

SEATTLE GENETICS INC /WA  
Form 10-K  
February 27, 2013  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2012

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**  
(State or other Jurisdiction of  
incorporation or organization)

**91-1874389**  
(I.R.S. Employer  
Identification No.)

**21823 30<sup>th</sup> 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
<b>Common Stock, par value \$0.001</b>	<b>The NASDAQ Stock Market LLC</b>

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

**None**

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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  NO

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

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  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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$1,101,486,651 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 74,578,137 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 120,437,524 shares of the registrant's Common Stock issued and outstanding as of February 20, 2013.

### 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 2013 Annual Meeting of Stockholders.

**Table of Contents**

**SEATTLE GENETICS, INC.**

**FORM 10-K**

**FOR THE YEAR ENDED DECEMBER 31, 2012**

**TABLE OF CONTENTS**

	<b>Page</b>
<b>PART I</b>	
Item 1. <u>Business</u>	1
Item 1A. <u>Risk Factors</u>	24
Item 1B. <u>Unresolved Staff Comments</u>	42
Item 2. <u>Properties</u>	42
Item 3. <u>Legal Proceedings</u>	42
Item 4. <u>Mine Safety Disclosures</u>	42
<b>PART II</b>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	43
Item 6. <u>Selected Financial Data</u>	45
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	46
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	62
Item 8. <u>Financial Statements and Supplementary Data</u>	63
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	90
Item 9A. <u>Controls and Procedures</u>	90
Item 9B. <u>Other Information</u>	90
<b>PART III</b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	91
Item 11. <u>Executive Compensation</u>	91
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	91
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	91
Item 14. <u>Principal Accounting Fees and Services</u>	91
<b>PART IV</b>	
Item 15. <u>Exhibits, Financial Statement Schedules</u>	92
<u>Signatures</u>	96

## Table of Contents

### 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. 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 monoclonal antibody-based therapies for cancer. Our lead product ADCETRIS<sup>®</sup>, or brentuximab vedotin, received accelerated approval in the United States in 2011 and approval with conditions in Canada in 2013 for patients with relapsed Hodgkin lymphoma or relapsed systemic anaplastic large cell lymphoma, or sALCL. ADCETRIS 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. We 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, and in other CD30-positive malignancies. In addition, we have four clinical-stage ADC programs, which consist of SGN-75, ASG-5ME, ASG-22ME and SGN-CD19A, as well as several preclinical product candidates, including SGN-CD33A and SGN-LIV1A.

We are collaborating with Millennium: The Takeda Oncology Company, or Millennium, to develop and commercialize ADCETRIS on a global basis. Under this collaboration, Seattle Genetics has retained commercial rights for ADCETRIS in the United States and its territories and in Canada, and Millennium has commercial rights in the rest of the world. ADCETRIS was granted conditional approval in the European Union in 2012 for patients with relapsed Hodgkin lymphoma or relapsed sALCL.

We also have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including AbbVie Biotechnology Ltd. (formerly part of Abbott Laboratories), or AbbVie; Bayer Pharmaceuticals Corporation, or Bayer; Celldex Therapeutics, Inc., or Celldex; Daiichi Sankyo Co., Ltd., or Daiichi Sankyo; Genentech, Inc., a member of the Roche Group, or Genentech; GlaxoSmithKline LLC, or GSK; Millennium, Pfizer, Inc., or Pfizer, and PSMA Development Company LLC, a subsidiary of Progenics Pharmaceuticals Inc., or Progenics; 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.

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

We began commercializing ADCETRIS in August 2011, and the commercial potential of ADCETRIS and our ability to realize that potential remains uncertain. Our success in commercializing ADCETRIS will require, among other things, effective sales, marketing, manufacturing, distribution, information systems and pricing

## **Table of Contents**

strategies, as well as compliance with applicable laws and regulations. The FDA granted accelerated approval of ADCETRIS which means that we are, among other things, obligated to conduct specific post-approval clinical studies to confirm patient benefit as a condition of that approval. In addition, we are exploring the use of ADCETRIS in earlier lines of therapy in patients with Hodgkin lymphoma and MTCL, including sALCL, and in other CD30-positive malignancies. In order to do this, we are required to conduct additional extensive clinical studies and, if these studies are successful, we intend to seek additional regulatory approvals. We and Millennium are conducting three phase III clinical trials of ADCETRIS, one in relapsed cutaneous T-cell lymphoma, or CTCL, the ALCANZA trial, one in front-line advanced classical Hodgkin lymphoma, the ECHELON-1 trial, and one in front-line MTCL, including sALCL, the ECHELON-2 trial. The FDA has agreed to special protocol assessment, or SPA, agreements for all three of these phase III clinical 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 submission to the FDA, if the trial achieves its endpoints. We and Millennium are also conducting a phase III clinical trial in post-transplant Hodgkin lymphoma patients, the AETHERA trial, to evaluate whether ADCETRIS can extend progression free survival versus placebo in patients following autologous stem cell transplant, or ASCT. We have an agreement with Ventana Medical Systems, Inc., a member of the Roche Group, or Ventana, under which Ventana will 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. A molecular companion diagnostic is not required for the current approved indications for ADCETRIS; however, we expect that a molecular companion diagnostic may be required by regulatory authorities to support regulatory approval of ADCETRIS in other CD30-positive malignancies.

Although we have begun to recognize revenue from ADCETRIS product sales in the United States and Canada, we have only limited experience commercializing ADCETRIS and our future ADCETRIS product sales will be difficult to predict from period to period. Future sales growth of ADCETRIS will be primarily dependent on our ability to expand the labeled indications of use. This will require additional time and investment in clinical trials. We also expect that amounts earned from our collaboration agreements will continue to be an important source of our revenues and cash flows.

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

ADCETRIS and our pipeline of 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 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. In contrast to natural products that are often more difficult to produce and link to antibodies, our drugs are synthetically produced and easier to scale for manufacturing. ADCETRIS, SGN-75, ASG-5ME, ASG-22ME, SGN-CD19A, SGN-CD33A and SGN-LIV1A 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.

We utilize additional 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 have high tumor to normal tissue binding characteristics, rapid internalization within target cells and utilize native or engineered attachment sites to

## **Table of Contents**

optimize drug conjugation. For unconjugated antibodies, we seek intrinsic antitumor activity through direct signaling and/or effector functions and lowered risk of adverse events or immune response. We have also developed a proprietary sugar enhanced antibody, or SEA, technology, which is a process to enhance the effector function of monoclonal antibodies to further increase their antitumor activity by selectively reducing sugars in the monoclonal antibodies, or defucosylation. In some cases, we evaluate the use of our monoclonal antibodies and ADCs in combination with conventional chemotherapy and other anticancer agents, which may result in increased antitumor activity.

## **Our Strategy**

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

*Successfully Commercialize ADCETRIS.* An important near-term objective is to continue our efforts to successfully commercialize ADCETRIS. We are focusing our efforts on commercializing ADCETRIS in the United States and Canada, including through the coordinated efforts of our sales, marketing, reimbursement and market planning groups. We are also supporting Millennium's efforts to commercially launch ADCETRIS in the European Union, as well as 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 many types of CD30-positive cancers. We have reported encouraging data and have ongoing clinical trials evaluating ADCETRIS in earlier lines of therapy for Hodgkin lymphoma and MTCL and in other types of CD30-positive lymphoma such as CTCL, peripheral T-cell lymphoma and some types of B-cell lymphomas including diffuse large B-cell lymphoma, or DLBCL. We are also conducting a phase III clinical trial in post-transplant Hodgkin lymphoma patients, the AETHERA trial, to evaluate whether ADCETRIS can extend progression free survival versus placebo in patients following ASCT. In addition, we are conducting a phase II clinical trial of ADCETRIS for patients with CD30-positive non-lymphoma malignancies, including multiple myeloma, leukemia and solid tumors. We are also supporting both corporate and investigator sponsored trials in different CD30-positive indications, including CTCL, front-line treatment of older patients with Hodgkin lymphoma, 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 scientific interest.

*Continue to Develop our Other Pipeline Programs.* We believe that it is important to maintain a diverse pipeline of antibody-based 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-75, ASG-5ME, ASG-22ME, and SGN-CD19A, as well as our preclinical programs, such as SGN-CD33A, SGN-LIV1A and several other research-stage programs that employ our proprietary technologies. In addition, we have ADC co-development agreements with Agensys, Genmab and OBT that provide us with future ADC product opportunities.

*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 strong financial terms and endeavor to retain significant product rights, such as our ADCETRIS collaboration with Millennium, in which we retained commercial rights in the United States and Canada.

*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-75, ASG-5ME, ASG-22ME, SGN-CD19A





**Table of Contents**

and several preclinical programs, including SGN-CD33A and SGN-LIV1A. 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, Daiichi Sankyo, Genentech, GSK, Millennium, Pfizer and Progenics, as well as ADC co-development agreements with Agensys, Genmab and OBT. Our ADC technology licensing deals have generated over \$200 million as of December 31, 2012 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 and monoclonal antibodies, 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 entered into such license agreements with Bristol-Myers Squibb Corporation, the University of Miami, and CLB Research and Development, among others. We also have active research collaborations with other biotechnology companies and academic institutions to help advance our ADC technology.

**Table of Contents****ADCETRIS and Product Candidate Development Pipeline**

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

**Name of Product or**

<b>Product Candidate</b>	<b>Description</b>	<b>Commercial Rights</b>	<b>Status</b>
ADCETRIS®	Anti-CD30 ADC	Seattle Genetics in United States and Canada; Millennium in rest of world	<p>ADCETRIS received accelerated approval in the United States in 2011, conditional approval in the European Union in 2012 and approval with conditions in Canada in 2013 for patients with relapsed Hodgkin lymphoma or relapsed sALCL.</p> <p>AETHERA phase III trial ongoing for patients with Hodgkin lymphoma at high risk of relapse following ASCT. Enrollment was completed in 2012.</p> <p>ECHELON-1 phase III randomized front-line trial ongoing for patients with advanced classical Hodgkin lymphoma comparing Adriamycin, vinblastine, bleomycin and dacarbazine, or ABVD, versus AVD plus ADCETRIS.</p> <p>ECHELON-2 phase III randomized front-line trial ongoing for patients with CD30-positive MTCL, including sALCL, comparing cyclophosphamide, doxorubicin, Oncovin (vincristine) and prednisone, or CHOP, versus CHP plus ADCETRIS.</p> <p>ALCANZA phase III trial ongoing for relapsed CD30-positive CTCL patients, comparing ADCETRIS versus investigator's choice of methotrexate or bexarotene.</p> <p>Phase II retreatment trial ongoing for patients with Hodgkin lymphoma or sALCL who have relapsed after previously responding to ADCETRIS.</p> <p>Phase II trial ongoing for patients with relapsed or refractory CD30-positive non-Hodgkin lymphomas, including DLBCL, peripheral T-cell lymphoma and other less common</p>

lymphoma subtypes.

Phase II CD30-screening and treatment trial ongoing for patients with CD30-positive non-lymphoma malignancies, including multiple myeloma, leukemia and solid tumors.

Phase II trial ongoing for patients age 60 or older with newly diagnosed Hodgkin lymphoma evaluating ADCETRIS as a front-line monotherapy.

