth, if any, will depend primarily on our ability to expand ADCETRIS labeled indications of use. Our efforts to expand ADCETRIS labeled indications of use will continue to require additional time and investment in clinical trials to complete and we may not be successful. Our ability to successfully commercialize ADCETRIS and to expand its labeled indications of use are subject to a number of risks and uncertainties, including those discussed in Part I, Item 1A of this Annual Report on Form 10-K. We also expect that amounts earned from our collaboration agreements 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 milestones by our collaborators under our existing collaboration and license agreements, including, in particular, our ADCETRIS collaboration with Takeda, as well as entering into 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 $286.8 million in 2014, compared to $269.3 million in 2013. This resulted from increased ADCETRIS net product sales and royalty revenues, partially offset by a decrease in collaboration and license agreement revenues. Total costs and expenses increased 10% to $364.1 million in 2014, compared to $332.1 million in 2013. This primarily reflects increased investment in our pipeline programs and clinical development efforts to explore additional potential applications of ADCETRIS, offset by decreased costs attributable to our ADCETRIS collaboration with Takeda. As of December 31, 2014, we had $313.4 million in cash, cash equivalents and short-term investments, and $210.8 million in total stockholders equity.

**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.

**Revenue Recognition**. Our revenues are comprised of ADCETRIS net product sales, amounts earned under our collaboration and licensing agreements and royalties. Revenue recognition is predicated upon persuasive

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evidence of an agreement existing, delivery of products or services being rendered, amounts payable being fixed or determinable, and collectibility being reasonably assured.

*Net product sales*

We sell ADCETRIS through a limited number of pharmaceutical distributors. Customers order ADCETRIS through these distributors and we typically ship product directly to the customer. We record product sales when title and risk of loss pass, which generally occurs upon delivery of the product to the customer. Product sales are recorded 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 our estimates that consider payer mix in target markets, industry benchmarks and experience to date. These estimates involve a substantial degree of judgment.

**Government-mandated rebates and chargebacks**: We have entered into a Medicaid Drug Rebate Agreement with the Centers for Medicare & Medicaid Services. This agreement provides for a rebate to participating states based on covered purchases of ADCETRIS. Medicaid rebates are invoiced to us by participating states. We estimate Medicaid rebates based on a third-party study of the payer mix for ADCETRIS, information on utilization by Medicaid-eligible patients who received assistance through SeaGen Secure, our patient assistance program, and experience to date. We also have completed our Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of ADCETRIS. 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 actual 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. We estimate product returns based on our experience to date. In addition, we consider our direct-ship distribution model, our belief that product is typically not 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 developed a proprietary technology for linking cytotoxic agents to monoclonal antibodies called antibody-drug conjugates, or ADCs. This proprietary technology is the basis of ADC collaborations that we have entered into in the ordinary course of our business with a number of biotechnology and pharmaceutical companies. Under these ADC collaboration agreements, we grant our collaborators research and commercial licenses to our technology and provide technology transfer services, technical advice, supplies and services for a period of time.

If there are continuing performance obligations, we use a time-based proportional performance model to recognize revenue over our performance period for the related agreement. Collaboration and license agreements

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are evaluated to determine whether the multiple elements and associated deliverables can be considered separate units of accounting. To date, the pre-commercial deliverables under our collaboration and license agreements have not qualified as separate units of accounting. The assessment of multiple element arrangements requires judgment in order to determine the appropriate point in time, or period of time, that revenue should be recognized. We believe that the development period used in each agreement is a reasonable estimate of the performance obligation period of such agreement. Accordingly, all amounts received or due, including any upfront payments, maintenance fees, development and regulatory milestone payments and reimbursement payments, are recognized as revenue over the performance obligation periods of each agreement. These performance obligation periods currently range from two to fourteen years. When no performance obligations are required of us, or following the completion of the performance obligation period, such amounts are recognized as revenue when collectibility is reasonably assured. Generally, all amounts received or due other than sales-based milestones and royalties are classified as collaboration and license agreement revenues as they are earned. Sales-based milestones and royalties are recognized as royalty revenue as they are reported to us.

Our collaboration and license agreements include contractual milestones. Generally, the milestone events contained in our collaboration and license agreements coincide with the progression of the collaborators product candidates from development to regulatory approval and then to commercialization and fall into the following categories.

Development milestones in our collaborations may include the following types of events:

- Designation of a product candidate or initiation of preclinical studies. Our collaborators must undertake significant preclinical research and studies to make a determination of the suitability of a product candidate and the time from those studies or designation to initiation of a clinical trial may take several years.

- Initiation of a phase 1 clinical trial. Generally, phase 1 clinical trials may take one to two years to complete.

- Initiation of a phase 2 clinical trial. Generally, phase 2 clinical trials may take one to three years to complete.

- Initiation of a phase 3 clinical trial. Generally, phase 3 clinical trials may take two to six years to complete.

Regulatory milestones in our collaborations may include the following types of events:

- Filing of regulatory applications for marketing approval such as a Biologics License Application in the United States or a Marketing Authorization Application in Europe. Generally, it may take up to twelve months to prepare and submit regulatory filings.

- Receiving marketing approval in a major market, such as in the United States, Europe, Japan or other significant countries. Generally it may take up to three years after a marketing application is submitted to obtain approval for marketing and pricing from the applicable regulatory agency.

Commercialization milestones in our collaborations may include the following types of events:

- First commercial sale in a particular market, such as in the United States, Europe, Japan or other significant countries.

Product sales in excess of a pre-specified threshold. The amount of time to achieve this type of milestone depends on several factors, including, but not limited to, the dollar amount of the threshold, the pricing of the product, market penetration of the product and the rate at which customers begin using the product.

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Our ADC collaborators are solely responsible for the development of their product candidates and the achievement of development, regulatory and commercial milestones in any of the categories identified above is based solely on the collaborators efforts.

In the case of our ADCETRIS collaboration with Takeda Pharmaceutical Company Limited ( 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.

The process of successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing a product candidate is highly uncertain and the attainment of any milestones is therefore uncertain and difficult to predict. In addition, 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. Similarly, even in those collaborations where we may have an active role in the development of the product candidate, such as our ADCETRIS collaboration with Takeda, the attainment of a milestone is based on the collaborator s activities and is generally outside of our direction and control.

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 when the applicable revenue recognition criteria have been met. 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 sales royalties, which are based on a percentage of Takeda s net sales at rates that range from the mid-teens to the mid-twenties based on sales volume, and commercial sales-based milestones. Takeda bears a portion of third-party royalty costs owed on its sales of ADCETRIS. This amount is included in royalty revenue in our consolidated financial statements. 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 quarter in which Takeda reports its sales activity to us, which is the quarter following the related sales. Royalty revenues also include certain amounts earned in connection with our ADC collaborations.

**Investments.** We have investments in debt securities in accordance with our investment policy. We classify our investments as available-for-sale, which are reported at estimated fair value with the related unrealized gains and losses included in accumulated other comprehensive income in stockholders equity. Realized gains and losses and declines in value of investments judged to be other-than-temporary are included in investment and other income, net. The fair value of our investments is subject to volatility. Declines in the fair value of our investments judged to be other-than-temporary could adversely affect our future operating results. We estimate fair values in accordance with a hierarchy prescribed by GAAP. This hierarchy prioritizes the inputs and assumptions used, and the valuation techniques used to measure fair value.

**Accrued Liabilities.** As part of the process of preparing financial statements, we are required to 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 fees due to contract research

organizations and other costs in conjunction with clinical trials, fees 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.

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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, lab supplies, drug manufacturing costs for our product candidates, and for ADCETRIS when used in research and clinical trials, contract and outside service fees and facilities and overhead expenses. Clinical trial expenses are a significant component of research and development expenses, and we outsource a significant portion of these costs to third parties. Our third party clinical trial expenses include investigator fees, site costs, clinical research organization costs, and costs for central laboratory testing and data management. Research and development activities are expensed as incurred. Costs associated with activities performed under research and development co-development collaborations are reflected in research and development expense. 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. Technology in-licensing fees, including milestones and maintenance fees, and other costs to acquire technologies for product candidates that have not yet received regulatory approval that are utilized in research and development and that are not expected to have alternative future use are expensed when incurred.

**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 charge this estimated fair value to expense over the vesting period of the arrangement using the graded-vesting attribution method for stock options which vest ratably over the vesting period.

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.

**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 assets will not be realized. 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 deferred tax asset would be made, a portion of which would increase income (or decrease losses) in the period in which such a determination was made.

**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 August 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 use in commercial sales. Production costs for our other product candidates continue to be charged to research and development expense.

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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.** In the normal course of business, we may become involved in various legal proceedings. 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.

On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, investments, accrued expenses, research and development, share-based compensation, income taxes, inventories and loss contingencies. 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.

**Results of Operations**

**Years Ended December 31, 2014, 2013 and 2012**

**Net product sales**

We sell ADCETRIS in the U.S. and Canada. Our net product sales were as follows ($ in thousands):

| | | | | Annual percentage change | |
|---|---|---|---|---|---|
| | 2014 | 2013 | 2012 | 2014/2013 | 2013/2012 |
| Net product sales | $ 178,198 | $ 144,665 | $ 138,200 | 23% | 5% |

Net product sales increased in 2014 compared to 2013 due to an increase in sales volume in 2014 and, to a lesser extent, from the effect of price increases in January and July of 2014. The increase in sales volume in 2014 was primarily driven by increased use of ADCETRIS across multiple lines of therapy for the treatment of Hodgkin lymphoma and sALCL and for treatment of other CD30-positive malignancies. Increased unit sales in Canada also contributed to the increase in sales volume. Canadian sales were augmented by the commencement of provincial reimbursement in Canada during 2014. The current approved label indications in the U.S. and Canada are (1) the treatment of patients with Hodgkin lymphoma after failure of ASCT, or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates, and (2) the treatment of patients with sALCL, after failure of at least one prior multi-agent chemotherapy regimen.

Net product sales increased in 2013 compared to 2012 due to a higher average selling price for ADCETRIS resulting from price increases that we instituted in January and July of 2013. Sales volumes decreased slightly from 2012 to 2013. We believe that the lower sales volume in the 2013 period was primarily due to the depletion of the prevalence pool of patients in ADCETRIS approved indications and the transition to an incidence-based flow of patients eligible for treatment with ADCETRIS.

We expect only moderate growth in ADCETRIS sales in 2015 compared to 2014. In this regard, we continue to expect that meaningful future ADCETRIS sales growth, if any, will be primarily dependent on our ability to expand the labeled indications of use.

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We record product sales net of estimated government-mandated rebates and chargebacks, distribution fees, product returns and other deductions. These are generally referred to as gross-to-net deductions. Gross-to-net deductions, net of related payments and credits, are summarized as follows:

| | December 31, 2014 | | | December 31, 2013 | | | December 31, 2012 | | |
|---|---|---|---|---|---|---|---|---|---|
| | Rebates & chargebacks | Distribution fees, product returns and other | Total | Rebates & chargebacks | Distribution fees, product returns and other | Total | Rebates & chargebacks | Distribution fees, product returns and other | Total |
| Balance, beginning of year | $ 4,525 | $ 1,523 | $ 6,048 | $ 4,131 | $ 1,601 | $ 5,732 | $ 895 | $ 1,036 | $ 1,931 |
| Provision related to current year sales | 31,541 | 4,370 | 35,911 | 19,794 | 3,538 | 23,332 | 14,999 | 3,790 | 18,789 |
| Adjustments for prior period sales | (913) | (62) | (975) | (938) | (148) | (1,086) | (412) | (14) | (426) |
| Payments/credits for current year sales | (28,038) | (3,753) | (31,791) | (17,495) | (2,812) | (20,307) | (11,195) | (2,502) | (13,697) |
| Payments/credits for prior year sales | (1,847) | (460) | (2,307) | (967) | (656) | (1,623) | (156) | (709) | (865) |
| Balance, end of year | $ 5,268 | $ 1,618 | $ 6,886 | $ 4,525 | $ 1,523 | $ 6,048 | $ 4,131 | $ 1,601 | $ 5,732 |

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 2014 and 2013 as a result of price increases we have instituted that exceeded the rate of inflation. 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 implemented a price increase at the beginning of 2015. As a result of this price increase, we expect gross-to-net deductions to increase in 2015. Distribution fees, product returns and other gross to net deductions were virtually unchanged as a percentage of our gross sales among the three years presented above.