**Table of Contents****Name of Product or**

<b>Product Candidate</b>	<b>Description</b>	<b>Commercial Rights</b>	<b>Status</b>
			Planned phase I/II second-line trial for patients with Hodgkin lymphoma after first relapse evaluating ADCETRIS in combination with bendamustine.
SGN-75	Anti-CD70 ADC	Seattle Genetics	Phase Ib trial ongoing to evaluate SGN-75 in combination with everolimus for relapsed or refractory renal cell carcinoma.
ASG-5ME	Anti-SLC44A4 ADC	50:50 co-development and commercialization with Agensys	Two phase I trials ongoing for metastatic pancreatic cancer and gastric cancer; and castration-resistant prostate cancer.
ASG-22ME	Anti-Nectin-4 ADC	50:50 co-development and commercialization with Agensys	Phase I trial ongoing for Nectin-4 -positive solid tumors.
SGN-CD19A	Anti-CD19 ADC	Seattle Genetics	Two phase I trials ongoing for relapsed or refractory B-cell acute lymphoblastic leukemia, or ALL, and relapsed or refractory B-cell non-Hodgkin lymphomas.

**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 but 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 Millennium on the global development and commercialization of ADCETRIS. Under this collaboration, we retain commercial rights in the United States and Canada. Millennium 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 U.S. Food and Drug Administration, or 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. These indications are based on response rate. There are no data available demonstrating improvement in patient-reported outcomes or survival with ADCETRIS.

**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.

**Europe.** 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.

## **Table of Contents**

### *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 III 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 III randomized trial comparing ADCETRIS in combination with AVD versus ABVD as front-line therapy in advanced classical Hodgkin lymphoma patients called the ECHELON-1 trial. The primary endpoint is progression free survival, with overall survival as a key secondary endpoint.

An ongoing phase III randomized, double-blind clinical trial comparing ADCETRIS in combination with CHP versus CHOP as front-line therapy in patients with CD30-positive MTCL, including sALCL, called the ECHELON-2 trial. The primary endpoint is progression free survival, 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 may be required in many other countries, including Canada and the European Union, comprising the market for ADCETRIS. The requirements of these post-approval clinical studies vary from country to country and may 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 were diagnosed in the United States during 2012, and an estimated 1,200 people died of the disease. Approximately 2,000 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 front-line therapy for malignant lymphomas has resulted in high remission rates. However, these front-line chemotherapy regimens have substantial associated toxicities and a significant number of lymphoma patients relapse and require additional treatments including other chemotherapy regimens and ASCT. We believe there is a strong need for new therapies for these patients. In addition to lymphoma, CD30 is also expressed in leukemia, multiple myeloma and solid tumors, which may provide additional market opportunities in the future.

### *Clinical Development Plan*

In collaboration with Millennium, 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 III Hodgkin Lymphoma Post-ASCT Relapse Prevention.* In April 2010, we initiated a phase III trial of ADCETRIS for post-transplant Hodgkin lymphoma patients, or the AETHERA trial. The AETHERA trial is a randomized, double-blind, placebo-controlled study to evaluate ADCETRIS versus placebo in 329 Hodgkin lymphoma patients following ASCT. Patients must be at high risk for residual Hodgkin lymphoma, defined as

---

**Table of Contents**

those with a history of refractory Hodgkin lymphoma, those who relapse or progress within one year from receiving front-line chemotherapy and/or those who have disease outside of the lymph nodes at the time of pre-ASCT relapse. The primary endpoint of the study is progression-free survival and secondary endpoints include overall survival, safety and tolerability. Patients receive ADCETRIS every three weeks for up to approximately one year. The AETHERA trial is being conducted at multiple centers in the United States, Europe and Russia, and will provide important safety data as well as data on the use of ADCETRIS in an earlier line of Hodgkin lymphoma therapy as part of an integrated second-line regimen with ASCT. We completed enrollment of the AETHERA trial during 2012.

*Phase III Front-line Hodgkin Lymphoma.* At the December 2012 American Society of Hematology, or ASH, meeting we announced results from a phase I dose-escalation combination trial in front-line 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 front-line therapy on study achieved a complete remission. Among the 22 evaluable patients in the ADCETRIS plus ABVD cohorts, 21 patients who completed front-line therapy on study achieved a complete remission. No pulmonary toxicity events were observed in the ADCETRIS plus AVD cohorts compared to pulmonary toxicity events reported in 44 percent of the patients that received ADCETRIS plus ABVD. Data from this trial supported initiation of an international phase III trial evaluating ADCETRIS as part of a front-line combination chemotherapy regimen in patients with previously untreated advanced Hodgkin lymphoma that we and Millennium announced in November 2012, the ECHELON-1 trial. The randomized, open-label, phase III trial is investigating ADCETRIS plus AVD versus ABVD as frontline therapy in patients with advanced classical Hodgkin lymphoma. The primary endpoint is modified progression free survival 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 expected 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 an SPA agreement from the FDA and also received scientific advice from the European Medicines Agency, or EMA. As noted above, 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, Canada and European Union.

*Phase III Front-line Mature T-Cell Lymphoma.* At the December 2012 ASH meeting, we announced results from a phase I dose-escalation combination trial to evaluate ADCETRIS plus chemotherapy for sALCL, which was subsequently amended to include patients with any CD30-positive MTCL. After completing combination therapy, 26 of 26 patients treated with ADCETRIS plus CHP had an objective response, including 23 patients with a complete remission. Based in part on these data, we and Millennium initiated a global randomized, double-blind, placebo-controlled multi-center phase III clinical trial in January 2013 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, the ECHELON-2 trial. The primary endpoint is progression-free survival 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 expected to enroll approximately 300 patients. A molecular companion diagnostic test will be 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 Millennium. The trial is being conducted under an SPA agreement from the FDA and also received scientific advice from the EMA. As noted above, 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, Canada and European Union.

*Phase III Cutaneous T-Cell Lymphoma.* In May 2012, we and Millennium opened a phase III trial of ADCETRIS for relapsed CD30-positive CTCL patients, or the ALCANZA trial. The ALCANZA trial is a randomized, open-label, phase III 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



**Table of Contents**

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, progression-free survival 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 from the FDA. The ALCANZA trial also received EMA scientific advice.

There are also currently two investigator-sponsored phase II trials of ADCETRIS ongoing in patients with CD30-positive CTCL and data from both of these studies were reported at the ASH meeting in December 2012. In an ongoing phase II clinical trial of CTCL patients with MF or Sezary syndrome conducted at Stanford University School of Medicine, Dr. Youn H. Kim reported interim results that included fourteen of 20 patients achieving an objective response across all stages of disease, including Stage IB, Stage IIB and Stage IVA/B. In an ongoing phase II clinical trial evaluating the use of ADCETRIS in CD30-positive CTCL patients, including lymphomatoid papulosis, or LyP, pcALCL, or MF conducted at The University of Texas MD Anderson Cancer Center, Dr. Madeleine Duvic reported interim results that included 31 of 46 patients achieving an objective response, including 19 of 19 with LyP and/or pcALCL and 12 of 27 with MF.

*Relapsed or Refractory CD30-Positive Non-Hodgkin Lymphoma.* In August 2011, we initiated a phase II 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 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 2012 ASH meeting from 64 evaluable patients, of which 22 patients achieved an objective response, including twelve complete remissions and ten partial remissions. In B-cell lymphoma subtypes, 14 of 42 evaluable patients achieved an objective response, including 11 of 25 DLBCL patients. In T-cell lymphoma subtypes, eight of 22 evaluable patients achieved an objective response, including five of ten angioimmunoblastic T-cell lymphoma patients. The most common treatment-emergent adverse events of any grade were fatigue, neutropenia, nausea, diarrhea and fever. The most common Grade 3 or 4 adverse event considered related to ADCETRIS treatment was neutropenia. Enrollment is ongoing and the study is expected to enroll more than 100 patients at multiple centers in the United States.

*Relapsed or Refractory CD30-Positive Non-Lymphoma Malignancies.* In October 2011, we initiated a phase II trial for patients with CD30-positive non-lymphoma malignancies, including multiple myeloma, leukemia and solid tumors. Eligible patients must have failed, refused or have been deemed ineligible for standard therapy. Assessment of CD30 expression will be performed according to a Seattle Genetics screening protocol that facilitates high-throughput assessment of patients with a variety of non-lymphoma malignancies to identify those eligible for the clinical trial. The primary endpoint of the phase II trial is characterization of the antitumor activity of ADCETRIS. In addition, the trial will assess safety and characterize the relationship of CD30 expression with antitumor activity. The study is expected to enroll approximately 80 patients at multiple centers in the United States. At the June 2012 American Society of Clinical Oncology annual meeting, we announced that at the time of data analysis, 1,637 patients had been screened and 38 patients with 17 different malignant diagnoses were CD30-positive per the protocol.

*Retreatment of Relapsed or Refractory Hodgkin Lymphoma and sALCL.* We are conducting a phase II trial of ADCETRIS for retreatment of patients with relapsed or refractory Hodgkin lymphoma or sALCL who have relapsed after previously achieving a complete or partial remission with ADCETRIS. The trial is designed to enroll up to 50 patients at multiple centers in the United States and Europe and is intended to assess the potential for patients to benefit from additional ADCETRIS treatment. In June 2012, we reported preliminary data demonstrating that objective responses were achieved in 16 out of 23 evaluable retreatment experiences, including nine complete remissions and seven partial remissions. In the first half of this year, we plan to submit a supplemental biologics license application, or sBLA, to the FDA supporting use of ADCETRIS for retreatment as well as treatment beyond 16 cycles of therapy.

## **Table of Contents**

*Front-line Therapy for Hodgkin Lymphoma Patients Age 60 and Over.* In October 2012, we initiated a phase II clinical trial evaluating ADCETRIS as a front-line therapy for patients age 60 or older with newly diagnosed Hodgkin lymphoma. The phase II single-arm, open-label clinical trial will evaluate the efficacy and tolerability of ADCETRIS as front-line monotherapy in patients age 60 or older with Hodgkin lymphoma. The trial is enrolling patients who are newly diagnosed and have received no prior Hodgkin lymphoma treatment. The primary endpoint of the trial is to assess the objective response rate, with key secondary endpoints of safety and tolerability, duration of response, complete remission rate and progression-free survival. The study is expected to enroll up to 20 patients at multiple centers in the United States.

*Second-line Therapy for Relapsed or Refractory Hodgkin Lymphoma Patients.* We and Millennium plan to initiate a phase I/II 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. Bendamustine is an alkylating agent used in the treatment of chronic lymphocytic leukemias and lymphomas.

*Investigator-Sponsored Studies.* As of December 31, 2012, there were 12 ongoing investigator sponsored trials of ADCETRIS in the U.S. In addition, we and Millennium 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 we have supported to date include the use of ADCETRIS in a number of malignant hematologic indications, including cutaneous T-cell lymphoma, older patients with untreated Hodgkin lymphoma and salvage therapy for patients with Hodgkin lymphoma prior to autologous hematopoietic stem cell transplantation. We are also supporting numerous other investigator-sponsored trial proposals for the use of ADCETRIS in other CD30-positive settings, such as novel combinations of therapy and graft versus host disease.

### ***SGN-75***

SGN-75 is an ADC composed of an anti-CD70 monoclonal antibody linked to a potent auristatin compound using our proprietary ADC technology. In November 2009, we initiated a single-agent phase I study of SGN-75 for patients with CD70-expressing relapsed or refractory renal cell carcinoma or non-Hodgkin lymphoma. This trial was designed to enroll up to 80 patients at multiple centers in the United States to evaluate the safety, tolerability, pharmacokinetic profile and antitumor activity of SGN-75. We defined a maximum tolerated dose and completed enrollment in this trial in the second half of 2011. Based on preclinical data suggesting synergy between auristatin-containing ADCs and mTOR inhibitors, including everolimus, we recently initiated a phase 1b study of SGN-75 combined with everolimus for relapsed or refractory renal cell carcinoma patients.

### ***ASG-5ME***

ASG-5ME is an ADC composed of an anti-SLC44A4 monoclonal antibody linked to a potent auristatin compound using our proprietary ADC technology. SLC44A4 is a novel target expressed on more than 80 percent of pancreatic, prostate and gastric cancer tumors and is also expressed in more than 50 percent of breast cancer tumors, based on preclinical data. We are developing ASG-5ME as a product candidate for the treatment of solid tumors under our co-development collaboration with Agensys.

We and Agensys initiated a phase I clinical trial of ASG-5ME for the treatment of metastatic pancreatic cancer in July 2010, which was broadened to include gastric cancer in 2012, and a phase I clinical trial of ASG-5ME for the treatment of castration-resistant prostate cancer in October 2010. Both trials are evaluating the safety, tolerability, pharmacokinetic profile and antitumor activity of ASG-5ME in order to identify a dose and schedule for potential future clinical trials. We completed enrollment in the pancreatic clinical trial in the second half of 2011 and data were reported at the January 2013 American Society of Clinical Oncology Gastrointestinal Cancers Symposium from 18 evaluable patients treated at the maximum tolerated dose, of which one patient achieved a partial response and six patients had stable disease. In addition, we are

continuing to dose-escalate and enroll additional patients in the castration-resistant prostate and gastric cancer clinical trials.

## **Table of Contents**

### ***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.

A phase I clinical trial of ASG-22ME for the treatment of Nectin-4-positive solid tumors was initiated in July 2011. This trial will evaluate the safety, tolerability, pharmacokinetic profile and antitumor activity of escalating doses of ASG-22ME. The maximum tolerated dose has not yet been established in this trial and dose escalation is continuing.

### ***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. 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 I, 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 is expected to enroll approximately 80 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 is expected to enroll approximately 25 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, progression-free survival and overall survival.

## **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, and identifying novel antigen targets and monoclonal antibodies 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.

*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.

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

*Novel Monoclonal Antibodies and Antigen Targets.* We are actively engaged in internal efforts to identify and develop monoclonal antibodies 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 Agensys, Genmab and OBT.

## **Table of Contents**

*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 our product candidates and our antibody-based technologies. For the years ended December 31, 2012, 2011, and 2010, we recorded \$170.3 million, \$163.4 million, and \$146.4 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.

### ***Millennium ADCETRIS Collaboration***

In December 2009, we entered into a collaboration agreement with Millennium to develop and commercialize ADCETRIS, under which Seattle Genetics retains commercial rights in the United States and its territories and in Canada, and Millennium and its Takeda affiliates have commercial rights in the rest of the world. Under the collaboration, we received an upfront payment of \$60 million and milestone payments totaling \$30 million related to regulatory submissions and approval of ADCETRIS by the European Commission. We are entitled to receive additional progress- and sales-dependent milestone payments of up to \$205 million based on Millennium'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 Millennium's licensed territories. Millennium also bears a portion of third party royalty costs owed on sales of ADCETRIS in its territory. Millennium is funding half of joint worldwide development costs under the collaboration, excluding costs solely related to development in Japan, which Millennium is solely responsible for funding. Although we are funding half of joint worldwide development costs, Millennium 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. Millennium may terminate the collaboration agreement for any reason upon prior written notice to us and we may terminate the collaboration agreement in certain circumstances. The collaboration agreement can also be terminated by mutual written consent of the parties. If neither party terminates the collaboration agreement, then the agreement automatically terminates on the expiration of all payment obligations.

### ***Agensys Co-Development Collaboration***

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

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. The agreement was expanded and modified in November 2009. As part of the modified agreement, Agensys paid us an upfront payment of \$12 million and the number of targets under the collaboration was expanded.

Under the co-development provisions of the collaboration agreement, we and Agensys are co-funding all development and commercialization costs for both ASG-5ME and ASG-22ME, and will share equally in any profits for these product candidates. We and Agensys initiated a phase I clinical trial of ASG-5ME for the

**Table of Contents**

treatment of metastatic pancreatic cancer in July 2010 that was broadened in 2012 to include gastric cancer and a phase I clinical trial of ASG-5ME for the treatment of castration-resistant prostate cancer in October 2010. A phase I clinical trial of ASG-22ME for the treatment of Nectin-4 positive solid tumors was initiated in July 2011.

Agensys is also conducting preclinical studies aimed at identifying ADC product candidates for additional targets, and we have the right to exercise a co-development option for one additional ADC product candidate upon submission of an IND by Agensys. Agensys has the right to develop and commercialize the other ADC product candidates on its own, subject to paying us fees, milestones and royalties. 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.

**ADC Collaborations**

We have active collaborations with nine 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 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 early stages of 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/or 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 collaborations, the number of targets licensed and current development status:

<b>Collaborator</b>	<b>Effective Date</b>	<b>Number of Targets</b>	<b>Development Status<sup>1</sup></b>
AbbVie	March 2011	Multiple <sup>2</sup>	Phase I
Bayer	September 2004	One	Phase I
Celldex	June 2004	Two	Phase II
Daiichi Sankyo	July 2008	One	Preclinical
Genentech	April 2002	Multiple	Phase II
GlaxoSmithKline	December 2009	Multiple	Preclinical
Millennium	March 2009	One	Phase I



Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

Pfizer

December 2010

One

Preclinical

Progenics

June 2005

One

Phase II

<sup>1</sup> For collaborations involving multiple targets, development status denotes the most advanced program under the collaboration.

<sup>2</sup> In October 2012, AbbVie paid us a \$25 million upfront fee to expand our collaboration relationship to include additional targets.

## **Table of Contents**

### ***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 antigen, which is expressed on numerous types of solid tumors. In April 2011, we entered into a second ADC research collaboration agreement with Genmab. Under the second agreement, Genmab has rights to utilize our ADC technology with its HuMax-CD74 antibody targeting CD74, which is expressed on both hematological malignancies and solid tumors. Under both agreements, 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 I clinical development. Genmab is responsible for research, manufacturing, preclinical development and phase I clinical trials of ADCs under the collaborations. We receive research support payments for any assistance provided to Genmab. If we opt into an ADC product at the end of phase I clinical trials, 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 to an ADC product, Genmab would pay us fees, milestones and mid-single digit royalties on worldwide net sales of the product.

### ***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 will generate panels of monoclonal antibodies against novel tumor-specific antigens identified using its proprietary Oxford Genome Anatomy Project (OGAP<sup>(R)</sup>) database. The antibodies generated by OBT will then be screened for activity using our ADC technology. The resulting ADCs may be selected by each company for further development and commercialization. Under the terms of the multi-year, multi-product agreement, we and OBT will 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 monoclonal antibody-based cancer targeting technologies, including patents, monoclonal antibodies, chemical linkers, a ribosome-inactivating protein and enabling technologies. Under the terms of the license agreement, we are required to pay royalties in the low single digits on net sales of products, including ADCETRIS, that incorporate patented technology 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 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

---

**Table of Contents**

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-5ME, and ASG-22ME, 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, our 27 issued patents will expire between 2014 and 2026 in the United States and Europe, and additional patent applications are pending that, if issued, could increase the patent term to 2030 for certain methods of treatment using ADCETRIS. Of these 27 patents, we own rights to sixteen patents and have exclusively licensed rights to eleven patents. For SGN-75 and our related ADC technology, our sixteen issued patents will expire between 2024 and 2028 and additional patent applications are pending that, if issued, could increase the patent term to 2031 for certain methods of treatment using SGN-75. Of these sixteen issued patents, we own rights to all sixteen patents. For ASG-5ME and our related ADC technology, our 27 issued patents will expire between 2014 and 2030. Of these 27 patents, we exclusively own rights to nine patents, have exclusively licensed rights to eleven patents, and have non-exclusive rights to seven patents. For ASG-22ME and our related ADC technology, our 22 issued patents will expire between 2014 and 2026 and additional patent applications are pending that, if issued, could increase the patent term to 2031. Of these 22 patents, we exclusively own rights to nine patents, have exclusively licensed rights to eleven patents, and have non-exclusive rights to two patents. For SGN-CD19A and our related ADC technology, our thirteen issued patents will expire between 2024 and 2029. Of these thirteen issued patents, we own rights to all thirteen patents. 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 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 corporate 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 patents 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. 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

## **Table of Contents**

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 companies that, if granted, may require us to license or challenge their validity upon commercialization of 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 any 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 proprietary information and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. These agreements provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of their relationship with us except in limited circumstances. These agreements also provide that we will own all inventions conceived 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, effectiveness, labeling, storage, 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, 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;

Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

submission to the FDA of a marketing authorization application in the form of either a New Drug Application, or NDA, or a Biologics License Application, or BLA, which must often be accompanied by a substantial user fee;

## **Table of Contents**

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, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30 day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may 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 I, 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 II 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 III 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 IV, 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 III trials to verify and describe the clinical benefit of ADCETRIS in its two approved indications. Phase I, phase II or phase III 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 effectiveness 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](http://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 ten months from submission of the application, while priority review is six months from submission of the application. The testing and approval process is likely to require substantial

## **Table of Contents**

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 risk management programs and 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 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 testing of ADCETRIS, including phase IV clinical trials, and surveillance programs to monitor the safety effects 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



## **Table of Contents**

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: the federal Anti-Kickback Statute, which prohibits soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent; and the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters and was amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. State law equivalents of each of the above federal laws, many of which differ from each other in significant ways and may not have the same effect, further complicate compliance efforts.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. In addition, as discussed below, beginning in 2014, a similar federal requirement will require manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals made in the previous calendar year. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

### ***Reimbursement***

Sales of ADCETRIS and any future products depend, in 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. 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 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 the Centers for Medicare & Medicaid Services, or CMS, and coverage and reimbursement for products and services under these programs are subject to changes in CMS regulations and interpretive policy determinations, in addition to statutory changes made by Congress. Congress has considered reducing Medicare payment rates, and legislation such as that related to sequestration, which refers to an automatic spending cut in the federal budget effected by funds being sequestered by the U.S. Treasury, could be enacted in the future reducing reimbursement levels. In addition, as a condition of federal funds being made available to cover our products under Medicaid, we are required to



---

**Table of Contents**

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.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as PPACA, is expected to have a significant impact on the health care industry. PPACA is expected 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 predict the impact of PPACA, as many of its reforms require the promulgation of detailed implementing regulations, which has not yet occurred.

Among the provisions of PPACA to impact to the biopharmaceutical industry are the following:

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.

Effective August 1, 2013, PPACA will require pharmaceutical manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any transfer of value made or distributed to such entities, as well as any investment interests held by physicians and their immediate family members. Manufacturers will be required to report this information beginning in 2014.

In June 2012, the U.S. Supreme Court upheld the constitutionality of the PPACA, except that the Court held unconstitutional the provision of PPACA authorizing the Secretary of the U.S. Department of Health and Human Services to withdraw all of a state's Medicaid funding if the state declines to participate in PPACA's expansion of Medicaid eligibility. Yet, some states have indicated that they intend to not implement certain sections of PPACA, and some members of the U.S. Congress are still working to repeal PPACA. As a result, 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.

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. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a



## **Table of Contents**

system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. 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. Historically, products launched in the European Union do not follow price structures of the U.S. and generally tend to be significantly lower.

## **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 therapies other than ADCETRIS for the treatment of relapsed Hodgkin lymphoma or specifically indicated for relapsed sALCL; however, Celgene's Istudax and Spectrum Pharmaceuticals' Folutyn are both approved for relapsed or refractory peripheral T-cell lymphoma, or PTCL, and we are aware of multiple investigational agents that are currently being studied, including Pfizer's crizotinib and Millennium's alistertib, which, if successful, may compete with ADCETRIS in the future. In addition, 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.