**Collaboration and license agreement revenues**

Collaboration and license agreement revenues reflect amounts earned under product collaborations and ADC collaboration and co-development agreements. These revenues reflect the earned portion of payments received by us including technology access and maintenance fees, milestone payments and reimbursement payments for research and development support we provide to our collaborators. Collaboration and license agreement revenues are summarized by collaborator as follows:

| Collaboration and license agreement revenues by collaborator ($ in thousands) | | | | Annual percentage change | |
|---|---|---|---|---|---|
| | 2014 | 2013 | 2012 | 2014/2013 | 2013/2012 |
| Takeda | $ 31,787 | $ 41,529 | $ 36,021 | (23%) | 15% |
| AbbVie | 14,851 | 22,924 | 9,839 | (35%) | 133% |
| Genentech | 7,791 | 8,438 | 6,174 | (8%) | 37% |
| Bayer | 5,062 | 12,000 | 0 | (58%) | N/A |
| Other | 9,065 | 21,890 | 15,513 | (59%) | 41% |
| Total | $ 68,556 | $ 106,781 | $ 67,547 | (36%) | 58% |

Revenues earned under our ADCETRIS and ADC collaborations with Takeda represented 46% of our collaboration and license agreement revenues in 2014, 39% in 2013 and 53% in 2012. Revenues from Takeda decreased in 2014 due to lower development cost reimbursements earned and drug supply activities under the ADCETRIS collaboration, offset partially by the earned amount of regulatory milestones achieved. The lower development cost reimbursements reflect an increase in collaboration activities performed by Takeda in 2014. The lower drug supply activities in 2014 are the result of Takeda developing independent supply relationships for its manufacture of ADCETRIS. Revenues from Takeda increased in 2013 from 2012 primarily as a result of amounts earned under the ADCETRIS collaboration, particularly as a result of the earned portion of net development cost reimbursements received by us for clinical trial and drug supply activities.

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Revenues from our other collaboration agreements, which include our ADC collaborations and our co-development collaborations, decreased in 2014 as compared to 2013 primarily as a result of fees associated with the extension of an ADC collaboration agreement in 2013, accelerated revenue recognition related to early termination of the development period under our co-development collaboration with Agensys during 2013, and a decrease in the earned portion of development milestones achieved by our ADC collaborators in 2014 compared to 2013. Revenues from our other collaboration agreements increased in 2013 as compared to 2012 primarily as a result of our entering a new ADC collaboration agreement with Bayer in June 2013, an expansion of the AbbVie ADC collaboration in both December 2013 and October 2012, and an increase in the earned portion of license fees and milestones achieved in 2013 by our collaborators.

Our collaboration and license agreement revenues are impacted by the term and duration of our collaboration agreements and by progress-dependent milestones, annual maintenance fees and reimbursement of materials and support services. Collaboration and license agreement revenues may vary substantially from year to year and quarter to quarter depending on the progress made by our collaborators with their product candidates, the level of support we provide to our collaborators, specifically to Takeda under our ADCETRIS collaboration, the timing of milestones achieved and our ability to enter into additional collaboration and co-development agreements. We expect our collaboration and license agreement revenues in 2015 to remain relatively consistent with 2014. We expect development funding from Takeda to decrease as a result of the level of development activities expected to be performed by Takeda under the ADCETRIS collaboration. This should be offset by the earned portion of development milestones achieved from our other collaborations. We have a significant balance of deferred revenue, representing prior payments from our collaborators that have not yet been recognized as revenue. This deferred revenue will be recognized as revenue in future periods using a time-based approach as we fulfill our performance obligations.

***Collaboration Agreements***

*Takeda*

The ADCETRIS collaboration provides for the global co-development of ADCETRIS by the companies and the commercialization of ADCETRIS by Takeda in its territory. We received a $60 million upfront payment and are entitled to receive progress-dependent milestone payments based on Takeda s achievement of certain events related to ADCETRIS development. Additionally, the companies equally co-fund the cost of development activities conducted under the collaboration. We recognize as collaboration revenue the upfront payment, progress-dependent development and regulatory milestone payments, and net development cost reimbursement payments from Takeda over the ten-year development period of the collaboration which began in December 2009. When the performance of development activities under the collaboration results in us making a reimbursement payment to Takeda, the effect is to reduce the amount of collaboration revenue that we record. We also receive reimbursement for the cost of drug product supplied to Takeda for its use and, in some cases, pay Takeda for drug product they supply to us. The earned portion of such payments received is also reflected as a component of collaboration revenue. We expect that development activities performed by Takeda will continue to exceed activities that we perform, particularly with respect to the conduct of clinical trials of ADCETRIS.

As of December 31, 2014, total future potential milestone payments to us under the ADCETRIS collaboration could total approximately $185 million. Of the remaining amount, up to approximately $7 million relates to the achievement of development milestones, up to approximately $118 million relates to the achievement of regulatory milestones and up to approximately $60 million relates to the achievement of commercial milestones. To date, $50 million in milestones have been achieved as a result of regulatory and commercial progress by Takeda.

*Agensys Co-Development Collaboration*

In January 2007, we entered into an agreement with Agensys to jointly research, develop and commercialize ADCs for the treatment of cancer. The collaboration encompasses combinations of our ADC technology with

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fully-human antibodies developed by Agensys to proprietary cancer targets. Under this collaboration, Agensys is conducting research and development aimed at identifying ADC product candidates for multiple designated antigens as well as clinical trials on various ADC product candidates.

The co-development provisions of the collaboration agreement included an initial co-development product candidate, ASG-5ME, and provided us with two options to co-develop additional product candidates. We have exercised all of our co-development options and are currently co-developing ASG-22ME and ASG-15ME. Development of ASG-5ME has been discontinued. We and Agensys are co-funding all development and commercialization costs for both ASG-22ME and ASG-15ME, and will share equally in any profits from these product candidates.

Agensys has the right to develop and commercialize other ADC product candidates on its own, subject to paying us annual maintenance fees, milestones, royalties and support fees for research and development services and material provided under the collaboration agreement.

*ADC Collaboration Agreements*

We have other active collaborations with a number of companies to allow them to use our proprietary ADC technology. Under our ADC collaborations we typically receive or are entitled to receive upfront cash payments, progress-dependent milestones and royalties on net sales of products incorporating our ADC technology, as well as annual maintenance fees and support fees for research and development services and materials provided under the agreements. These amounts are recognized as revenue as they are realized, or over the performance obligation period of the agreements during which we provide limited support to the collaborator, if any. Our ADC collaborators are responsible for development, manufacturing and commercialization of any ADC product candidates that result from the collaborations and are solely responsible for the achievement of any of the potential milestones under these collaborations.

As of December 31, 2014, our ADC collaborations and co-development agreements had generated over $300 million in collaboration and license agreement revenues, primarily in the form of upfront payments. Total milestone payments to us under our current ADC and co-development collaborations could total up to approximately $4.7 billion if all potential product candidates achieved all of their milestone events. Of this amount, approximately $0.8 billion relates to the achievement of development milestones, approximately $1.9 billion relates to the achievement of regulatory milestones and approximately $2.0 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. In addition, most of our current collaborations are at early stages of development. 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 in a collaborator abandoning or delaying development of its product candidates. As such, the milestone payments associated with our ADC and co-development collaborations involve a substantial degree of risk to achieve 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 collaborations.

**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, which are based on a percentage of Takeda s net sales at 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 sales of ADCETRIS in its territory. This amount is included in our royalty revenues. In October 2012, Takeda began its commercial launch of ADCETRIS in the European

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Union upon receiving conditional marketing authorization from the European Commission for ADCETRIS in two indications. Takeda has since received regulatory approval in additional countries and, where applicable, Takeda also made ADCETRIS available under its international named patient program. Our royalty revenues and cost of royalty revenues were as follows ($ in thousands):

| | | | | Annual percentage change | |
|---|---|---|---|---|---|
| | 2014 | 2013 | 2012 | 2014/2013 | 2013/2012 |
| Royalty revenues | $ 40,004 | $ 17,818 | $ 5,065 | 125% | 252% |
| Cost of royalty revenues | 11,545 | 7,385 | 1,923 | 56% | 284% |

Royalty revenues and cost of royalty revenues increased in 2014 primarily as a result of regulatory approvals of ADCETRIS in additional countries in 2014, as well as increases in the royalty rate based on sales volumes. Royalty revenues in 2014 also included a $5 million sales milestone triggered by Takeda. Royalty revenues from Takeda and cost of royalty revenues increased in 2013 primarily as a result of a full year of commercial sales in the European Union and regulatory approvals of ADCETRIS in additional countries in 2013. We expect that royalty revenues and cost of royalties will increase in 2015 as compared to 2014, primarily as a result of increased commercialization efforts by Takeda in the additional countries where it has received regulatory approvals.

**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. We began capitalizing ADCETRIS manufacturing costs as inventory following the accelerated approval of ADCETRIS by the FDA. The cost of product manufactured prior to FDA approval was expensed as research and development expense as incurred and was combined with other research and development expenses. While we track the quantities of individual ADCETRIS product lots, we did not track pre-FDA approval manufacturing costs in our inventory system and therefore the manufacturing cost of ADCETRIS produced prior to FDA approval is not reasonably determinable. Most of the product produced prior to FDA approval became available for us to use commercially as well as for use in research and development. We expect that our cost of sales as a percentage of sales will continue to increase in future periods as any remaining product manufactured prior to FDA approval, and therefore fully expensed previously, is consumed. This cost benefit is expected to continue to a lesser extent over the next twelve months, but is expected to decline based on when the components of the specific drug lots sold were produced and when they are consumed. The time period over which this reduced-cost inventory is consumed will depend on a number of factors, including the amount of future ADCETRIS sales, the ultimate use of this inventory in commercial sales, clinical development or other research activities, and the ability to utilize inventory prior to its expiration date. We expect, as this reduced-cost inventory is used, the percentage of total cost of sales for sales of ADCETRIS will increase into the low-to-mid teens. Cost of sales increased during 2014, 2013 and 2012 due to a higher average cost of product sold and, in 2014 and 2012, increased sales volumes.

**Research and development**

Our research and development expenses are summarized as follows:

| Research and development ($ in thousands) | | | | Annual percentage change | |
|---|---|---|---|---|---|
| | 2014 | 2013 | 2012 | 2014/2013 | 2013/2012 |
| Research | $ 28,698 | $ 27,844 | $ 17,409 | 3% | 60% |
| Development and contract manufacturing | 83,326 | 89,853 | 60,780 | (7%) | 48% |
| Clinical | 118,719 | 100,930 | 92,108 | 18% | 10% |

| | | | | | |
|---|---|---|---|---|---|
| Total research and development expenses | $ 230,743 | $ 218,627 | $ 170,297 | 6% | 28% |

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Research expenses include, among other things, personnel, occupancy and laboratory expenses and technology access fees associated with the discovery and identification of new monoclonal antibodies and related technologies and the development of novel classes of stable linkers and cell-killing agents for our ADC technology. Research expenses also include research activities associated with our product candidates, such as preclinical translational biology and *in vitro* and *in vivo* studies. The increase in research expenses in 2014 reflects increases in compensation costs due to increased staffing levels and increased discovery activities in support of our growing pipeline of product candidates. The increase in research expenses in 2013 reflects increased discovery activities, an opt in fee we paid to co-develop ASG-15ME, expansion of our laboratory facilities, and increased compensation related costs.