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; 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 Pfizer, ImmunoGen and Medarex, a subsidiary of Bristol-Myers Squibb, all of which have ADC technology. Pfizer is conducting a phase III 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

---

## **Table of Contents**

directed at the same antigen targets or for the treatment of the same diseases as our product candidates. For example, we believe Medarex has anti-CD30 and anti-CD70 antibody programs, Amgen and Wyeth have anti-CD19 programs and Xencor has an anti-CD30 antibody program that may be competitive with ADCETRIS or our product candidates. In addition, our ADC collaboration partners 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. These include antibodies such as Genentech's Rituxan, proteasome inhibitors such as Millennium's Velcade, HDAC inhibitors such as Celgene's Istodax, immunomodulatory agents such as Celgene's Revlimid and Spectrum Pharmaceuticals Folutyn, kinase inhibitors such as Pharmacyclic's Ibrutinib, P13K inhibitors developed by Gilead and Infinity, such as GS-1101 and IPI-145, and cytotoxic drugs such as Bayer's/Onyx's Nexavar, Celgene's Vidaza, Cephalon's Treanda, Pfizer's crizotinib and Millennium's alistertib.

## **Manufacturing**

We 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 ADCETRIS and other ADCs, several contract manufacturers, including Sigma Aldrich Fine Chemicals, or SAFC, perform drug-linker manufacturing and several other contract manufacturers perform conjugation of the drug-linker to the antibody. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including shipping and storage of our product candidates.

We established our commercial scale supply chain for ADCETRIS prior to commercial launch. 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 III trials. 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 Millennium with their needs of ADCETRIS 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.

## **Table of Contents**

### **Commercial Operations**

We have allocated commercial resources, including sales, marketing, supply chain management and reimbursement capabilities, to commercialize ADCETRIS in the United States and Canada. We believe the U.S. and Canadian markets for ADCETRIS in 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. Millennium has commercial rights in the rest of the world. ADCETRIS was granted conditional approval in the European Union in 2012 for patients with relapsed Hodgkin lymphoma or relapsed sALCL and Millennium is also pursuing regulatory approvals in 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 ship product directly to the health care provider. Three of our major distributors, together with entities under their common control AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation each accounted for 10% or more of our total revenue in 2012 and 2011, respectively. Revenues generated outside the United States were less than 10% of our total revenues for the years ended December 31, 2012, 2011 and 2010.

### **Employees**

As of December 31, 2012, we had 538 employees. Of these employees, 365 were engaged in or support research, development and clinical activities, 82 were in administrative and business related positions, and 91 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<sup>th</sup> 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](http://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.



## **Table of Contents**

### **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 Millennium are unable to successfully commercialize ADCETRIS for the treatment of patients in its approved indications, our ability to generate significant revenue or achieve profitability will be adversely affected.*

In August 2011, we obtained accelerated approval from the United States Food and Drug Administration, or FDA, for ADCETRIS<sup>®</sup> (brentuximab vedotin) for two indications: (1) the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant, or 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 systemic anaplastic large cell lymphoma, or sALCL, after failure of at least one prior multi-agent chemotherapy regimen. There are no data available demonstrating improvement in patient-reported outcomes or survival with ADCETRIS. ADCETRIS is our only product approved for marketing by the FDA and our ability to generate revenue from product sales and achieve profitability is substantially dependent on our ability to successfully commercialize ADCETRIS for the treatment of patients in its two approved indications. We may not be able to fully realize the commercial potential of ADCETRIS for a number of reasons, including:

the market penetration rate of ADCETRIS may be lower, or the duration of therapy in patients in ADCETRIS two approved indications may be shorter, than our projections;

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 and prevalence of patients in ADCETRIS two approved indications is limited and may be lower than our projections;

results from our required post-approval studies may fail to verify the clinical benefit of ADCETRIS in either or both of its approved indications, which could result in the withdrawal of ADCETRIS from the market;

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

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

our limited experience in marketing, selling and distributing 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;

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

there may be changed or increased regulatory restrictions;

there may be additional changes to the label for ADCETRIS, including the boxed warning, that further restrict how we market and sell ADCETRIS, including as a result of data collected from required post-approval studies or as the result of adverse events observed in these or other studies;

## Table of Contents

we may not have adequate financial or other resources to successfully commercialize ADCETRIS; and

we may not be able to obtain adequate commercial supplies of ADCETRIS to meet demand or at an acceptable cost.

If we are unable to successfully commercialize ADCETRIS in its two approved indications or our estimates of the incidence and prevalence of patients in such indications is incorrect, our ability to generate revenue from product sales and achieve profitability will be adversely affected and our stock price would likely decline.

In December 2009, we entered into an agreement with Millennium to develop and commercialize ADCETRIS, under which we have commercial rights in the United States and its territories and Canada, and Millennium has commercial rights in the rest of the world. The success of this collaboration and the activities of Millennium will significantly impact the potential commercialization of ADCETRIS in countries other than the United States and in Canada. On October 31, 2012, Millennium announced that it had received conditional marketing authorization for ADCETRIS from the European Commission for two indications: (1) the treatment of adult patients with relapsed or refractory CD30-positive Hodgkin lymphoma following ASCT or following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option, and (2) the treatment of adult patients with relapsed or refractory sALCL. 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 Millennium received conditional marketing authorization from the European Commission, we cannot control the amount and timing of resources that Millennium dedicates to the commercialization of ADCETRIS, or to its marketing and distribution, and our ability to generate revenues from ADCETRIS product sales by Millennium depends on Millennium's ability to achieve market acceptance of, and to otherwise effectively market, ADCETRIS for its approved indications in its territory.

We currently expect that future ADCETRIS sales growth 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 mature T-cell lymphoma, or MTCL, including sALCL, and in a range of CD30-positive hematologic malignancies and solid tumor indications, including relapsed cutaneous T-cell lymphoma, or CTCL. This will require additional time and investment in clinical trials and there can be no assurance that we and/or Millennium will obtain and maintain the necessary regulatory approvals to market ADCETRIS for any additional indications or to market ADCETRIS at all in jurisdictions other than the United States, Canada, and the European Union. We and Millennium also recently announced that we formed a collaboration with Ventana Medical Systems, Inc., or Ventana, under which Ventana will 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 Millennium receive the required regulatory approvals to market ADCETRIS for any additional indications or in additional jurisdictions, we and Millennium may not be able to successfully commercialize ADCETRIS, including for the reasons set forth above.

***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 a limited amount of historical sales data and although we have provided sales guidance for ADCETRIS, 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 sales of ADCETRIS in the future may 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



## **Table of Contents**

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:

the 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 due to different levels of utilization by entities entitled to government rebates and discounts and changes in patient demographics;

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 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 Millennium, 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.

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 FDA-required ADCETRIS post-approval confirmatory studies as well as the post-approval confirmatory studies that Millennium is required to

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

conduct as a condition to the conditional marketing authorization of ADCETRIS by the European Commission. In addition, reports of adverse events or safety concerns involving ADCETRIS could result in the FDA or European or other 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. We cannot assure you 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

---

## **Table of Contents**

competition easier or make it more difficult or expensive for us to distribute ADCETRIS. For example, in January 2012, we announced that the prescribing information for ADCETRIS had been updated to include the following information: (1) 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, (2) a discussion in the PML warning and precaution provision regarding other possible contributing factors to PML such as other prior therapies and underlying disease, symptoms to be aware of and suggested methodologies for diagnosis of PML, and (3) a contraindication warning of the concomitant use of ADCETRIS and bleomycin due to pulmonary toxicity.

***The target patient population for ADCETRIS approved indications is small, has not been definitively determined and may turn out to be lower than expected, which could adversely affect our ability to achieve profitability in the future.***

The incidence and prevalence of patients in ADCETRIS approved indications has not been definitively determined, but we believe the number of patients in ADCETRIS approved indications is relatively low. The number of such patients may turn out to be lower than expected or may not otherwise be amenable to treatment with ADCETRIS, all of which would adversely affect our results of operations and our ability to achieve profitability. Further, initial sales of ADCETRIS may have depleted the prevalence pool of patients in the approved indications more quickly than expected, which if correct, may negatively impact sales of ADCETRIS in the future and could adversely affect our results of operations and our ability to achieve profitability.

***Even though we have obtained accelerated 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 conditional approval regulations in the U.S. and 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 conditional approval, we are subject to certain post-approval requirements pursuant to which we are conducting additional confirmatory phase III 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 the FDA, Health Canada 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. 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 recent 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 positive benefit-risk balance. Millennium's failure to provide this additional clinical data or to confirm the positive benefit-risk balance, could result in the European Commission withdrawing approval of ADCETRIS in the European Union, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Millennium 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





**Table of Contents**

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 Millennium;

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 Millennium might not be permitted to market ADCETRIS and our business would suffer.

*The status of coverage and reimbursement from third-party payers for newly approved prescription drug products is uncertain and failure to obtain adequate coverage and reimbursement could limit our ability to generate revenue.*

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

Our ability to successfully commercialize ADCETRIS for its approved indications or for other future indications will depend, in part, on 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. Significant uncertainty exists as to the coverage and reimbursement of newly approved prescription drug products.

Healthcare providers and third-party payers use coding systems to identify diagnoses, procedures, services, drugs, pharmaceutical devices, equipment and other health-related items and services. Proper coding is an integral component to receiving appropriate reimbursement for the administration of ADCETRIS and related services. The majority of payers use nationally recognized code sets to report medical conditions, services and drugs. Although we received our permanent reimbursement codes for ADCETRIS, healthcare providers prescribing ADCETRIS may incorrectly use these codes, which may result in payment delays or incorrect payment levels. We cannot predict whether our customers will receive adequate reimbursement for ADCETRIS.

Government and other third-party payers increasingly are attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for indications for which the FDA has not granted approval. Third-party insurance

## **Table of Contents**

coverage may not be available to patients for ADCETRIS. If government and other third-party payers do not provide adequate coverage and reimbursement levels for ADCETRIS, market acceptance of ADCETRIS would be adversely affected.

*If our competitors develop and market products that are more effective than ADCETRIS, our commercial opportunity will be reduced or eliminated.*

Even though we have obtained approval in the United States and Millennium has obtained approval in the European Union to market ADCETRIS in two indications, our commercial opportunity will be reduced or eliminated if our competitors develop and market products that are more effective, have fewer side effects or are less expensive than ADCETRIS for its two approved indications or any other potential indication. Our competitors include large, fully-integrated pharmaceutical companies and more established biotechnology companies, both of which have significant resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals and marketing. 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 competitors will succeed in developing technologies that are more effective than those used in ADCETRIS, or that would render our technology obsolete or noncompetitive.

*We are subject to various state and federal healthcare related laws and regulations that may impact the commercialization of ADCETRIS 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, the federal False Claims Act and HIPAA/HITECH. 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. 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. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the 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 pharmaceutical, medical device and other healthcare companies to have to defend a False Claims Act action. When an entity is determined to have violated the 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. Various states have also enacted laws modeled after the federal False Claims Act.

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters and was amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information.

## **Table of Contents**

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.

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 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 the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations.

***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. Although we have recently begun to commercialize ADCETRIS and we continue to earn amounts under our collaboration agreements, our revenue and profit potential is unproven and our limited operating 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 Millennium 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 other product candidates



---

**Table of Contents**

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. Moreover, even though certain of our clinical trials, including our three phase III clinical trials of ADCETRIS that we are conducting with Millennium, are being conducted under a special protocol assessment, or SPA, with the FDA, an SPA with the FDA 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, an 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, an 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 an 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 to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards, or IRBs, for reexamination, which may impact the costs, timing or successful completion of a clinical trial. 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.

*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, 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 Millennium, 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 significantly increase patient size required for phase III studies of ADCETRIS that we are required to conduct 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 United States dollar to the foreign currency where the trial is being conducted may impact our actual costs.

**Table of Contents**

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 or halt our clinical trials of ADCETRIS or any of our product candidates for numerous reasons, including:

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;

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;

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 IRB approval to conduct a clinical trial at a prospective site;

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, during 2011 we announced that, based on a phase I 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. The FDA has since approved changes to the ADCETRIS label to add 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 results or adverse medical events, including patient fatalities that may be attributable to ADCETRIS during a clinical trial could cause it to be redone or terminated or negatively affect our ability to market ADCETRIS or expand into other indications. 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.

---

**Table of Contents**

*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 some of our current and future product candidates. For example, we entered into a collaboration agreement with Millennium in December 2009 that granted Millennium rights to develop and commercialize ADCETRIS outside of the United States and Canada. We also have ADC collaborations with AbbVie, Bayer, Celldex, Daiichi Sankyo, GSK, Genentech, Millennium, Pfizer and Progenics, 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 Millennium 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 Millennium. 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the U.S. 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 will have the effect of reducing the revenue generated by our sales of ADCETRIS and any future commercial products we may have. In addition, we anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the price that we receive

## **Table of Contents**

for any approved product, which may harm our business. 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, European government austerity measures or further healthcare reform measures in the European Union could adversely affect demand and pricing for ADCETRIS, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Millennium in the European Union.

*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, most 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 Millennium's ability and willingness to market the approved product outside of the United States and Canada. The loss of our collaborators, especially Millennium, 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.

*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, we sell ADCETRIS through a limited number of pharmaceutical distributors. Healthcare providers order ADCETRIS through these distributors. We receive orders from distributors and ship product directly to the healthcare provider. We do not promote ADCETRIS to these distributors and they do not set or determine demand for ADCETRIS; however, our ability to successfully 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 rely upon a limited number of manufacturers to supply such drug products. For the monoclonal antibody used in ADCETRIS, we have contracted with AbbVie for clinical and commercial supply. For ADCETRIS and other ADCs, several contract manufacturers, including SAFC, supply us with drug-linker and other contract manufacturers perform conjugation of the drug-linker to the antibody. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including shipping and storage of ADCETRIS. 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



## **Table of Contents**

shipments, loss of product in the manufacturing process, a shortfall in ADCETRIS, or the inability to sell our products in the U.S. or abroad. In addition, 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-75, ASG-5ME, ASG-22ME, SGN-CD19A, SGN-CD33A and SGN-LIV1A product candidates are 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, Daiichi Sankyo, Genentech, Genmab, GSK, Millennium, Pfizer and Progenics, and our co-development agreements with Agensys, Genmab, and OBT. Although ADCETRIS has received marketing approval in the United States and in the European Union, ADCETRIS is our first and only ADC product that has 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 and 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 four clinical-stage ADC programs, which consist of SGN-75, ASG-5ME, ASG-22ME and SGN-CD19A, as well as several preclinical product candidates, including SGN-CD33A and SGN-LIV1A. 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. Moreover, we still have only limited data from our phase I trials of SGN-75, ASG-5ME, ASG-22ME, and SGN-CD19A. 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 Millennium, 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



## Table of Contents

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;

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 Millennium;

the cost of establishing and maintaining clinical and commercial supplies of ADCETRIS and/or our collaborators may develop;

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 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 other 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, CLB-Research and Development, the University of Miami and Spirogen, 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 other product candidates. Further, we may have disputes with our licensors, which may impact our ability to develop and commercialize ADCETRIS or our other product candidates or require us to enter into additional licenses. For example, we have filed for declaratory relief against one of our licensors with respect to one of our proprietary drug technologies and it has made additional claims against us related to our use of this technology. An adverse result in this dispute, or other potential future disputes with our licensees, may impact our ability to develop and commercialize ADCETRIS and our other 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 other 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.



## **Table of Contents**

***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 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 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 continue to 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 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. 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.

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



## **Table of Contents**

allow third parties to use our proprietary technologies without a license from us or our collaborators, which may also result in loss of future royalty payments. Furthermore, if such challenges to our rights are not resolved promptly in our favor, our existing business relationships may be jeopardized and we could be delayed or prevented from entering into new collaborations or from commercializing potential products, which could adversely affect our business and results of operations. In addition, we may challenge the patent or other intellectual property rights of third parties and if we are unsuccessful in actions we bring against the rights of such parties, through litigation or otherwise, and it is determined that we infringe the intellectual property rights of such parties, we may be prevented from commercializing potential products in the relevant jurisdiction, or may be required to obtain licenses to those rights or develop or obtain alternative technologies, any of which could harm our business.

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

We are highly dependent on the efforts and abilities of the principal members of our senior management. Additionally, we have scientific personnel with significant and unique expertise in monoclonal antibodies, ADCs and related technologies. 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 our products successfully, 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.

*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 Istudax and Spectrum Pharmaceuticals' Folutyn are both approved for relapsed or refractory PTCL and we are aware of multiple investigational agents that are currently being studied, including Pfizer's crizotinib and Millennium's alistertib, 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.

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, Aventis, Bayer, Biogen IDEC, Bristol-Myers Squibb, Celgene, Eisai, Genentech, GSK, Gilead, ImmunoGen, Infinity, Merck, Millennium, Novartis, Pfizer, Pharmacyclics, Sanofi-Aventis, Spectrum Pharmaceuticals, and Teva are developing and/or marketing products or technologies that may compete with ours, and some of these companies, including 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,



## **Table of Contents**

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 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.

***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 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 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 our business could be adversely affected.***

We rely on information technology systems to keep financial records, maintain laboratory and corporate records, communicate with staff and external parties and operate other critical functions. 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

## **Table of Contents**

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.

*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 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 2012, our closing stock price fluctuated between \$22.98 and \$27.38 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, and the European Union;

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

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 our competitors;

announcements regarding the results of the clinical trials we and/or Millennium 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;



**Table of Contents**

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 process;

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

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 67.3 percent of our voting power as of February 20, 2013. 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,

## **Table of Contents**

certain provisions of our charter documents, including provisions eliminating the ability of stockholders to take action by written consent and limiting the ability of stockholders to raise matters at a meeting of stockholders without giving advance notice, may have the effect of delaying or preventing changes in control or management of Seattle Genetics, which could have an adverse effect on the market price of our stock. In addition, our charter documents provide for a classified board, which may make it more difficult for a third party to gain control of our Board of Directors. Similarly, state anti-takeover laws in Delaware and Washington related to corporate takeovers may prevent or delay a change of control of Seattle Genetics.

### **Item 1B. Unresolved Staff Comments**

None.

### **Item 2. Properties**

Our headquarters are in Bothell, Washington, where we lease three buildings totaling approximately 195,000 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 and one of our leases includes an early termination option exercisable upon providing notice of our intent to accelerate the termination date of the lease and payment of a termination fee.

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.



**Table of Contents****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 20, 2013, there were 120,437,524 shares of our common stock outstanding, which were held by approximately 84 holders of record of our common stock. On February 20, 2013, the closing price of our common stock as reported on the NASDAQ Global Select Market was \$27.46 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:

	<b>High</b>	<b>Low</b>
<b>2011</b>		
First Quarter	\$ 17.45	\$ 13.94
Second Quarter	21.41	14.86
Third Quarter	21.15	12.29
Fourth Quarter	22.40	14.61
<b>2012</b>		
First Quarter	\$ 21.04	\$ 16.34
Second Quarter	26.02	17.09
Third Quarter	29.83	22.68
Fourth Quarter	27.83	21.05
<b>2013</b>		
First Quarter (through February 20, 2013)	\$ 30.85	\$ 23.31

*Dividend Policy*

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

*Sales of Unregistered Securities and Issuer Repurchases of Securities*

Other than sales disclosed in previous quarterly reports on Form 10-Q or current reports on Form 8-K, we did not make any unregistered sales of shares of our common stock in 2012. In addition, we did not repurchase any of our equity securities during the fourth quarter of 2012.



**Table of Contents*****Stock Performance Graph***

We show below the cumulative total return to our stockholders during the period from December 31, 2007 through December 31, 2012 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, 2007 in our common stock and each of the indexes listed above, including reinvestment of dividends, if any.

	Years ended					
	12/07	12/08	12/09	12/10	12/11	12/12
<b>Seattle Genetics, Inc.</b>	<b>100.00</b>	<b>78.42</b>	<b>89.12</b>	<b>131.14</b>	<b>146.62</b>	<b>203.25</b>
<b>NASDAQ Composite</b>	<b>100.00</b>	<b>59.03</b>	<b>82.25</b>	<b>97.32</b>	<b>98.63</b>	<b>110.78</b>
<b>NASDAQ Pharmaceutical</b>	<b>100.00</b>	<b>97.45</b>	<b>104.75</b>	<b>111.47</b>	<b>123.06</b>	<b>164.89</b>
<b>NASDAQ Biotechnology</b>	<b>100.00</b>	<b>93.40</b>	<b>103.19</b>	<b>113.89</b>	<b>129.12</b>	<b>163.33</b>

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.

**Table of Contents****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, 2012, 2011 and 2010 and Consolidated Balance Sheet data as of December 31, 2012 and 2011 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, 2009 and 2008 and Consolidated Balance Sheet data as of December 31, 2010, 2009 and 2008 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.

	2012	2011	Years ended December 31,		2008
			2010	2009	
	(in thousands, except for per share amounts)				
<b>Consolidated Statements of Comprehensive Loss Data:</b>					
Revenues:					
Net product sales	\$ 138,200	\$ 43,241	\$ 0	\$ 0	\$ 0
Collaboration and license agreement revenues	67,547	51,537	107,470	51,965	35,236
Royalty revenues	5,065	0	0	0	0
Total revenues	210,812	94,778	107,470	51,965	35,236
Costs and expenses:					
Cost of sales	11,546	3,115	0	0	0
Cost of royalty revenues	1,923	0	0	0	0
Research and development	170,297	163,396	146,410	119,139	110,944
Selling, general and administrative	84,300	72,659	29,258	17,683	16,078
Loss from operations	(57,254)	(144,392)	(68,198)	(84,857)	(91,786)
Investment and other income (loss), net	3,472	(7,638)	1,933	3,174	6,285
Net loss	\$ (53,782)	\$ (152,030)	\$ (66,265)	\$ (81,683)	\$ (85,501)
Net loss per share - basic and diluted	\$ (0.46)	\$ (1.34)	\$ (0.66)	\$ (0.90)	\$ (1.09)
Shares used in computation of net loss per share - basic and diluted	117,851	113,098	101,055	90,988	78,724

	2012	2011	December 31,		2008
			2010	2009	
	(in thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and investment securities	\$ 364,258	\$ 330,696	\$ 294,840	\$ 287,730	\$ 160,708
Working capital	340,283	308,441	249,295	244,081	70,496
Total assets	471,422	425,216	329,936	388,333	187,717
Stockholders' equity	226,148	218,849	161,518	206,200	79,018



**Table of Contents****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 document 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 monoclonal antibody-based therapies for cancer. Our lead product ADCETRIS<sup>®</sup>, or brentuximab vedotin, received accelerated approval in the United States in 2011 and approval with conditions in Canada in 2013 for patients with relapsed Hodgkin lymphoma or relapsed systemic anaplastic large cell lymphoma, or sALCL. ADCETRIS 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. We 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, and in other CD30-positive malignancies. In addition, we have four clinical-stage ADC programs, which consist of SGN-75, ASG-5ME, ASG-22ME and SGN-CD19A, as well as several preclinical product candidates, including SGN-CD33A and SGN-LIV1A.