Development and contract manufacturing expenses include personnel and occupancy expenses and external contract manufacturing costs for the scale up and pre-approval manufacturing of drug product used in research and our clinical trials and for drug product supplied to our collaborators. Development and contract manufacturing expenses also include quality control and assurance activities, and storage and shipment of our product candidates. The 2014 decrease in development and contract manufacturing expenses resulted primarily from a decrease in drug product supplied to Takeda under the ADCETRIS collaboration as compared to 2013, partially offset by increases in activities to support our growing pipeline of product candidates and an increase in compensation-related costs. The 2013 increase in development and contract manufacturing expenses resulted primarily from an increase in the amount of drug product provided to Takeda under the ADCETRIS collaboration. Costs also increased during 2013 due to costs from the expansion of our laboratory facilities, and an increase in compensation-related costs.

Clinical expenses include personnel expenses, travel, occupancy costs and external clinical trial costs including clinical site expenses, clinical research organization charges, contractors and regulatory activities associated with conducting human clinical trials, including investigational new drug, or IND, enabling pharmacology and toxicology studies. The increase in clinical expenses in both 2014 and 2013 reflects increased clinical trial activity for ADCETRIS and our other product candidates. In addition, compensation and related costs increased in both 2014 and 2013 as a result of increased staffing levels.

We utilize our employee and infrastructure resources across multiple development projects as well as our discovery and research programs directed towards identifying monoclonal antibodies and new classes of stable linkers and cell-killing agents for our ADC program. 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-by-project basis as it relates to our infrastructure, facility, employee and other indirect costs. We do, however, separately track significant third-party costs including clinical trial costs, manufacturing costs and other contracted service costs on a project-by-project basis.

The following table shows expenses incurred for research, contract manufacturing of our product candidates and clinical and regulatory services provided by third parties as well as pre-commercial milestone payments for in-licensed technology for ADCETRIS and each of our clinical-stage product candidates. The table also presents other third-party costs and overhead consisting of personnel, facilities and other indirect costs not directly charged to these development programs.

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| Product candidates ($ in thousands) | 2014 | 2013 | 2012 | Annual percentage change 2014/2013 | Annual percentage change 2013/2012 | (5 years) January 1, 2010 to December 31, 2014 |
|---|---|---|---|---|---|---|
| ADCETRIS (brentuximab vedotin) | $ 53,473 | $ 71,167 | $ 41,392 | (25%) | 72% | $ 272,751 |
| SGN-CD33A | 7,371 | 3,084 | 12,200 | 139% | (75%) | 23,151 |
| SGN-CD19A | 7,276 | 6,087 | 3,739 | 20% | 63% | 28,125 |
| SGN-CD70A | 3,819 | 6,430 | 1,159 | (41%) | 455% | 11,408 |
| SGN-LIV1A | 2,481 | 2,478 | 6,012 | 0% | (59%) | 11,012 |
| ASG-22ME | 2,100 | 2,410 | 6,016 | (13%) | (60%) | 16,965 |
| ASG-15ME | 1,596 | 5,780 | 0 | (72%) | N/A | 7,376 |
| Total third-party costs | 78,116 | 97,436 | 70,518 | (20%) | 38% | 370,788 |
| Other costs and overhead | 152,627 | 121,191 | 99,779 | 26% | 21% | 558,685 |
| Total research and development | $ 230,743 | $ 218,627 | $ 170,297 | 6% | 28% | $ 929,473 |

Third-party costs for ADCETRIS decreased in 2014 primarily due to a decrease in activities related to drug product supplied to Takeda, partially offset by increased clinical trial costs driven primarily by the ongoing ECHELON-2 trial. Third-party costs for ADCETRIS increased in 2013 due to increased collaboration activities related to drug supply to Takeda and increased clinical trial activity, including costs for the ongoing ECHELON-2 trial.

The development costs for our product candidates typically accelerate in preparation for an IND submission to the FDA and then decrease until the subsequent clinical trials commence. The decrease in costs for SGN-CD70A from 2013 to 2014, the increase in costs for SGN-CD70A from 2012 to 2013, and the decreases in costs for SGN-CD33A, ASG-22ME and SGN-LIV1A from 2012 to 2013 reflect this pattern of increased costs in preparation for an IND followed by a reduction in cost following the related IND submissions.

Third-party costs for SGN-CD33A increased in 2014 due to increased clinical trial costs for ongoing studies and additional drug supply activities.

Third-party costs for SGN-CD19A increased in 2014 and 2013 due to increasing costs for ongoing clinical trial activity.

Our ASG-15ME and ASG-22ME product candidates are being co-developed with Agensys. The costs for these programs include an opt in fee and our share of the related development costs subsequent to our opt in. The opt in fees for ASG-15ME and ASG-22ME were incurred in 2013 and 2011, respectively.

Other costs and overhead include third-party costs of our other programs which are primarily in the pre-clinical phase and costs associated with personnel and facilities. The overall increase reflects increasing efforts on our earlier-stage pipeline programs. These costs increased during 2014 reflecting a $10.2 million increase in third-party costs attributable to our other programs, as well as a $13.6 million increase in compensation related costs due to an increase in our staffing levels and an increase of approximately $3.9 million in the cost of laboratory facilities. These costs also increased during 2013 reflecting a $2.8 million increase in third-party costs attributable to our other programs, as well as a $7.9 million increase in compensation related costs due to an increase in our staffing levels and an increase of approximately $7.0 million in the cost of additional laboratory facilities in 2013.

Our expenditures on our ADCETRIS clinical development program and on our current and future preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. 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

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upon the type, complexity, novelty and intended use of a product candidate. Likewise, in order to expand ADCETRIS labeled indications of use, we are required to conduct additional extensive clinical studies. 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.

Reports of adverse events or safety concerns involving ADCETRIS and our product candidates could interrupt, delay or halt clinical trials of ADCETRIS and our product candidates, including the ADCETRIS post-approval confirmatory studies that are required as a condition to our regulatory approvals.

Our strategy has included entering into collaborations with third parties. In these situations, the preclinical development or clinical trial process for a product candidate and the estimated completion date are largely under the control of that third party and not under our control. We cannot forecast with any degree of certainty which of our product candidates will be subject to future collaborations or how such arrangements would affect our development plans or capital requirements.

We anticipate that our total research and development expenses in 2015 will increase compared to 2014 due to increased clinical trial expenses for ADCETRIS related to studies to evaluate other potential uses of ADCETRIS, some of which are required post-approval confirmatory studies, and as a result of amounts incurred to continue the development of our product candidates. 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 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**

| Selling, general and administrative ($ in thousands) | 2014 | 2013 | 2012 | Annual percentage change 2014/2013 | Annual percentage change 2013/2012 |
|---|---|---|---|---|---|
| Selling, general and administrative | $ 104,320 | $ 92,354 | $ 84,300 | 13% | 10% |

Selling, general and administrative expenses in 2014 primarily reflect a $9.8 million increase in compensation related costs and an increase in fees related to ongoing legal matters as compared to 2013. Selling, general and administrative expenses in 2013 primarily reflect an $8.2 million increase in compensation related costs as compared to 2012.

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We anticipate that selling, general and administrative expenses will increase in 2015 compared to 2014 as we continue our commercial activities in support of the commercialization of ADCETRIS, as well as our support of general operations.

**Investment and other income, net**

| Investment and other income, net ($ in thousands) | 2014 | 2013 | 2012 |
|---|---|---|---|
| Total | $ 1,222 | $ 341 | $ 3,472 |

Investment and other income, net increased in 2014 compared to 2013. The increase in investment income in 2014 primarily reflects the gain on the sale of a security. Investment and other income, net decreased in 2013 compared to 2012 as the 2012 amount includes a recovery from a former investment advisor in settlement of claims we made against the advisor.

**Liquidity and capital resources**

| | December 31, | | |
|---|---|---|---|
| Selected balance sheet and cash flow data ($ in thousands) | 2014 | 2013 | 2012 |
| Cash, cash equivalents and short-term investments | $ 313,413 | $ 374,267 | $ 364,258 |
| Working capital | 282,093 | 338,058 | 340,283 |
| Stockholders equity | 210,834 | 230,185 | 226,148 |

| | Years ended December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| Cash provided by (used in): | | | |
| Operating activities | $ (59,999) | $ (1,110) | $ 10,881 |
| Investing activities | 36,622 | (24,636) | (79,576) |
| Financing activities | 16,188 | 35,199 | 35,724 |

The changes in net cash used in operating activities are primarily related to our net loss, working capital fluctuations and changes in our non-cash expenses. Fluctuations in cash provided by (used in) operating activities among the three years presented resulted from changes in these three factors, particularly working capital, which is highly variable. The changes in cash provided by investing activities reflects differing amounts incurred for capital expenditures and differences between the proceeds received from sale and maturity of our investments and amounts reinvested. Net cash provided by financing activities resulted from the proceeds of stock option exercises and our employee stock purchase plan.

We have financed the majority of our operations through the issuance of equity securities, by amounts received pursuant to product collaborations, our ADC collaborations and through collections from commercial sales of ADCETRIS. To a lesser degree, we have also financed our operations through royalty revenues and interest earned on cash, cash equivalents and investment securities. These financing and revenue sources have historically allowed us to maintain adequate levels of cash and investments.

Our cash, cash equivalents, and short-term 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

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portfolio prior to their scheduled maturities, which may result in a loss. As of December 31, 2014, we had $313.4 million held in cash reserves or investments scheduled to mature within the next twelve months.

At our currently planned spending rates we believe that our 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. 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 required post-approval studies and additional studies to potentially expand ADCETRIS labeled indications of use or to advance our other ADC pipeline programs. Further, 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. Any of these factors could lead to a need for us to raise additional capital.

We are required to conduct additional confirmatory and safety phase 3 post-approval studies of ADCETRIS as part of our regulatory approvals. These are large studies that are being conducted over a lengthy period of time and although we have commenced these studies, based on the expected length of these studies and the inherent uncertainty of clinical trial costs, we may be required to raise additional capital in order to complete the studies. In this regard, whether we have sufficient funding to complete these studies will be partially dependent upon cash received from sales of ADCETRIS, which may not be sufficient to complete these studies. Our inability to obtain funds sufficient to complete these studies and establish confirmatory evidence of efficacy for ADCETRIS would have material adverse consequences to us, including the loss of marketing approval for ADCETRIS. These required post-approval studies will also continue to significantly increase our clinical trial expenses, which could increase our losses and/or negatively impact our ability to achieve or maintain profitability.

We expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees and support our preclinical development, manufacturing and clinical trial activities, including the post-approval studies we are required to and are currently conducting for ADCETRIS, as well as position ADCETRIS for potential additional regulatory approvals, and we may therefore need to raise significant amounts of additional capital. 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.

***Commitments***

The following table reflects our future minimum contractual commitments as of December 31, 2014 (in thousands):

| | Total | 2015 | 2016 | 2017 | 2018 | 2019 | Thereafter |
|---|---|---|---|---|---|---|---|
| Operating leases | $ 22,768 | $ 5,017 | $ 5,184 | $ 5,348 | $ 3,010 | $ 753 | $ 3,456 |
| Tenant improvements | 617 | 617 | 0 | 0 | 0 | 0 | 0 |
| Manufacturing, license & collaboration agreements | 127,260 | 45,051 | 13,532 | 15,163 | 14,700 | 14,824 | 23,990 |
| Total | $ 150,645 | $ 50,685 | $ 18,716 | $ 20,511 | $ 17,710 | $ 15,577 | $ 27,446 |

We have entered into leases for our office and laboratory facilities expiring in 2018 through 2024 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.

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A substantial portion of the minimum payments under manufacturing, license and collaboration agreements represents contractual obligations 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 low to mid single-digit royalties 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. The above table also excludes up to approximately $61.1 million in potential future milestone payments to third parties under license agreements for ADCETRIS and our clinical-stage development programs, which generally become due and payable only upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones. Milestone payments under these agreements through December 31, 2014 have totaled $12.6 million. 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***

In May 2014, the Financial Accounting Standards Board issued an accounting standards update entitled ASU 2014-09, Revenue from Contracts with Customers. The standard requires entities to recognize revenue through an evaluation that includes identification of the contract, identification of the performance obligations, determination of the transaction price, allocation of the transaction price to the performance obligations, and recognition of revenue as the entity satisfies the performance obligations. The standard will become effective for us beginning January 1, 2017. We are currently evaluating the guidance to determine the potential impact on our financial condition, results of operations and cash flows, and financial statement disclosures.

**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 do not have any derivative financial instruments in our investment portfolio. We currently have holdings in U.S. Treasury securities. Our investment securities consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Short-term investments | $ 256,486 | $ 310,151 |

We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of $1.0 million in the fair value of our investments as of December 31, 2014. In addition, a hypothetical decrease of 10% in the effective yield of our investments would reduce our expected investment income by less than $0.1 million over the next twelve months based on our investment balance at December 31, 2014.

***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, 2014, primarily related to contract manufacturing and ex-U.S. clinical trial activities, and we expect to continue to do so. 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**

**Seattle Genetics, Inc.**

**Index to Financial Statements**

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of

Seattle Genetics, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of comprehensive loss, stockholders equity and cash flows present fairly, in all material respects, the financial position of Seattle Genetics, Inc. and its subsidiary at December 31, 2014 and 2013 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 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, 2014, based on criteria established in *Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for these 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 these financial statements and on the Company s internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. 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.

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 27, 2015

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**Seattle Genetics, Inc.**

**Consolidated Balance Sheets**

**(In thousands, except par value)**

| | December 31, 2014 | December 31, 2013 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 56,927 | $ 64,116 |
| Short-term investments | 256,486 | 310,151 |
| Accounts receivable, net | 39,248 | 29,508 |
| Inventories | 43,451 | 27,073 |
| Prepaid expenses and other current assets | 11,874 | 6,408 |
| Total current assets | 407,986 | 437,256 |
| Property and equipment, net | 46,129 | 40,787 |
| Other non-current assets | 4,850 | 5,855 |
| Total assets | $ 458,965 | $ 483,898 |
| **Liabilities and Stockholders Equity** | | |
| Current liabilities | | |
| Accounts payable and accrued liabilities | $ 77,681 | $ 59,348 |
| Current portion of deferred revenue | 48,212 | 39,850 |
| Total current liabilities | 125,893 | 99,198 |
| Long-term liabilities | | |
| Deferred revenue, less current portion | 117,648 | 149,191 |
| Deferred rent and other long-term liabilities | 4,590 | 5,324 |
| Total long-term liabilities | 122,238 | 154,515 |
| Commitments and contingencies | | |
| Stockholders equity | | |
| Preferred stock, $0.001 par value, 5,000 shares authorized; none issued | 0 | 0 |
| Common stock, $0.001 par value, 250,000 shares authorized; 123,973 shares issued and outstanding at December 31, 2014 and 122,615 shares issued and outstanding at December 31, 2013 | 124 | 123 |
| Additional paid-in capital | 1,017,182 | 960,375 |
| Accumulated other comprehensive loss | (29) | (11) |
| Accumulated deficit | (806,443) | (730,302) |
| Total stockholders equity | 210,834 | 230,185 |
| Total liabilities and stockholders equity | $ 458,965 | $ 483,898 |

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, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| Revenues | | | |
| Net product sales | $ 178,198 | $ 144,665 | $ 138,200 |
| Collaboration and license agreement revenues | 68,556 | 106,781 | 67,547 |
| Royalty revenues | 40,004 | 17,818 | 5,065 |
| Total revenues | 286,758 | 269,264 | 210,812 |
| Costs and expenses | | | |
| Cost of sales | 17,513 | 13,759 | 11,546 |
| Cost of royalty revenues | 11,545 | 7,385 | 1,923 |
| Research and development | 230,743 | 218,627 | 170,297 |
| Selling, general and administrative | 104,320 | 92,354 | 84,300 |
| Total costs and expenses | 364,121 | 332,125 | 268,066 |
| Loss from operations | (77,363) | (62,861) | (57,254) |
| Investment and other income, net | 1,222 | 341 | 3,472 |
| Net loss | $ (76,141) | $ (62,520) | $ (53,782) |
| Net loss per share basic and diluted | $ (0.62) | $ (0.51) | $ (0.46) |
| Shares used in computation of net loss per share basic and diluted | 123,408 | 121,575 | 117,851 |
| Comprehensive loss: | | | |
| Net loss | $ (76,141) | $ (62,520) | $ (53,782) |
| Other comprehensive gain (loss) unrealized gain (loss) on securities available for sale | (18) | (48) | 17 |
| Comprehensive loss | $ (76,159) | $ (62,568) | $ (53,765) |

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, 2011 | 116,023 | $ 116 | $ 832,713 | $ 20 | $ (614,000) | $ 218,849 |
| Net loss | 0 | 0 | 0 | 0 | (53,782) | (53,782) |
| Other comprehensive income | 0 | 0 | 0 | 17 | 0 | 17 |
| Issuance of common stock for employee stock purchase plan | 288 | 0 | 4,284 | 0 | 0 | 4,284 |
| Stock option exercises | 3,399 | 4 | 31,436 | 0 | 0 | 31,440 |
| Share-based compensation | 0 | 0 | 25,340 | 0 | 0 | 25,340 |
| Balances at December 31, 2012 | 119,710 | 120 | 893,773 | 37 | (667,782) | 226,148 |
| Net loss | 0 | 0 | 0 | 0 | (62,520) | (62,520) |
| Other comprehensive loss | 0 | 0 | 0 | (48) | 0 | (48) |
| Issuance of common stock for employee stock purchase plan | 196 | 0 | 4,566 | 0 | 0 | 4,566 |
| Stock option exercises | 2,600 | 3 | 30,630 | 0 | 0 | 30,633 |
| Restricted stock vested during the period, net | 109 | 0 | 0 | 0 | 0 | 0 |
| Share-based compensation | 0 | 0 | 31,406 | 0 | 0 | 31,406 |
| Balances at December 31, 2013 | 122,615 | 123 | 960,375 | (11) | (730,302) | 230,185 |
| Net loss | 0 | 0 | 0 | 0 | (76,141) | (76,141) |
| Other comprehensive loss | 0 | 0 | 0 | (18) | 0 | (18) |
| Issuance of common stock for employee stock purchase plan | 150 | 0 | 4,939 | 0 | 0 | 4,939 |
| Stock option exercises | 886 | 1 | 11,249 | 0 | 0 | 11,250 |
| Restricted stock vested during the period, net | 322 | 0 | 0 | 0 | 0 | 0 |
| Share-based compensation | 0 | 0 | 40,619 | 0 | 0 | 40,619 |
| Balances at December 31, 2014 | 123,973 | $ 124 | $ 1,017,182 | $ (29) | $ (806,443) | $ 210,834 |

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, | | |
|---|---|---|---|
| | **2014** | **2013** | **2012** |
| **Operating activities** | | | |
| Net loss | $ (76,141) | $ (62,520) | $ (53,782) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities | | | |
| Share-based compensation | 40,619 | 31,406 | 25,340 |
| Depreciation and amortization | 12,490 | 8,615 | 6,159 |
| Amortization of premiums, accretion of discounts and gain (loss) on investments | (150) | 1,883 | 2,574 |
| Changes in operating assets and liabilities | | | |
| Accounts receivable, net | (9,740) | 3,935 | 21,512 |
| Inventories | (16,378) | 10,674 | (28,278) |
| Prepaid expenses and other assets | (5,232) | (1,817) | (1,551) |
| Accounts payable and accrued liabilities | 18,448 | 1,493 | 3,082 |
| Deferred rent and other long-term liabilities | (734) | (606) | 716 |
| Deferred revenue | (23,181) | 5,827 | 35,109 |
| Net cash provided by (used in) operating activities | (59,999) | (1,110) | 10,881 |
| **Investing activities** | | | |
| Purchases of securities available for sale | (451,274) | (483,182) | (505,066) |
| Proceeds from maturities of securities available for sale | 504,100 | 480,700 | 425,151 |
| Proceeds from sales of securities available for sale | 972 | 0 | 10,824 |
| Purchases of property and equipment | (17,176) | (22,154) | (10,485) |
| Net cash provided by (used in) investing activities | 36,622 | (24,636) | (79,576) |
| **Financing activities** | | | |
| Proceeds from exercise of stock options and employee stock purchase plan | 16,188 | 35,199 | 35,724 |
| Net cash provided by financing activities | 16,188 | 35,199 | 35,724 |
| Net increase (decrease) in cash and cash equivalents | (7,189) | 9,453 | (32,971) |
| Cash and cash equivalents at beginning of year | 64,116 | 54,663 | 87,634 |
| Cash and cash equivalents at end of year | $ 56,927 | $ 64,116 | $ 54,663 |

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 Basis of Presentation**

*Organization*

The Company is a biotechnology company focused on the development and commercialization of targeted therapies for the treatment of cancer. The Company s marketed product ADCETRIS®, or brentuximab vedotin, is an antibody-drug conjugate, or ADC, comprising an anti-CD30 monoclonal antibody attached by a protease-cleavable linker to a microtubule disrupting agent, monomethyl auristatin E (MMAE), utilizing the Company s proprietary technology.

*Basis of presentation*

The accompanying consolidated financial statements reflect the accounts of Seattle Genetics, Inc. and its wholly-owned subsidiary, Seattle Genetics UK, Ltd. (collectively Seattle Genetics or the Company ). The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). All significant intercompany transactions and balances have been eliminated. The Company operates in one reporting segment: the development and commercialization of pharmaceutical products on its own behalf or in collaboration with others.

*Capital Requirements*

To execute the Company s growth plans, it 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 the Company cannot maintain adequate funds, it may be required to delay, reduce the scope of or eliminate one or more of its development programs. Additional financing may not be available when needed, or if available, the Company may not be able to obtain financing on favorable terms.

*Use of estimates*

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America, or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities at the date of the financial statements, and that affect the reported amounts of revenues, costs and expenses during the reporting period. Actual results could differ from those estimates.

**2. Significant Accounting Policies**

*Cash and cash equivalents*

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

*Non-cash investing activities*

The Company had $1.6 million and $1.7 million of accrued capital expenditures as of December 31, 2014 and December 31, 2013, respectively. Accrued capital expenditures have been treated as a non-cash investing activity and, accordingly, are not reflected in the statement of cash flows.

*Investments*

The Company classifies its securities as available-for-sale, which are reported at estimated fair value with unrealized gains and losses included in accumulated other comprehensive loss in stockholders equity. Realized gains, realized losses and declines in the value of securities judged to be other-than-temporary, are included in investment and other income, net. The cost of investments for purposes of computing realized and unrealized

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

gains and losses is based on the specific identification method. Amortization of premiums and accretion of discounts are included in investment and other income, net. Interest and dividends earned on all securities are included in investment and other income, net. Investments in securities with maturities of less than one year, or where management s intent is to use the investments to fund current operations, or to make them available for current operations, are classified as short-term investments.

If the estimated fair value of a security is below its carrying value, the Company evaluates whether it is more likely than not that it 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. The Company also evaluates whether or not it intends 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, the Company considers 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 charged against investment and other income, net.

*Inventories*

The Company considers regulatory approval of product candidates to be uncertain. Accordingly, it charges manufacturing costs to research and development expense until such time as a product has received regulatory approval for commercial sale. Following approval by the FDA in August 2011, ADCETRIS production costs 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 the Company s other product candidates continue to be charged to research and development expense.