We are collaborating with Millennium: The Takeda Oncology Company, or Millennium, to develop and commercialize ADCETRIS on a global basis. Under this collaboration, Seattle Genetics has retained commercial rights for ADCETRIS in the United States and its territories and in Canada, and Millennium has commercial rights in the rest of the world. ADCETRIS was granted conditional approval in the European Union in 2012 for patients with relapsed Hodgkin lymphoma or relapsed sALCL.

We also have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including AbbVie Biotechnology Ltd. (formerly part of Abbott Laboratories), or AbbVie; Bayer Pharmaceuticals Corporation, or Bayer; Celldex Therapeutics, Inc., or Celldex; Daiichi Sankyo Co., Ltd., or Daiichi Sankyo; Genentech, Inc., a member of the Roche Group, or Genentech; GlaxoSmithKline LLC, or GSK; Millennium, Pfizer, Inc., or Pfizer, and PSMA Development Company LLC, a subsidiary of Progenics Pharmaceuticals Inc., or Progenics; 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.

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

We began commercializing ADCETRIS in August 2011, and the commercial potential of ADCETRIS and our ability to realize that potential remains uncertain. Our success in commercializing ADCETRIS will require, among other things, effective sales, marketing, manufacturing, distribution, information systems and pricing strategies, as well as compliance with applicable laws and regulations. The FDA granted accelerated approval of

**Table of Contents**

ADCETRIS which means that we are, among other things, obligated to conduct specific post-approval clinical studies to confirm patient benefit as a condition of that approval. In addition, we are exploring the use of ADCETRIS in earlier lines of therapy in patients with Hodgkin lymphoma and MTCL, including sALCL, and in other CD30-positive malignancies. In order to do this, we are required to conduct additional extensive clinical studies and, if these studies are successful, we intend to seek additional regulatory approvals. We and Millennium are conducting three phase III clinical trials of ADCETRIS, one in relapsed cutaneous T-cell lymphoma, or CTCL, the ALCANZA trial, one in front-line advanced classical Hodgkin lymphoma, the ECHELON-1 trial, and one in front-line MTCL, including sALCL, the ECHELON-2 trial. The FDA has agreed to special protocol assessment, or SPA, agreements for all three of these phase III clinical 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 submission to the FDA if the trial achieves its primary endpoints. The primary end point in the front-line Hodgkin lymphoma and front-line MTCL trials is modified progression free survival per independent review facility assessment. The primary endpoint in the CTCL trial is overall response rate, lasting at least 4 months, with ADCETRIS in patients with CD30-positive mycosis fungoides or primary cutaneous anaplastic large cell lymphoma compared to that achieved with therapy in the control arm. We and Millennium are also conducting a phase III clinical trial in post-transplant Hodgkin lymphoma patients, the AETHERA trial, to evaluate whether ADCETRIS can extend progression free survival versus placebo in patients following autologous stem cell transplant, or ASCT. We have an agreement with Ventana Medical Systems, Inc., a member of the Roche Group, or Ventana, under which Ventana will 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. A molecular companion diagnostic is not required for the current approved indications for ADCETRIS; however, we expect that a molecular companion diagnostic may be required by regulatory authorities to support regulatory approval of ADCETRIS in other CD30-positive malignancies. All of these activities will require substantial amounts of capital and may not ultimately prove successful. Our other 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. 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 other product candidates. Our commitment of resources to the continuing development, regulatory and commercialization activities for ADCETRIS and the research, continued development and manufacturing of our other 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 have begun to recognize revenue from ADCETRIS product sales in the United States and Canada, we have only limited experience commercializing ADCETRIS and our future ADCETRIS product sales will be difficult to accurately predict from period to period. While we expect that our ADCETRIS net sales will be in the range of \$130 million to \$140 million in 2013, our product sales revenue may vary significantly from period to period and may be affected by a variety of factors, including the 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 health care cost containment and other austerity measures in the U.S. and worldwide. In addition, we believe that the number of patients in ADCETRIS approved indications is relatively small and that our ongoing sales will be primarily attributable to the incidence of new patients who have recently failed earlier lines of cancer therapy and become eligible for ADCETRIS within the current approved indications. For these and other reasons, we expect that future ADCETRIS sales growth will be primarily dependent on our ability to expand the labeled indications of use. This will 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

## **Table of Contents**

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 and clinical milestones by our collaborators under our existing collaboration and license agreements, including, in particular, our ADCETRIS collaboration with Millennium, 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*

Our revenues are generated from a combination of ADCETRIS sales, which began during August 2011, collaboration and license agreements and royalties from the sale of ADCETRIS outside the United States and Canada. Collaboration revenues reflect the earned amount of upfront technology access fees, milestone payments, reimbursement for support and materials supplied to our collaborators, and development cost-sharing under our product collaborations. Under our ADCETRIS collaboration with Millennium, we are entitled to receive royalties based on a percentage of Millennium's net sales in its territories. Total revenues increased to \$210.8 million in 2012, compared to \$94.8 million in 2011. This increase primarily reflects our product sales of ADCETRIS during the 2012 period. Our collaboration and license agreement revenue also increased primarily as a result of our ADCETRIS collaboration with Millennium. Total costs and expenses increased 12% to \$268.1 million in 2012, compared to \$239.2 million in 2011. The most significant increase was related to our commercial organization which was established during 2011, but was in place for the entire 2012 period. As of December 31, 2012, we had \$364.3 million in cash, cash equivalents and short-term investments, and \$226.1 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 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. Healthcare providers order ADCETRIS through these distributors. We receive orders from distributors and ship product directly to the customer. We record product sales when title and risk of loss pass. This generally occurs upon delivery to the customer. Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, product returns and other deductions. Reserves are established for these deductions and actual amounts incurred are offset against applicable reserves. We reflect these reserves 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 reserves 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:** We have entered into a Medicaid Drug Rebate Agreement, or MDRA, 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 estimated Medicaid rebates based on a third party study of the payer mix for

## Table of Contents

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 interim Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on their purchases of ADCETRIS. We have entered into a Pharmaceutical Pricing Agreement, or PPA, with the Secretary of Health and Human Services which enables certain private 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 discounted price for healthcare providers entitled to FSS discounts or PHS pricing. 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 fee for distribution services that they perform on our behalf. We are able to calculate the amount due for each distributor based on the amount of sales to each distributor and the negotiated fee. We allow for the return of product that is within 30 days of its expiration date or that is damaged. We estimated product returns based on historical industry information of return rates for other specialty pharmaceutical products. In addition, we considered 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 reimbursement and financial assistance to qualifying patients in the U.S. and its territories who meet various financial need criteria and are underinsured or cannot cover the cost of commercial coinsurance amounts through SeaGen Secure. Estimated contributions for commercial coinsurance are deducted from gross sales. These contributions 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 use a time-based proportional performance model to recognize revenue over our performance obligation period and adopted ASU 2009-13 entitled Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force in 2011. Under this standard, payments received by us are recognized as revenue over the performance period of the collaboration. 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 deliverables under our collaboration and license agreements have not qualified as separate units of accounting. Accordingly, all amounts received or due, including any upfront payments, maintenance fees, milestone payments and reimbursement payments, are recognized as revenue over the performance obligation periods of each agreement, which range from two to fourteen years for our current agreements. Following the completion of the performance obligation period, such amounts received or due will be recognized as revenue when collectibility is reasonably assured. 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.

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 the suitability of a product candidate or initiation of preclinical studies. Our collaborators must undertake significant preclinical research and studies to make a determination 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 I clinical trial. Generally, phase I clinical trials may take one to two years to complete.

## **Table of Contents**

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

Initiation or completion of a phase III clinical trial. Generally, phase III 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 or Japan. Generally it may take up to three years after a marketing application is submitted to obtain full 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 or Europe.

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.

Our proprietary ADC technology is the basis of our ADC collaborations that we have entered into in the ordinary course of our business with a number of biotechnology and pharmaceutical companies. Under our 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 time periods ranging from two to fourteen years. Our ADC collaborators are solely responsible for the development of their product candidates and the achievement of a milestone in any of the categories identified above is based solely on the collaborators' efforts. In the case of our other collaboration and license agreements, such as our ADCETRIS collaboration with Millennium or our co-development agreement with Agensys, our proprietary products or product candidates may be covered by the collaboration or we may be involved in certain development activities; however, the achievement of milestone events under these agreements is based on activities undertaken by the collaborator.

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 we may receive from our ADC collaborators 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 Millennium, the attainment of a milestone is based on the collaborator's activities and is generally outside our direction and control.

We generally invoice our collaborators on a monthly or quarterly basis, or upon completion of the effort or achievement of a milestone, based on the terms of each agreement. Amounts due, but not billed to a collaborator, if any, are included in accounts receivable in our consolidated balance sheets. 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.

## **Table of Contents**

### *Royalty revenues and cost of royalty revenues*

Royalty revenues reflect amounts earned under the ADCETRIS collaboration with Millennium. Royalties are based on a percentage of Millennium's net sales in its territory at rates that range from the mid-teens to the mid-twenties based on sales volume. Millennium bears a portion of third party royalty costs owed on sales of ADCETRIS in its territory. 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 the sale of ADCETRIS in Millennium's territory. Royalty amounts on sales of ADCETRIS in Millennium's territory are recognized in the quarter in which Millennium reports its sales activity to us, which is the quarter following the related sales.

**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 (loss), 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.

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. Research and development activities are expensed as incurred. 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. Clinical trial expenses are a significant component of research and development expenses, and include investigator fees, site costs, clinical research organization costs, and costs to other third party vendors for central laboratory testing and data management. Costs associated with activities performed under research and development co-development collaborations are reflected in research and development expense. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are capitalized and recognized as expense as the related goods are delivered or the related services are performed.

**Share-based Compensation.** We expense the fair value of share-based payment transactions in our consolidated financial statements. We use the Black-Scholes option pricing model to determine the fair value of

## **Table of Contents**

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.

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% on either the two-year or three-year anniversary of the grant date. 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. We began issuing RSUs in 2011 and in 2012, we increased the relative weighting of RSUs as a component of total stock awards.

**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. Production costs for our other product candidates continue to be charged to research and development expense.

We value our inventories at the lower of cost or market value. Cost is determined on a specific identification basis. Inventory includes the cost of materials, third-party contract manufacturing and overhead associated with the production of ADCETRIS. We would write-down inventory cost to net realizable value if we were to determine that we had any excess, obsolete or unsalable inventory.

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 and inventories. 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, 2012, 2011 and 2010**

#### **Net product sales**

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

We began selling ADCETRIS following its accelerated approval by the FDA in August 2011. Our net product sales increased to \$138.2 million in 2012 compared to \$43.2 million in 2011. Our 2012 net sales include product sold in Canada through a Special Access Program, or SAP, that allows physicians to request access on a limited basis to drugs that are not yet available for sale in Canada.

**Table of Contents**

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, 2012			December 31, 2011		
	Rebates & chargebacks	Distribution fees, product returns and other	Total	Rebates & chargebacks	Distribution fees, product returns and other	Total
Balance, beginning of year	\$ 895	\$ 1,036	\$ 1,931	\$	\$	\$
Provision related to current year sales	14,999	3,790	18,789	900	1,243	2,143
Adjustments for prior period sales	(412)	(14)	(426)			
Payments/credits for current year sales	(11,195)	(2,502)	(13,697)	(5)	(207)	(212)
Payments/credits for prior year sales	(156)	(709)	(865)			
Balance, end of year	\$ 4,131	\$ 1,601	\$ 5,732	\$ 895	\$ 1,036	\$ 1,931

Deductions from gross sales increased in 2012 compared to 2011 as a result of the timing of government discount programs becoming effective. We expect fluctuations in future gross-to-net discounts primarily as a result of the amount of government mandated discounts and rebates.