The Company values its 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 the Company identifies excess, obsolete or unsalable inventory, its value is written down to net realizable value.

*Property and equipment*

Property and equipment are stated at cost and are depreciated using the straight-line method over the estimated useful lives of the assets, which are generally as follows:

| | Years |
|---|---|
| Laboratory equipment | 5 |
| Furniture and fixtures | 5 |

| | |
|---|---|
| Computers, software and office equipment | 3 |

Leasehold improvements are amortized over the shorter of the remaining lease 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 the consolidated statement of comprehensive loss at the time of disposition and have not been significant. Expenditures for additions and improvements to the Company s facilities are capitalized and expenditures for maintenance and repairs are charged to expense as incurred. Concessions received by the Company 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.

*Impairment of long-lived assets*

The Company assesses the impairment of long-lived assets, primarily property and equipment and intangible assets, included in other non-current assets, whenever events or changes in business circumstances

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

indicate that the carrying amounts of the assets may not be fully recoverable. When such events occur, management determines 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. The Company has not recognized any impairment losses through December 31, 2014 as there have been no events warranting an impairment analysis. The Company s long-lived assets are located in the United States.

*Revenue recognition*

The Company s revenues are comprised of ADCETRIS net product sales, amounts earned under its collaboration and licensing agreements and royalties. Revenue recognition is predicated upon persuasive evidence of an agreement existing, delivery of products or services being rendered, amounts payable being fixed or determinable, and collectibility being reasonably assured.

*Net product sales*

The Company sells ADCETRIS through a limited number of pharmaceutical distributors in the U.S. and Canada. Customers order ADCETRIS through these distributors and the Company typically ships product directly to the customer. The Company records product sales when title and risk of loss pass, which generally occurs upon delivery of the product to the customer. Product sales are recorded 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. The Company reflects 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 payer mix in target markets, industry benchmarks and experience to date. These estimates involve a substantial degree of judgment.

**Government-mandated rebates and chargebacks**: The Company has 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 the Company by the various state programs. The Company estimates Medicaid rebates based on a third-party study of the payer mix for ADCETRIS, information on utilization by Medicaid-eligible patients who received assistance through SeaGen Secure®, the Company s patient assistance program, and experience to date. The Company has also completed a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of ADCETRIS. The Company has 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 the Company for the difference between wholesale acquisition cost and the applicable discounted price. As a result of the Company s direct-ship distribution model, it can determine the entities purchasing ADCETRIS and this information enables the Company to estimate expected chargebacks for FSS and PHS purchases based on each entity s eligibility for the FSS and PHS programs. The Company also reviews historical rebate and chargeback information to further refine these estimates.

**Distribution fees, product returns and other deductions**: The Company s distributors charge a volume-based fee for distribution services that they perform for the Company. The Company allows for the return of product that is within 30 days of its expiration date or that is damaged. The Company estimates product returns based on its experience to date. In addition, the Company considers its direct-ship distribution model, its belief that product is typically not held in the distribution channel, and the expected rapid use of the product by

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

healthcare providers. The Company provides 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 the Company s actual experience.

*Collaboration and license agreement revenues*

The Company has developed a proprietary technology for linking cytotoxic agents to monoclonal antibodies called antibody-drug conjugates, or ADCs. This proprietary technology is the basis of ADC collaborations that the Company has entered into in the ordinary course of its business with a number of biotechnology and pharmaceutical companies. Under these ADC collaboration agreements, the Company grants its collaborators research and commercial licenses to the Company s technology and provides technology transfer services, technical advice, supplies and services for a period of time.

If there are continuing performance obligations, the Company uses a time-based proportional performance model to recognize revenue over the Company s performance period for the related agreement. Collaboration and license agreements are evaluated to determine whether the multiple elements and associated deliverables can be considered separate units of accounting. To date, the pre-commercial deliverables under the Company s collaboration and license agreements have not qualified as separate units of accounting. The assessment of multiple element arrangements requires judgment in order to determine the appropriate point in time, or period of time, that revenue should be recognized. The Company believes that the development period in each agreement is a reasonable estimate of the performance obligation period of such agreement. Accordingly, all amounts received or due, including any upfront payments, maintenance fees, development and regulatory milestone payments and reimbursement payments, are recognized as revenue over the performance obligation periods of each agreement. These performance obligation periods currently range from two to fourteen years. When no performance obligations are required of the Company, or following the completion of the performance obligation period, such amounts are recognized as revenue when collectibility is reasonably assured. Generally, all amounts received or due other than sales-based milestones and royalties are classified as collaboration and license agreement revenues as they are earned. Sales-based milestones and royalties are recognized as royalty revenue as they are reported to the Company.

The Company s collaboration and license agreements include contractual milestones. Generally, the milestone events contained in the Company s collaboration and license agreements coincide with the progression of the collaborators product candidates from development, to regulatory approval and then to commercialization and fall into the following categories.

Development milestones in the Company s collaborations may include the following types of events:

Designation of a product candidate or initiation of preclinical studies. The Company s collaborators must undertake significant preclinical research and studies to make a determination of the suitability of a product candidate and the time from those studies or designation to initiation of a clinical trial may take several years.

Initiation of a phase 1 clinical trial. Generally, phase 1 clinical trials may take one to two years to complete.

Initiation of a phase 2 clinical trial. Generally, phase 2 clinical trials may take one to three years to complete.

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

Initiation of a phase 3 clinical trial. Generally, phase 3 clinical trials may take two to six years to complete.

Regulatory milestones in the Company s collaborations may include the following types of events:

Filing of regulatory applications for marketing approval such as a Biologics License Application in the United States or a Marketing Authorization Application in Europe. Generally, it may take up to twelve months to prepare and submit regulatory filings.

Receiving marketing approval in a major market, such as in the United States, Europe, Japan or other significant countries. Generally it may take up to three years after a marketing application is submitted to obtain approval for marketing and pricing from the applicable regulatory agency.

Commercialization milestones in the Company s collaborations may include the following types of events:

First commercial sale in a particular market, such as in the United States, Europe, Japan or other significant countries.

Product sales in excess of a pre-specified threshold. The amount of time to achieve this type of milestone depends on several factors, including, but not limited to, the dollar amount of the threshold, the pricing of the product, market penetration of the product and the rate at which customers begin using the product.

The Company s 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.

In the case of the Company s ADCETRIS collaboration with Takeda Pharmaceutical Company Limited ( Takeda ), the Company may be involved in certain development activities; however, the achievement of milestone events under the agreement is based on activities undertaken by Takeda.

The process of successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing a product candidate is highly uncertain and the attainment of any milestones is therefore uncertain and difficult to predict. In addition, since the Company does not take a substantive role or control the research, development or commercialization of any products generated by its ADC collaborators, the Company is not able to reasonably estimate when, if at all, any milestone payments or royalties may be payable to the Company by its ADC collaborators. As such, the milestone payments associated with its ADC collaborations involve a substantial degree of uncertainty and risk that they may never be received. Similarly, even in those collaborations where the Company may have an active role in the development of the product candidate, such as the Company s ADCETRIS collaboration with Takeda, the attainment of a milestone is based on the collaborator s activities and is generally outside the direction and control of the Company.

The Company generally invoices its 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 when the applicable revenue recognition criteria have been met. 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 sales royalties, which are based on a percentage of Takeda s net sales at rates that range from

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

the mid-teens to the mid-twenties based on sales volume, and commercial sales-based milestones. Takeda bears a portion of third-party royalty costs owed on its sales of ADCETRIS. This amount is included in royalty revenue in the Company s consolidated financial statements. Cost of royalty revenues reflects amounts owed to the Company s third-party licensors related to Takeda s sales of ADCETRIS. These amounts are recognized in the quarter in which Takeda reports its sales activity to the Company, which is the quarter following the related sales. Royalty revenues also include amounts earned in connection with the Company s ADC collaborations.

*Research and development expenses*

Research and development, or R&D, expenses consist of salaries, benefits and other headcount related costs of the Company s 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. Clinical trial expenses are a significant component of research and development expenses, and the Company outsources a significant portion of these costs to third parties. Third party clinical trial expenses include investigator fees, site costs, clinical research organization costs, and costs for central laboratory testing and data management. R&D activities are expensed as incurred. In-licensing fees, milestones, maintenance fees and other costs to acquire technologies that are 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. Costs associated with activities performed under co-development collaborations are reflected in R&D expense. 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 charges to expense of 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. The Company incurred $10.1 million, $11.1 million, and $13.0 million in advertising expense during 2014, 2013, and 2012, respectively.

*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 fair value. The 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.

*Concentration of credit risk*

Cash, cash equivalents and investments are invested in accordance with the Company s investment policy. The policy includes guidelines for the investment of cash reserves and is reviewed periodically to minimize credit risk. Most of the Company s investments are not federally insured. The Company has accounts receivable from the sale of ADCETRIS from a small number of distributors. The Company does not require collateral on amounts due from its distributors or its collaborators and is therefore subject to credit risk. The Company has not experienced any significant credit losses to date as a result of credit risk concentration and does not consider an allowance for doubtful accounts to be necessary.

*Major customers*

The Company sells 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

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

revenues and greater than 10% of accounts receivable as noted below. In addition, one of the Company s collaborators accounted for greater than 10% of total revenues as noted below. Revenues generated outside the United States, 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 in the periods presented:

| | Percent of total revenues for the years ended December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| Distributor A | 22% | 18% | 22% |
| Distributor B | 20% | 18% | 21% |
| Distributor C | 16% | 15% | 19% |
| Collaborator A | 25% | 22% | 19% |

The following table presents each major distributor that accounted for more than 10% of accounts receivable as of the dates presented:

| | Percent of total accounts receivable at December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Distributor A | 32% | 30% |
| Distributor B | 32% | 31% |
| Distributor C | 22% | 23% |

*Major suppliers*

The use of a relatively small number of contract manufacturers to supply drug product necessary for the Company s commercial operations and clinical trials creates a concentration of risk for the Company. While primarily one source of supply is utilized for certain components of ADCETRIS and each of the Company s product candidates, other sources are available should the Company need to change suppliers. The Company also endeavors to maintain reasonable levels of drug supply for its use. A change in suppliers, however, could cause a delay in delivery of drug product which could result in the interruption of commercial operations or clinical trials. Such an event would adversely affect the Company s business.

*Other non-current assets*

Included in other non-current assets are intangible assets resulting from milestone payments 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.

| | December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Intangible assets | $ 5,650 | $ 5,650 |
| Less: accumulated amortization | (2,572) | (1,801) |
| Total | $ 3,078 | $ 3,849 |

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

Amortization expenses on intangible assets was $0.8 million for each of the years ended December 31, 2014, 2013, and 2012, respectively. Assuming no changes in the cost basis of intangible assets, the estimated aggregate amortization for the next five years will total $3.1 million.

*Income taxes*

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the differences between the financial statement and tax bases of assets and liabilities using tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that the net deferred tax asset will not be realized. The Company has provided a full valuation allowance against its deferred tax assets for all periods presented.

*Share-based compensation*

The Company uses the graded-vesting attribution method for recognizing compensation expense for its stock options and the straight-line method for recognizing compensation expense for its restricted stock units ( RSUs ). Compensation expense is recognized 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.

*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. The Company s comprehensive loss is comprised of net loss and unrealized gains and losses on investments.

*Legal matters*

In the normal course of its business, the Company may become involved in various legal proceedings. The Company does not expect any current legal proceedings to have a material adverse effect on the Company s business. Legal fees incurred as a result of the Company s involvement in legal proceedings are expensed as incurred.

On March 31, 2014, Arizona State University and related entities, or Arizona State, filed a patent infringement lawsuit against the Company concerning a U.S. patent licensed from Arizona State. The Company believes that it has meritorious defenses to Arizona State s claims. At this time, the Company does not believe that a loss is probable and does not have a reasonable basis on which to develop a range of potential loss in the event of an unfavorable outcome in this dispute. While the Company believes a loss is not probable, it is possible that a liability could be incurred in the future.