**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. The increase in collaboration revenues from 2011 to 2012 primarily reflects amounts earned under our collaborations with Millennium and AbbVie. Collaboration and license agreement revenues during 2010 from Genentech were primarily comprised of revenues earned under our dacetuzumab collaboration with Genentech that ended in June 2010. We continue to have an ADC collaboration with Genentech. Collaboration and license agreement revenues are summarized by collaborator as follows:

Collaboration and license agreement revenues by collaborator (\$ in thousands)	Annual percentage change				
	2012	2011	2010	2012/2011	2011/2010
Millennium	\$ 36,021	\$ 27,914	\$ 16,040	29%	74%
AbbVie	9,839	3,721	219	164%	1,599%
Genentech	6,174	5,302	82,819	16%	(94%)
Agensys	4,834	3,957	2,256	22%	75%
Other	10,679	10,643	6,136	0%	73%
Total	\$ 67,547	\$ 51,537	\$ 107,470	31%	(52%)

Our revenues are impacted by the term and duration of our collaboration and co-development agreements and by progress-dependent milestones, annual maintenance fees and reimbursement of materials and support services as our collaborators advance their ADC product candidates through the development process. Revenues may vary substantially from year to year and quarter to quarter depending on the progress made by

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

our collaborators with their product candidates, the level of support we provide to our collaborators, specifically to Millennium 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 to increase in 2013 compared to 2012, primarily as a result of our ADCETRIS collaboration with Millennium and our expanded relationship with AbbVie. 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.

## **Table of Contents**

### ***Product Collaboration Agreements***

#### ***Millennium ADCETRIS and ADC Collaborations***

Revenues earned under our ADCETRIS and ADC collaborations with Millennium represented 53% of our collaboration and license agreement revenues in 2012, 54% in 2011 and 15% in 2010. Revenues from Millennium increased in 2012 and 2011 from prior year amounts primarily as a result of amounts earned under the ADCETRIS collaboration, particularly as a result of the earned portion of net development cost reimbursements and milestone payments associated with the European Union's conditional marketing authorization of ADCETRIS in 2012.

Under the ADCETRIS collaboration, we are entitled to receive progress- and sales-dependent milestone payments based on Millennium's achievement of certain events related to ADCETRIS for which Millennium is responsible and development funding equal to 50% of joint development costs. We are also entitled to tiered royalties at percentages starting in the mid-teens and escalating to the mid-twenties based on net sales of ADCETRIS within Millennium's licensed territories. Millennium also bears a portion of third party royalty costs owed on sales of ADCETRIS in its territory. Total future potential milestone payments to us under the ADCETRIS collaboration could total approximately \$205 million. Of the remaining amount, up to approximately \$7 million relates to the achievement of development milestones, up to approximately \$133 million relates to the achievement of regulatory milestones and up to approximately \$65 million relates to the achievement of commercial milestones. In 2011, we received a \$5 million milestone payment as a result of the acceptance of Millennium's Marketing Authorization Application, or MAA, by the European Medicines Agency, or EMA. In October 2012, we received two milestone payments totaling \$25 million resulting from the European Union's conditional marketing authorization of ADCETRIS.

We recognize as collaboration revenue the \$60 million upfront collaboration payment, milestone payments and net development cost reimbursement payments to us over the ten-year development period of the collaboration. We receive reimbursement funding from Millennium equal to one-half of the cost of joint development activities that are performed by us under the collaboration. To the extent that Millennium performs development activities under the collaboration, our development cost reimbursement payments from Millennium are reduced by half of those costs.

#### ***Genentech***

We have an ADC collaboration with Genentech and, in 2010, we also had a product collaboration with Genentech. The decrease in Genentech collaboration revenues after 2010 resulted from the termination of the product collaboration. Amounts earned under our collaborations with Genentech accounted for 9%, 10% and 77% of our collaboration and license agreement revenues for the years ended December 31, 2012, 2011 and 2010, respectively. The 2012 revenues increased from 2011 as a result of the earned portion of milestones received in 2012.

#### ***Collaboration and Co-Development Agreement with Agensys***

We have entered into an agreement with Agensys to jointly research, develop and commercialize ADCs for cancer. Under this collaboration and co-development agreement, Agensys is conducting preclinical studies aimed at identifying ADC product candidates for multiple designated antigens. We are currently co-developing ASG-5ME and ASG-22ME, and we have the right to exercise a co-development option for one additional ADC product candidate upon Agensys' submission of an investigational new drug application, or IND, to the FDA. Agensys has the right to develop and commercialize the other ADC product candidates on its own, subject to paying us fees, milestones, royalties and support



## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

fees for research and development services and material provided under the agreement. Either party may opt out of co-development and profit-sharing in return for receiving milestones and royalties from the continuing party. Amounts received for product candidates being developed solely by Agensys will be recognized as revenue over the performance obligation period of the collaboration agreement using a time-based approach. Revenues attributable to the Agensys agreement increased in 2012 and 2011 from prior year amounts due to payments made to exercise additional exclusive licenses for ADC product candidates.

---

## **Table of Contents**

### ***Other ADC Collaboration Agreements***

We have other active ADC collaborations with a number of companies to allow them to use our proprietary ADC technology. 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 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 over the performance obligation period of the agreements during which we provide limited support to the collaborator. As of December 31, 2012, our ADC collaborations had generated over \$200 million, primarily in the form of upfront payments. Total milestone payments to us under our current ADC collaborations could approximate up to \$3.8 billion if all potential product candidates achieved all of the milestone events under all of our current ADC collaborations. Of this amount, approximately \$0.8 billion relates to the achievement of development milestones, approximately \$1.7 billion relates to the achievement of regulatory milestones and approximately \$1.3 billion relates to the achievement of commercial milestones. 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. Since we do not 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 by our ADC collaborators. In addition, our current ADC 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 an ADC collaborator's business strategy and financial difficulties or other factors could result in an ADC collaborator abandoning or delaying development of its ADC product candidates. As such, the milestone payments associated with our ADC 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 provided for under our ADC collaborations and it is possible that we may never receive any significant milestone payments under our ADC collaborations.

AbbVie revenues for 2012 reflect the earned portion of a \$25 million upfront payment related to an ADC collaboration entered into in October 2012, and an \$8 million upfront payment, milestone payments, and reimbursable support we provided to AbbVie under an earlier ADC collaboration agreement that we entered into in March 2011.

### **Royalty Revenues and Cost of Royalty Revenues**

Royalty revenues recognized in 2012 relate to ADCETRIS sales by Millennium under its international named patient program. Cost of royalty revenues reflects amounts owed to our third party licensors related to Millennium's sale of ADCETRIS in its territory. In October 2012, Millennium received conditional marketing authorization from the European Commission for ADCETRIS in two indications. Millennium began commercial launch of ADCETRIS in the European Union in the fourth quarter of 2012. We expect that royalty revenues and cost of royalty revenues will increase in 2013 as a result of this European Commission approval and commercial sales of ADCETRIS by Millennium.

### **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 by the FDA in August 2011. 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 is expected to be available for us to use commercially. We expect that our cost of sales as a percentage of sales will increase in future periods as product manufactured prior



**Table of Contents**

to FDA approval, and therefore fully expensed, is consumed. This cost benefit will vary based on when the components of the specific drug lots sold were produced and is expected to continue to some extent for at least the next twelve months; however, 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 either 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 costs of sales for sales of ADCETRIS will increase into the low to mid teens.

**Research and development**

Our research and development expenses are summarized as follows:

Research and development (\$ in thousands)	Annual percentage change				
	2012	2011	2010	2012/2011	2011/2010
Research	\$ 16,172	\$ 19,362	\$ 19,036	(16%)	2%
Development and contract manufacturing	56,888	63,631	60,479	(11%)	5%
Clinical	85,227	70,583	58,665	21%	20%
Share-based compensation expense	12,010	9,820	8,230	22%	19%
<b>Total research and development expenses</b>	<b>\$ 170,297</b>	<b>\$ 163,396</b>	<b>\$ 146,410</b>	<b>4%</b>	<b>12%</b>

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 decrease in research expenses during 2012 was due primarily to the timing of technology access fees.

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 for use in research and our clinical trials. Development and contract manufacturing expenses also include quality control and assurance activities, and storage and shipment services of our product candidates, including ADCETRIS prior to its approval by the FDA in August 2011. The 2012 decrease in development and contract manufacturing expenses resulted primarily from lower ADCETRIS manufacturing costs which were expensed to research and development expense prior to FDA approval in August 2011 and capitalized as inventory thereafter. The 2011 increase was primarily due to activity related to our SGN-CD19A product candidate as well as higher compensation costs related to an increase in staffing levels.

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 IND-enabling pharmacology and toxicology studies. The 2012 increase in clinical expenses reflects costs for pre-clinical toxicity studies related to our SGN-CD33A and SGN-LIV1A product candidates as well as costs to develop a companion diagnostic test for identifying CD-30-positive malignancies that might respond to treatment with ADCETRIS. Clinical expenses in 2011 increased as we expanded the scope of clinical activities for our ADCETRIS program. In addition, compensation costs increased in both 2012 and 2011 as a result of increased staffing levels.

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

Share-based compensation expense reflects the non-cash charge associated with stock options, restricted stock units and our employee stock purchase plan. The fair value of all employee share-based payments is charged to expense over the vesting period of the related arrangement. The increases in share-based compensation expense for 2012 and 2011 were primarily due to a higher average value per share for our more recent equity grants primarily attributable to an increase in our stock price.

**Table of Contents**

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 milestone payments for in-licensed technology for each of our product candidates. The table also presents other costs and overhead consisting of personnel, facilities and other indirect costs not directly charged to development programs:

Product candidates (\$ in thousands)	2012	2011	2010	Annual percentage change		(5 years) January 1, 2008 to December 31, 2012
				2012/2011	2011/2010	
ADCETRIS (brentuximab vedotin)	\$ 41,392	\$ 52,640	\$ 54,079	(21%)	(3%)	\$ 196,184
SGN-CD33A	12,200	496	0	2,360%	N/A	12,696
ASG-22ME	6,016	6,439	0	(7%)	N/A	12,455
SGN-LIV1A	6,012	41	0	14,563%	N/A	6,053
SGN-CD19A	3,739	9,747	1,276	(62%)	664%	15,019
ASG-5ME	884	3,118	2,968	(72%)	5%	11,498
SGN-75	844	2,409	4,339	(65%)	(44%)	12,975
Total third-party costs	71,087	74,890	62,662	(5%)	20%	266,880
Other costs and overhead	87,200	78,686	75,518	11%	4%	399,519
Share-based compensation expense	12,010	9,820	8,230	22%	19%	43,787
Total research and development	\$ 170,297	\$ 163,396	\$ 146,410	4%	12%	\$ 710,186

Third party costs for ADCETRIS decreased in 2012 from 2011, primarily as a result of manufacturing costs which were expensed to research and development for part of the 2011 period and capitalized as inventory thereafter. We began capitalizing ADCETRIS production costs as inventory following accelerated approval of ADCETRIS by the FDA in August 2011. However, ADCETRIS inventory that is deployed into clinical, research or development use is charged to research and development expense when it is no longer available for commercial use. Third party costs for ADCETRIS decreased in 2011 from 2010, primarily due to lower technology access fees partially offset by higher clinical trials costs.

Third party costs for SGN-CD33A and SGN-LIV1A increased significantly in 2012 from 2011 as we initiated contract manufacturing campaigns in 2012 in anticipation of planned IND submissions to the FDA in 2013 in preparation for potential clinical trials.

In June 2011, we exercised an option under our agreement with Agensys to co-develop ASG-22ME. In addition to the payment of an option fee, we now co-fund fifty percent of the development costs of this program. Costs in 2011 also included an opt-in fee.