*Certain risks and uncertainties*

The Company s revenues are derived from ADCETRIS sales and royalties and from collaboration and license agreements. ADCETRIS is the Company s only product available for sale and is subject to regulation by the FDA in the United States and other regulatory agencies outside the United States as well as competition by other pharmaceutical companies. The Company s collaboration and license agreement revenues are derived from a relatively small number of agreements. Each of these agreements can be terminated by the Company s collaborators at their discretion. The Company is also subject to risks common to companies in the pharmaceutical industry, including risks and uncertainties related to commercial success and acceptance of ADCETRIS and the Company s potential future products by patients, physicians and payers, competition from

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

other products, regulatory approvals, regulatory requirements and protection of intellectual property. Also, drug development is a lengthy process characterized by a relatively low rate of success. The Company may commit substantial resources toward developing product candidates that never result in further development, achieve regulatory approvals or achieve commercial success. Likewise, the Company has committed and expects to continue to commit substantial resources towards additional clinical development of ADCETRIS in an effort to expand ADCETRIS labeled indications of use, and there can be no assurance that the Company 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, the Company indemnifies its directors, certain employees and other parties, including distributors, collaboration partners, lessors and other parties that perform certain work on behalf of, or for the Company or take licenses to the Company s technologies. The Company has agreed to hold these parties harmless against losses arising from the Company s breach of representations or covenants, intellectual property infringement or other claims made against these parties in performance of their work with the Company. These agreements typically limit the time within which the party may seek indemnification by the Company 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. The Company excluded all RSUs and options to purchase common stock from the calculation of diluted net loss per share as such securities are anti-dilutive for all periods presented.

The following table presents the weighted-average shares that have been excluded from the number of shares used to calculate basic and diluted net loss per share (in thousands):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| Stock options and RSUs | 11,868 | 11,745 | 13,483 |

*Recent accounting pronouncements*

In May 2014, the Financial Accounting Standards Board issued an accounting standards update entitled ASU 2014-09, Revenue from Contracts with Customers. The standard requires entities to recognize revenue through an evaluation that includes identification of the contract, identification of the performance obligations, determination of the transaction price, allocation of the transaction price to the performance obligations, and recognition of revenue as the entity satisfies the performance obligations. The standard will become effective for the Company beginning January 1, 2017. The Company is currently evaluating the guidance to determine the potential impact on its financial condition, results of operations and cash flows, and financial statement disclosures.

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**3. Short-term investments**

Short-term investments consisted of available-for-sale securities as follows (in thousands):

| | Amortized cost | Gross unrealized gains | Gross unrealized losses | Fair value |
|---|---|---|---|---|
| December 31, 2014 | | | | |
| U.S. Treasury securities | $ 256,515 | $ 2 | $ (31) | $ 256,486 |
| | | | | |
| Contractual Maturities | | | | |
| Due in one year or less | $ 256,515 | | | $ 256,486 |

| | Amortized cost | Gross unrealized gains | Gross unrealized losses | Fair value |
|---|---|---|---|---|
| December 31, 2013 | | | | |
| U.S. Treasury securities | $ 310,162 | $ 7 | $ (18) | $ 310,151 |
| | | | | |
| Contractual Maturities | | | | |
| Due in one year or less | $ 310,162 | | | $ 310,151 |

The aggregate estimated fair value of the Company s investments with unrealized losses was as follows (in thousands):

| | Period of continuous unrealized loss | | | |
|---|---|---|---|---|
| | 12 Months or less | | Greater than 12 months | |
| | Fair value | Gross unrealized losses | Fair value | Gross unrealized losses |
| December 31, 2014 | | | | |
| U.S. Treasury securities | $ 205,966 | $ (31) | $ NA | $ NA |
| | | | | |
| December 31, 2013 | | | | |
| U.S. Treasury securities | $ 188,599 | $ (18) | $ NA | $ NA |

**4. Fair Value**

The Company holds short-term available-for-sale securities that are measured at fair value which is determined on a recurring basis according to a fair value hierarchy that prioritizes the inputs and assumptions used, and the valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described as follows:

| | |
|---|---|
| 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. |

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

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. The Company considers 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.

Level 1 investments, which include investments that are valued based on quoted market prices in active markets, consisted of U.S. Treasury securities. The Company did not hold any Level 2 or 3 investments as of December 31, 2014 or 2013 and did not transfer any investments in or out of Levels 1, 2 and 3 during the years ended December 31, 2014 or 2013.

The following table presents the Company s available-for-sale securities by level within the fair value hierarchy (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 |
| As of December 31, 2014 | | | | |
| Cash equivalents U.S. Treasury securities | $ 5,003 | $ 0 | $ 0 | $ 5,003 |
| Short-term investments U.S. Treasury securities | 256,486 | 0 | 0 | 256,486 |
| Total | $ 261,489 | $ 0 | $ 0 | $ 261,489 |

| | 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 |
| As of December 31, 2013 | | | | |
| Short-term investments U.S. Treasury securities | $ 310,151 | $ 0 | $ 0 | $ 310,151 |

**5. Inventories**

The following table presents the Company s inventories of ADCETRIS (in thousands):

| | December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Raw materials | $ 35,865 | $ 25,386 |
| Work in process | 3,920 | 431 |
| Finished goods | 3,666 | 1,256 |
| Total | $ 43,451 | $ 27,073 |

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**6. Property and equipment**

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

| | December 31, | |
|---|---|---|
| | **2014** | **2013** |
| Leasehold improvements | $ 49,118 | $ 40,217 |
| Laboratory equipment | 27,968 | 22,866 |
| Computers, software and office equipment | 9,264 | 8,654 |
| Furniture and fixtures | 5,944 | 5,415 |
| | 92,294 | 77,152 |
| Less: accumulated depreciation and amortization | (46,165) | (36,365) |
| Total | $ 46,129 | $ 40,787 |

Depreciation and amortization expenses on property and equipment totaled $11.7 million, $7.8 million, and $5.4 million for the years ended December 31, 2014, 2013, and 2012, respectively. Leasehold improvements included $0.4 million of construction in process at December 31, 2014.

**7. Accounts payable and accrued liabilities**

Accounts payable and accrued liabilities consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | **2014** | **2013** |
| Employee compensation and benefits | $ 21,957 | $ 18,321 |
| Trade accounts payable | 17,245 | 13,407 |
| Clinical trial and related costs | 16,466 | 12,602 |
| Contract manufacturing | 10,764 | 6,997 |
| Third-party royalties and government rebates | 7,804 | 6,074 |
| Other | 3,445 | 1,947 |
| Total | $ 77,681 | $ 59,348 |

**8. Income taxes**

Because of the Company s history of net operating losses, it has not paid income taxes since its inception and the Company had no material unrecognized tax benefits that could affect the Company s financial statements as of December 31, 2014 or 2013.

The Company s deferred tax assets primarily consist of net operating loss, or NOL, carryforwards, deferred revenue, capitalized research and development expense and tax credit carryforwards. 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, 2014, the Company has federal and state NOL carryforwards totaling $568.2 million expiring from 2020 to 2034 if not utilized, and tax credit carryforwards of $53.7 million expiring from 2021 to 2034.

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. The Company evaluated ownership changes through the year ended December 31, 2014 and believes that it is

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

likely that its NOLs should not be limited under Section 382 as of December 31, 2014. It is possible that there may be a change in ownership in the future, which would limit the Company s ability to utilize its NOL. Any limitation may result in the expiration of the NOL and tax credit carryforwards before utilization.

The Company s net deferred tax assets consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Deferred tax assets | | |
| Net operating loss carryforwards | $ 158,187 | $ 132,419 |
| Deferred revenue | 54,523 | 60,810 |
| Tax credit carryforwards | 53,705 | 44,055 |
| Share-based compensation | 25,095 | 16,463 |
| Capitalized research and development | 8,053 | 11,489 |
| Depreciation and amortization | 4,423 | 2,864 |
| Other | 13,706 | 12,360 |
| Total deferred tax assets | 317,692 | 280,460 |
| Less: valuation allowance | (317,692) | (280,460) |
| Net deferred tax assets | $ 0 | $ 0 |

Increases in the valuation allowance were $37.2 million in 2014, and $29.9 million in 2013.

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

| | Years ended December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| Statutory federal income tax rate | (35%) | (35%) | (35%) |
| Tax credits | (10) | (16) | (3) |
| State income taxes and other | (4) | 3 | 3 |
| Valuation allowance | 49 | 48 | 35 |
| Effective tax rate | 0% | 0% | 0% |

The Company does not anticipate any significant changes to its 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 1998 to 2014 remain subject to future examination for federal income taxes.

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**9. Collaboration and license agreements**

The Company has entered into various product, collaboration and license agreements with pharmaceutical and biotechnology companies. Revenues recognized under these agreements were as follows (in thousands):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| Takeda | $ 31,787 | $ 41,529 | $ 36,021 |
| AbbVie | 14,851 | 22,924 | 9,839 |
| Genentech | 7,791 | 8,438 | 6,174 |
| Bayer | 5,062 | 12,000 | 0 |
| Other | 9,065 | 21,890 | 15,513 |
| Total | $ 68,556 | $ 106,781 | $ 67,547 |

*Takeda*

The ADCETRIS collaboration provides for the global co-development of ADCETRIS by the companies and the commercialization of ADCETRIS by Takeda in its territory. Under this collaboration, the Company has retained commercial rights for ADCETRIS in the United States 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 development activities conducted under the collaboration. In Japan, Takeda is solely responsible for development costs. Costs incurred by the Company associated with co-development activities performed under this collaboration are included in research and development expense in the accompanying consolidated statements of comprehensive loss.

The Company recognizes as collaboration revenue the upfront payment, progress-dependent development and regulatory milestone payments, and net development cost reimbursement payments from Takeda over the ten-year development period of the collaboration which began in December 2009. When the performance of development activities under the collaboration results in the Company making a reimbursement payment to Takeda, the effect is to reduce the amount of collaboration revenue recorded by the Company. The Company also receives reimbursement for the cost of drug product supplied to Takeda for its use and, in some cases, pays Takeda for drug product they supply to the Company. The earned portion of payments received is reflected as a component of collaboration revenue.

The Company is also entitled to receive royalties based on a percentage of Takeda s net sales of ADCETRIS in its territory ranging from the mid-teens to the mid-twenties based on sales volume and sales-based milestones. Takeda also bears a portion of third-party royalty costs owed on its sales of ADCETRIS. 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 the Company, and the Company 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.

*Agensys*

The Company has entered into an agreement with Agensys to jointly research, develop and commercialize ADCs for the treatment of cancer. The agreement included an initial co-development product candidate, ASG-5ME, and provided the Company with two options to co-develop additional product candidates. The Company

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

has exercised all its co-development options and is currently co-developing ASG-22ME and ASG-15ME. Development of ASG-5ME has been discontinued. The Company and Agensys co-fund the development of these product candidates and will share future profits, if any, on a 50:50 basis. Either party may opt out of co-development and profit-sharing in return for receiving milestones and royalties from the continuing party.

Costs associated with co-development activities performed under this collaboration are included in research and development expense in the accompanying consolidated statements of comprehensive loss. The Agensys collaboration agreement defines a mechanism for calculating the costs of co-development activities and for reimbursing the other party in order to maintain an equal sharing of development costs. Third-party costs are billed at actual cost and internal labor and support costs are billed at a contractual rate. The following table summarizes research and development expenses incurred by the Company and funding provided to Agensys under the collaboration to achieve equal cost sharing.

| | Years ended December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| Research and development expense using contractual rates | $ 275 | $ 2,574 | $ 4,885 |
| Co-development funding to Agensys | 3,785 | 8,096 | 5,484 |
| Total | $ 4,060 | $ 10,670 | $ 10,369 |

The agreement also allows Agensys to develop and commercialize other ADC product candidates on its own, subject to paying the Company annual maintenance fees, milestones, royalties and support fees for research and development services and material provided under the agreement. Amounts received for product candidates being developed solely by Agensys are recognized in revenues as they become due.

*ADC collaboration agreements*

The Company has entered into collaborations for its ADC technology with a number of biotechnology and pharmaceutical companies. Under the ADC collaborations, which the Company enters into in the ordinary course of business, the Company has granted research and commercial licenses to use its technology in conjunction with the collaborator s technology. The Company also has agreed to conduct limited development activities and to provide other materials, supplies and services to its ADC collaborators during the performance obligation period of the collaboration. The Company receives upfront cash payments, progress- and sales-dependent milestones for the achievement by its collaborators of certain events, annual maintenance fees and support fees for research and development services and materials provided under the agreements. The Company is also entitled to receive royalties on net sales of any resulting products incorporating its ADC technology. The Company s ADC collaborators are solely responsible for research, product development, manufacturing and commercialization of all products under the agreements.

**10. License agreements**

The Company has 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, including the following:

*Bristol-Myers Squibb.* In March 1998, the Company obtained rights to some of its technologies and product candidates, portions of which are exclusive, through a license agreement with Bristol-Myers Squibb. Through this license, the Company secured rights to monoclonal antibody-based cancer targeting technologies, including patents, monoclonal antibodies, chemical linkers, including the linker used in ADCETRIS and other

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

product candidates, a ribosome-inactivating protein and enabling technologies. Under the terms of the license agreement, the Company is required to pay a low single-digit royalty on net sales of products, including ADCETRIS, that incorporate patented technology licensed from Bristol-Myers Squibb.

*University of Miami.* In September 1999, the Company 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, the Company made an upfront payment and progress-dependent milestone payments. The Company is obligated to pay annual maintenance fees and a low single-digit royalty on net sales of products, including ADCETRIS, incorporating technology licensed from the University of Miami.

*Other Licenses*. The Company has other non-exclusive licenses to other technology used in ADCETRIS that require the Company to pay royalties ranging from the low to mid-single digits on net sales of ADCETRIS.

**11. Commitments and contingencies**

The Company is obligated to make future minimum payments under four operating leases for approximately 255,000 square feet of space used for general office and research and development purposes. The leases expire in 2018 through 2024 and include options to renew at the then fair market rental for the facilities.

The lease agreements contain scheduled rent increases and provide for tenant improvement allowances. Accordingly, the Company has recorded a deferred rent liability of $4.1 million at December 31, 2014 and $5.0 million at December 31, 2013. This deferred rent liability is amortized over the term of the related lease.

Assuming the Company does not exercise any extensions, future minimum lease payments under all noncancelable operating leases are set forth below. In addition, noncancelable obligations under other agreements, such as future obligations related to manufacturing ADCETRIS and the Company s product candidates, are as follows (in thousands):

| | Leases | Other Agreements |
|---|---|---|
| Years ending December 31, | | |
| 2015 | $ 5,017 | $ 45,668 |
| 2016 | 5,184 | 13,532 |
| 2017 | 5,348 | 15,163 |
| 2018 | 3,010 | 14,700 |

| | | |
|---|---|---|
| 2019 | 753 | 14,824 |
| Thereafter | 3,456 | 23,990 |
| | $ 22,768 | $ 127,877 |

Rent expense attributable to noncancelable operating leases totaled approximately $3.6 million, $3.3 million, and $3.6 million for the years ended December 31, 2014, 2013, and 2012, respectively. Minimum contractual payments to be made by the Company under other agreements do not include up to approximately $61.1 million in additional payments that are contingent upon achievement of certain progress-dependent milestones, as well as the payment of single-digit 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.

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**12. Stockholders equity**

*Common stock*

At December 31, 2014, shares of common stock reserved for future issuance are as follows (in thousands):

| | |
|---|---|
| Stock options and RSUs outstanding | 12,565 |
| Shares available for future grant under the 2007 Equity Incentive Plan | 4,782 |
| Employee stock purchase plan shares available for future issuance | 165 |
| Total | 17,512 |

**13. Share-based compensation**

*2007 Equity Incentive Plan*

In 2007, the Company adopted the 2007 Equity Incentive Plan, or the 2007 Plan, that provides for the issuance of the Company s common stock to employees, including officers, directors and consultants of the Company and its affiliates. The 2007 Plan was amended and restated in May 2014 to reserve an additional 4,500,000 shares thereunder, such that an aggregate of 21,000,000 shares of the Company s common stock were reserved for issuance under the 2007 Plan at December 31, 2014. Under the 2007 Plan, the Company may issue stock options (including incentive stock options and nonstatutory stock options), restricted stock, RSUs, stock appreciation rights and other similar types of awards (including awards, such as RSUs, that do not require the awardee to pay any amount in connection with receiving the shares or that have an exercise or purchase price that is less than the grant date fair market value of the Company s stock). No awardee may be granted, in any calendar year under the 2007 Plan, options or stock awards covering more than 1,000,000 shares. The 2007 Plan was also amended and restated in May 2014 to extend its term through May 2024 unless it is terminated earlier pursuant to its terms.

Restricted stock grants are awards of a specific number of shares of the Company s common stock. RSUs represent a promise to deliver shares of the Company s common stock, or an amount of cash or property equal to the value of the underlying shares, at a future date. Stock appreciation rights are rights to receive cash and/or shares of the Company s common stock based on the amount by which the exercise date fair market value of a specific number of shares exceeds the grant date fair market value of the exercised portion of the stock appreciation right. The Company has only issued options to purchase shares of common stock and RSUs under the 2007 Plan.

Incentive stock options under the 2007 Plan may be granted only to employees of the Company or its subsidiaries. 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 have a maximum term of ten years from the date of grant. In the case of options granted to holders of more than 10% of the voting power of the Company, the exercise price may not be less than 110% of the fair market value of the common stock on the date the option is granted and the term of the option may not exceed five years. The Company may grant options with exercise prices lower than the fair market value of its common stock on the date of grant in connection with an acquisition by the Company of another company. Options become exercisable in whole or in part from time to time as determined by the Board of Directors, which administers the 2007 Plan. Generally, options granted to employees and the initial option grant to new members of the Company s board of directors ( directors ) 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. In addition to their initial grant, directors also receive annual RSU and option grants that vest one year from the date of grant. RSUs granted to employees and the initial RSU grant to new directors vest 100% on the third anniversary of the beginning of the vesting period.

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

The Equity Plan provides for (i) the full acceleration of vesting of equity awards, including stock options and RSUs, upon a change in control (as defined in the 2007 Plan) if the successor company does not assume, substitute or otherwise replace the stock awards upon the change in control; and (ii) the full acceleration of vesting of any equity awards, including stock options and RSUs, 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.

Each equity award agreement under the 2007 Plan contains provisions regarding (i) the number of shares subject to the equity award, (ii) the purchase or exercise price of the shares, if any, and the means of payment for the shares, (iii) in the case of stock options, the type of option and term of the option; (iv) the performance criteria (including qualifying performance criteria), if any, and level of achievement versus these criteria that will determine the number of shares granted, issued, retainable and vested, as applicable, (v) such terms and conditions on the grant, issuance, vesting and forfeiture of the shares, as applicable, as may be determined from time to time by the plan administrator, (vi) restrictions on the transferability of the equity award or the shares, and (vii) such further terms and conditions, in each case not inconsistent with the 2007 Plan, as may be determined from time to time by the plan administrator; provided, however, that each stock award must have a minimum vesting period of one year from the date of grant.

*Share-based compensation*

The Company recorded total share based compensation cost of $40.6 million, $31.4 million, and $25.3 million for the years ended December 31, 2014, 2013, and 2012, respectively. No tax benefit was recognized related to share-based compensation cost since the Company has not reported taxable income to date and has established a full valuation allowance to offset all of the potential tax benefits associated with its deferred tax assets. During 2014, 2013, and 2012, $1.4 million, $1.2 million, and $1.1 million of share based compensation costs were included in production overhead used in the determination of inventory cost, respectively.

*Valuation assumptions*

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

| | 2007 Plan Years ended December 31, | | | Employee Stock Purchase Plan Years ended December 31, | | |
|---|---|---|---|---|---|---|
| | 2014 | 2013 | 2012 | 2014 | 2013 | 2012 |
| Risk-free interest rate | 1.7% | 1.6% | 0.8% | 0.1% | 0.1% | 0.1% |
| Expected lives in years | 5.5 | 5.6 | 5.7 | 0.5 | 0.5 | 0.5 |
| Expected dividends | 0% | 0% | 0% | 0% | 0% | 0% |
| Expected volatility | 44% | 50% | 52% | 41% | 35% | 42% |

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

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. The Company s computation of expected life was determined based on its 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. The Company has never paid cash dividends and does not currently intend to pay cash dividends, thus has assumed a 0% dividend yield. The Company s computation of expected volatility is based on the historical volatility of the Company s stock price. Determination of all of these assumptions involves management s best estimates at the time, which impact the fair value of the awards calculated under the Black-Scholes methodology, and ultimately the expense that will be recognized over the life of the award.

*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) |
|---|---|---|---|---|
| Balances at December 31, 2013 | 10,270,409 | $ 18.23 | | |
| Granted | 1,539,847 | 43.05 | | |
| Exercised | (886,037) | 12.70 | | |
| Forfeited/expired | (194,928) | 30.00 | | |
| Balances at December 31, 2014 | 10,729,291 | $ 22.04 | 6.39 | $ 136,018 |
| Expected to vest | 10,461,734 | $ 21.58 | 6.32 | $ 135,707 |
| Options exercisable | 7,490,161 | $ 15.66 | 5.38 | $ 127,274 |

The weighted average grant-date fair values of options granted with exercise prices equal to market were $18.24, $18.88, and $11.92 for the years ended December 31, 2104, 2013, and 2012, respectively.

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the quoted price of the Company s common stock for all options that were in-the-money at December 31, 2014. The aggregate intrinsic value of options exercised was $27.7 million during 2014, $61.3 million during 2013, and $48.3 million during 2012, determined as of the date of option exercise. As of December 31, 2014, there was approximately $27.7 million of total unrecognized compensation cost related to unvested option arrangements, as adjusted for expected forfeitures, granted under the 2007 Plan. That cost is expected to be recognized over a weighted-average period of 1.34 years. The Company utilizes newly issued shares to satisfy option exercises.

*RSU activity*

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

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

A summary of RSU activity under the 2007 Plan is as follows:

| Non-vested RSUs | Share equivalent | Weighted-average grant date fair value |
|---|---|---|
| Non-vested at December 31, 2013 | 1,566,697 | $ 29.40 |
| Changes during the period: | | |
| Granted | 685,920 | 43.31 |
| Vested | (322,188) | 17.49 |
| Forfeited | (94,807) | 33.14 |
| Non-vested at December 31, 2014 | 1,835,622 | $ 40.05 |

The total value of RSUs that vested during 2014 (measured on the date of vesting) was $13.5 million. As of December 31, 2014, there was approximately $34.9 million of total unrecognized compensation cost related to non-vested RSU awards that will be recognized as expense over a weighted-average period of 1.62 years. The Company recognizes compensation cost for RSUs on a straight-line basis over the requisite service period for the entire award, as adjusted for expected forfeitures. The Company will utilize newly issued shares for RSUs that vest.

*Employee Stock Purchase Plan*

The Company has an Amended and Restated 2000 Employee Stock Purchase Plan, or the Stock Purchase Plan, with a total of 165,137 shares of common stock available for issuance as of December 31, 2014. Activity under the Stock Purchase Plan for the years ended December 31, was as follows:

| | Shares Purchased | Weighted-average purchase price per share |
|---|---|---|
| 2014 | 149,576 | $ 33.02 |
| 2013 | 196,446 | $ 23.24 |
| 2012 | 287,841 | $ 14.88 |

Under the current terms of the Stock Purchase Plan, shares are purchased at the lower of 85 percent of the fair market value of the Company s common stock on either the first day or the last day of each six month offering period.

**14. Employee benefit plan**

The Company has a 401(k) Plan for all of its employees. The 401(k) Plan allows eligible employees to defer, at the employee s discretion, up to 75% of their pretax compensation up to the IRS annual limit. The Company has a 401(k) matching program whereby the Company may, at its discretion, match a portion of an employee s contributions, not to exceed a prescribed annual limit. The Company s matching contribution vests over four years from the start of employment. Under this matching program, the Company contributed a total of approximately $2.2 million in 2014, $1.9 million in 2013, and $2.1 million in 2012.

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**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**15. Condensed Quarterly Financial Data (unaudited)**

The following table contains selected unaudited financial data for each quarter of 2014 and 2013. The unaudited information should be read in conjunction with the Company s financial statements and related notes included elsewhere in this report. The Company believes 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.

**Quarterly Financial Data (in thousands, except per share data):**

| | Three months ended | | | |
|---|---|---|---|---|
| | **March 31,** | **June 30,** | **September 30,** | **December 31,** |
| **2014** | | | | |
| Total revenues | $ 68,271 | $ 68,308 | $ 75,853 | $ 74,326 |
| Net loss | $ (16,301) | $ (17,590) | $ (15,566) | $ (26,684) |
| Net loss per share basic and diluted | $ (0.13) | $ (0.14) | $ (0.13) | $ (0.22) |
| **2013** | | | | |
| Total revenues | $ 57,328 | $ 73,558 | $ 70,969 | $ 67,409 |
| Net loss | $ (16,264) | $ (6,899) | $ (23,686) | $ (15,671) |
| Net loss per share basic and diluted | $ (0.14) | $ (0.06) | $ (0.19) | $ (0.13) |

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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, 2014 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, 2014.

The effectiveness of our internal control over financial reporting as of December 31, 2014 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included in Item 8 in this Annual Report on Form 10-K.

**Item 9B. Other Information**

None.

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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 2014 fiscal year pursuant to Regulation 14A for our 2015 Annual Meeting of Stockholders, or the 2015 Proxy Statement, and the information to be included in the 2015 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 2015 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 Code of Ethics appearing in the 2015 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 2015 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 2015 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 2015 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 2015 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 2015 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 2015 Proxy Statement. Such information is incorporated herein by reference.

**Item 14. Principal Accounting Fees and Services**

The information required by this Item may be found under the section entitled Proposal No. 3 Ratification of Appointment of Independent Registered Public Accounting Firm appearing in the 2015 Proxy Statement. Such information is incorporated herein by reference.

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**PART IV**

**Item 15. Exhibits, Financial Statement Schedules**

**(a) The following documents are filed as part of this report:**

(1) Financial Statements and Report of Independent Registered Public Accounting Firm

(2) Financial Statement Schedules

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.

(3) 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).

**(b) Exhibits**

| Exhibit Number | Exhibit Description | Incorporation By Reference | | | |
|---|---|---|---|---|---|
| | | Form | SEC File No. | Exhibit | Filing Date |
| 3.1 | Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc. | 10-Q | 000-32405 | 3.1 | 11/07/2008 |
| 3.2 | Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc. | 8-K | 000-32405 | 3.3 | 05/26/2011 |
| 3.3 | Amended and Restated Bylaws of Seattle Genetics, Inc. | 10-Q | 333-50266 | 3.2 | 08/12/2003 |
| 4.1 | Specimen Stock Certificate. | S-1/A | 333-50266 | 4.1 | 02/08/2001 |
| 4.2 | Investor Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders. | 10-Q | 000-32405 | 4.3 | 11/07/2008 |
| 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 | 12/05/2000 |
| 10.4 | 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 |
| 10.5 | 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 |
| 10.6 | Lease Agreement dated December 1, 2000 between Seattle Genetics, Inc. and WCM132-302, LLC. | S-1/A | 333-50266 | 10.21 | 01/04/2001 |

| | | | | | |
|---|---|---|---|---|---|
| 10.7 | First Amendment to Lease dated May 28, 2003 between Seattle Genetics, Inc. and B&N 141-302, LLC. | 10-Q | 333-50266 | 10.1 | 08/12/2003 |

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| Exhibit Number | Exhibit Description | Incorporation By Reference | | | |
|---|---|---|---|---|---|
| | | Form | SEC File No. | Exhibit | Filing Date |
| 10.8 | Second Amendment to Lease dated July 1, 2008 between Seattle Genetics, Inc. and B&N 141-302, LLC. | 10-Q | 000-32405 | 10.1 | 11/07/2008 |
| 10.9 | Third Amendment to Lease dated May 9, 2011 between Seattle Genetics, Inc. and B&N 141-302, LLC. | 10-Q | 000-32405 | 10.2 | 08/05/2011 |
| 10.10 | Office Lease dated May 9, 2011 between Seattle Genetics, Inc. and WCM Highlands II, LLC. | 10-Q | 000-32405 | 10.1 | 08/05/2011 |
| 10.11 | Collaboration and License Agreement dated January 7, 2007 between Seattle Genetics, Inc. and Agensys, Inc. | 10-Q | 000-32405 | 10.1 | 05/08/2007 |
| 10.12 | 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 | 03/12/2010 |
| 10.13 | 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 | 03/12/2010 |
| 10.14 | Commercial Supply Agreement dated December 1, 2010 between Seattle Genetics, Inc. and SAFC, an operating division of Sigma-Aldrich, Inc. | 10-Q | 000-32405 | 10.1 | 11/04/2011 |
| 10.15+ | Development and Supply Agreement dated February 23, 2004 between Seattle Genetics, Inc. and Abbott Laboratories. | | | | |
| 10.16 | 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 | 08/08/2008 |
| 10.17 | 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 | 11/04/2011 |
| 10.18 | 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 | 11/04/2011 |
| 10.19 | Fourth Amendment to Development and Supply Agreement dated April 18, 2010 between Seattle Genetics, Inc. and Abbott Laboratories, Inc. | 10-Q | 000-32405 | 10.6 | 11/04/2011 |
| 10.20 | 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 | 11/04/2011 |
| 10.21 | 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 | 11/04/2011 |
| 10.22 | 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 | 02/27/2013 |

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| Exhibit Number | Exhibit Description | Incorporation By Reference | | | |
|---|---|---|---|---|---|
| | | Form | SEC File No. | Exhibit | Filing Date |
| 10.23* | Form of Indemnification Agreement between Seattle Genetics, Inc. and each of its officers and directors. | S-1/A | 333-50266 | 10.29 | 01/04/2001 |
| 10.24* | Amended and Restated 1998 Stock Option Plan, effective as of August 4, 2009. | 10-Q | 000-32405 | 10.1 | 8/10/2009 |
| 10.25* | 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 | 03/15/2005 |
| 10.26* | 2000 Directors Stock Option Plan, as amended February 5, 2010. | 10-K | 000-32405 | 10.13 | 03/12/2010 |
| 10.27* | Form Notice of Grant and Stock Option Agreement under Seattle Genetics, Inc. 2000 Directors Stock Option Plan. | 10-K | 000-32405 | 10.12 | 03/15/2005 |
| 10.28* | Amended and Restated 2000 Employee Stock Purchase Plan, effective May 20, 2011. | 10-Q | 000-32405 | 10.3 | 08/05/2011 |
| 10.29* | Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan, effective as of May 18, 2012. | 10-Q | 000-32405 | 10.1 | 08/08/2012 |
| 10.30* | Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan, effective as of May 16, 2014. | 10-Q | 000-32405 | 10.1 | 08/08/2014 |
| 10.31* | Form Stock Option Agreement for employees under Seattle Genetics, Inc. 2007 Equity Incentive Plan. | 10-K | 000-32405 | 10.44 | 03/13/2009 |
| 10.32* | 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 | 08/30/2011 |
| 10.33* | 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 | 08/05/2011 |
| 10.34* | 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 | 02/28/2014 |
| 10.35* | Amended and Restated Employment Agreement, dated December 15, 2008, between Seattle Genetics, Inc. and Clay B. Siegall. | 10-K | 000-32405 | 10.48 | 03/13/2009 |
| 10.36* | Amended and Restated Employment Agreement, dated December 15, 2008, between Seattle Genetics, Inc. and Todd E. Simpson. | 10-K | 000-32405 | 10.49 | 03/13/2009 |
| 10.37* | Amended and Restated Employment Agreement, dated December 15, 2008, between Seattle Genetics, Inc. and Eric L. Dobmeier. | 10-K | 000-32405 | 10.50 | 03/13/2009 |
| 10.38* | Employment Agreement, dated April 1, 2009, between Seattle Genetics, Inc. and Vaughn Himes. | 10-K | 000-32405 | 10.43 | 03/12/2010 |

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| Exhibit Number | Exhibit Description | Incorporation By Reference | | | |
|---|---|---|---|---|---|
| | | Form | SEC File No. | Exhibit | Filing Date |
| 10.39* | Employment Agreement, dated April 16, 2012 between Seattle Genetics, Inc. and Chris Boerner. | 10-Q | 000-32405 | 10.2 | 08/08/2012 |
| 10.40* | Employment Agreement, dated October 5, 2010, between Seattle Genetics, Inc. and Jonathan Drachman. | 10-K | 000-32405 | 10.39 | 02/28/2014 |
| 10.41+ | Employment Agreement, dated November 17, 2014, between Seattle Genetics, Inc. and Jean Liu | | | | |
| 10.42+ | Employment Agreement, dated February 18, 2015, between Seattle Genetics, Inc. and Darren Cline. | | | | |
| 10.43* | Seattle Genetics, Inc. 2014 Senior Executive Annual Bonus Plan | 10-K | 000-32405 | 10.41 | 02/28/2014 |
| 10.44* | Seattle Genetics, Inc. 2015 Senior Executive Annual Bonus Plan. | 8-K | 000-32405 | 10.1 | 02/06/2015 |
| 10.45+* | Compensation Information for Executive Officers and Directors. | | | | |
| 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.

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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 27, 2015

By: /s/ CLAY B. SIEGALL
Clay B. Siegall

*President & Chief Executive Officer*

*(Principal Executive Officer)*

Date: February 27, 2015

By: /s/ TODD E. SIMPSON
Todd E. Simpson

*Chief Financial Officer*

*(Principal Financial and Accounting Officer)*

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

| Signature | Title | Date |
|---|---|---|
| /s/ CLAY B. SIEGALL<br>Clay B. Siegall | Director, President & CEO (Principal Executive Officer) | February 27, 2015 |
| /s/ TODD E. SIMPSON<br>Todd E. Simpson | Chief Financial Officer (Principal Financial and Accounting Officer) | February 27, 2015 |
| /s/ SRINIVAS AKKARAJU<br>Srinivas Akkaraju | Director | February 27, 2015 |
| /s/ FELIX BAKER<br>Felix Baker | Director | February 27, 2015 |
| /s/ DAVID W. GRYSKA<br>David W. Gryska | Director | February 27, 2015 |
| /s/ MARC E. LIPPMAN | Director | February 27, 2015 |

| | | |
|---|---|---|
| Marc E. Lippman | | |
| /s/ JOHN P. MCLAUGHLIN | Director | February 27, 2015 |
| John P. McLaughlin | | |
| /s/ JOHN A. ORWIN | Director | February 27, 2015 |
| John A. Orwin | | |
| /s/ NANCY A. SIMONIAN | Director | February 27, 2015 |
| Nancy A. Simonian | | |
| /s/ DANIEL G. WELCH | Director | February 27, 2015 |
| Daniel G. Welch | | |