Third party costs for SGN-CD19A decreased in 2012 from 2011 primarily as a result of the timing of contract manufacturing and other activities in preparation for an IND that was submitted to the FDA earlier in 2012 and preparation for clinical trials that began in 2013. Third party costs for SGN-CD19A increased in 2011 from 2010 primarily as a result of higher IND-enabling activities incurred in 2011 in preparation for our

clinical trials.

## **Table of Contents**

Third party costs for ASG-5ME decreased in 2012 from 2011 primarily as a result of higher manufacturing and clinical trial costs in 2011. Third party costs for ASG-5ME increased in 2011 from 2010 primarily as a result of the costs of two phase I clinical trials initiated during 2010.

Third party costs for SGN-75 decreased in 2012 compared to 2011 as a result of higher manufacturing and clinical trial costs in 2011. Third party costs for SGN-75 decreased by 44% in 2011 compared to 2010 as a result of lower manufacturing costs.

Other costs and overhead include costs associated with personnel and facilities. These costs increased in 2012 and in 2011, primarily reflecting an increase in staffing levels in our development and clinical groups from the comparable prior year periods.

Our expenditures on 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 upon the type, complexity, novelty and intended use of a product candidate. 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 2013 will increase compared to 2012 due to increased clinical trial expenses for ADCETRIS related to additional studies to evaluate other potential uses of ADCETRIS, some of which are post-approval commitment trials, and as a result of amounts incurred to continue the development of our ADC product candidates. Certain ADCETRIS development activities, including some clinical studies, will be conducted by Millennium, the costs of which will not be 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

**Table of Contents**

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 indications or of any of our product candidates.

**Selling, general and administrative**

Selling, general and administrative (\$ in thousands)	2012	2011	2010	Annual percentage change	
				2012/2011	2011/2010
Selling, general and administrative, excluding share-based compensation expense	\$ 70,970	\$ 62,495	\$ 23,158	14%	170%
Share-based compensation expense	13,330	10,164	6,100	31%	67%
<b>Total selling, general and administrative expenses</b>	<b>\$ 84,300</b>	<b>\$ 72,659</b>	<b>\$ 29,258</b>	<b>16%</b>	<b>148%</b>

The increases in selling, general and administrative expenses, excluding share-based compensation expense reflects the costs incurred by our commercial organization which was established during 2011 and was in place for the entire 2012 period. Share-based compensation expense reflects the non-cash charge associated with stock options, restricted stock units and our employee stock purchase plan. The fair value of all employee share-based payments is charged to expense over the vesting period of the related share-based payment. The increases in share-based compensation expense included in selling, general and administrative expenses were attributable to a higher weighted-average grant date fair value of our more recent share-based awards due to an increase in our stock price during the periods. The increase in 2011 also reflects a larger number of optioned shares subject to expense recognition as a result of our increased staffing level. We anticipate that selling, general and administrative expenses will increase in 2013 as we continue our commercial activities in support of the commercialization of ADCETRIS.

**Investment and other income (loss), net**

Investment and other income (loss), net (\$ in thousands)	2012	2011	2010
Total	\$ 3,472	\$ (7,638)	\$ 1,933

In 2012, investment and other income (loss), net totaled \$3.5 million which reflects a recovery from a former investment advisor in settlement of claims against the advisor concerning our previous holdings in auction rate securities. The net investment loss in 2011 reflects an \$8.7 million realized loss related to an other-than-temporary impairment in the value of our auction rate securities.

**Liquidity and capital resources**

Selected balance sheet and cashflow data (\$ in thousands)	2012	December 31,	
		2011	2010
Cash, cash equivalents and investments	\$ 364,258	\$ 330,696	\$ 294,840
Working capital	340,283	308,441	249,295

Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

Stockholders equity	226,148	218,849	161,518
	<b>Years ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
Cash provided by (used in):			
Operating activities	\$ 11,481	\$ (124,031)	\$ 6,808
Investing activities	(80,176)	2,554	(11,544)
Financing activities	35,724	187,984	7,377

## **Table of Contents**

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, more recently, 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 sources have historically allowed us to maintain adequate levels of cash and investments.

The increase in cash, cash equivalents and short-term investments in 2012 was primarily due to collections from commercial sales of ADCETRIS and amounts generated from product collaborations and ADC licensing activities. In 2011, the increase was due primarily to proceeds from the sale of common stock and amounts generated from product collaborations and ADC licensing activities.

The reduction of cash used in operating activities in 2012 as compared to 2011 reflects a reduction in our net loss, cash collected from sales of ADCETRIS and amounts received from our product and ADC collaborations. We generated cash from our operating activities in 2010 primarily due to an upfront payment received pursuant to our ADCETRIS product collaboration. Financing activities reflect proceeds from the exercise of stock options and the employee stock purchase plan and, in 2011, proceeds from an underwritten public offering of common stock. Investing activities primarily reflect the investment of cash and sales and maturities of those investments. We have structured our investment portfolio to provide working capital as needed to fund our operations. Our cash, cash equivalents and investments are held in a variety of non-interest bearing bank accounts and interest-bearing instruments subject to investment guidelines allowing for holdings in U.S. government and agency securities, corporate securities, taxable municipal bonds, commercial paper and money market accounts.

Our investment portfolio is structured to provide for investment maturities and access to cash to fund our anticipated working capital needs. However, if our liquidity needs should be accelerated for any reason in the near term, or investments do not pay at maturity, we may be required to sell investment securities in our portfolio prior to their scheduled maturities, which may result in a loss. As of December 31, 2012, we had \$364.3 million held in cash reserves or debt securities scheduled to mature within the next twelve months.

At our currently planned spending rate 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 the use of ADCETRIS or to advance our other ADC pipeline programs. Further, in the event of a termination of the ADCETRIS collaboration agreement with Millennium, we would not receive development cost sharing payments, nor would we receive milestone payments or royalties for the development or sale of ADCETRIS in Millennium's territories. Any of these factors could lead to a need for us to raise additional capital.

We are required to conduct additional confirmatory phase III post-approval studies of ADCETRIS as part of our regulatory approvals. These are large studies that will be 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 may have material adverse consequences to us, including the loss of marketing approval for ADCETRIS. These required post-approval studies will also 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



**Table of Contents**

activities, including the post-approval studies we must conduct 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.

We anticipate that our ADCETRIS net sales will be in the range of \$130 million to \$140 million in 2013. We anticipate that our revenues from collaboration and license agreements will be in the range of \$65 million to \$75 million in 2013 and will be generated from fees, milestones and reimbursements earned through our ADCETRIS and ADC collaborations. Research and development expenses are expected to be in the range of \$210 million to \$230 million in 2013. Selling, general and administration expenses are expected to be in the range of \$85 million to \$95 million in 2013. Operating expenses will be directed primarily towards commercialization and clinical trials of ADCETRIS, development and clinical activities for SGN-75, ASG-5ME, ASG-22ME and SGN-CD19A, and IND-enabling activities for SGN-CD33A and SGN-LIV1A. Cost of sales is expected to be approximately \$15 million in 2013, representing a range of 10 percent to 12 percent of anticipated net sales. Non-cash expenses are expected to be approximately \$40 million in 2013, primarily attributable to share-based compensation expense. These estimates are forward-looking information that are subject to a number of risks and uncertainties, including the risks and uncertainties described in this Annual Report on Form 10-K under the heading Item 1A Risk Factors, and represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K. Accordingly, these estimates are necessarily subject to change.

**Commitments**

The following table reflects our future minimum contractual commitments as of December 31, 2012 (in thousands):

	Total	2013	2014	2015	2016	2017	Thereafter
Operating leases	\$ 24,040	\$ 4,071	\$ 4,208	\$ 4,348	\$ 4,495	\$ 4,639	\$ 2,279
Tenant improvements	3,412	3,412	0	0	0	0	0
Manufacturing, license & collaboration agreements	134,912	36,983	16,462	12,629	12,358	1,677	54,803
Total	\$ 162,364	\$ 44,466	\$ 20,670	\$ 16,977	\$ 16,853	\$ 6,316	\$ 57,082

We have entered into leases for our office and laboratory facilities expiring in 2018 that contain rate escalations and options for us to extend the leases. One of these leases includes an early termination option. Operating lease obligations in the table above do not assume the exercise by us of any termination or extension options.

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 a royalty 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 not estimable. The above table also excludes up to approximately \$10.0 million in potential future milestone payments to third parties under license and collaboration agreements for ADCETRIS and our other later-stage development programs, which generally become due and payable only upon the achievement of certain developmental, clinical, regulatory and/or



**Table of Contents**

commercial milestones. Milestone payments under these agreements through December 31, 2012 have totaled \$11.7 million. These contingent payments have not been included in the above table and will not be included until the event triggering such payment or obligation has occurred.

***Recent accounting pronouncements***

In July 2012, the Financial Accounting Standards Board completed an accounting standards update entitled ASU 2012-02, Intangibles - Goodwill and Other that revises the requirements around how entities test indefinite-lived intangible assets, other than goodwill, for impairment. The guidance will allow entities to first assess qualitative factors to determine whether it is necessary to perform a quantitative impairment test. If entities determine, on the basis of qualitative factors, that the fair value of the indefinite-lived intangible asset is more likely than not greater than the carrying amount, a quantitative calculation would not be needed. We will adopt this standard in the first quarter of 2013 and do not expect the adoption of this standard to have an impact on our consolidated financial statements.

**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,	
	2012	2011
Short-term investments	\$ 309,595	\$ 243,062

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, 2012. 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, 2012.

***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. We have conducted some transactions in foreign currencies during the year ended December 31, 2012, 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 and British Pound. 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.





**Table of Contents**

**Item 8. Financial Statements and Supplementary Data**

**Seattle Genetics, Inc.**

**Index to Financial Statements**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	64
<u>Consolidated Balance Sheets</u>	65
<u>Consolidated Statements of Comprehensive Loss</u>	66
<u>Consolidated Statements of Stockholders' Equity</u>	67
<u>Consolidated Statements of Cash Flows</u>	68
<u>Notes to Consolidated Financial Statements</u>	69

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders

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, 2012 and 2011 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 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, 2012, based on criteria established in *Internal Control Integrated Framework* 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, 2013



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

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 54,663	\$ 87,634
Short-term investments	309,595	243,062
Interest receivable	893	641
Accounts receivable, net	33,443	54,955
Inventories	37,747	9,469
Prepaid expenses and other current assets	4,519	3,820
<b>Total current assets</b>	<b>440,860</b>	<b>399,581</b>
Property and equipment, net	24,752	19,652
Other non-current assets	5,810	5,983
<b>Total assets</b>	<b>\$ 471,422</b>	<b>\$ 425,216</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable and accrued liabilities	\$ 56,130	\$ 53,048
Current portion of deferred revenue	44,447	38,092
<b>Total current liabilities</b>	<b>100,577</b>	<b>91,140</b>
Long-term liabilities		
Deferred revenue, less current portion	138,767	110,013
Deferred rent and other long-term liabilities	5,930	5,214
<b>Total long-term liabilities</b>	<b>144,697</b>	<b>115,227</b>
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; 119,710 shares issued and outstanding at December 31, 2012 and 116,023 shares issued and outstanding at December 31, 2011	120	116
Additional paid-in capital	893,773	832,713
Accumulated other comprehensive income	37	20
Accumulated deficit	(667,782)	(614,000)
<b>Total stockholders' equity</b>	<b>226,148</b>	<b>218,849</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 471,422</b>	<b>\$ 425,216</b>

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

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

	Years ended December 31,		
	2012	2011	2010
<b>Revenues</b>			
Net product sales	\$ 138,200	\$ 43,241	\$ 0
Collaboration and license agreement revenues	67,547	51,537	107,470
Royalty revenues	5,065	0	0
<b>Total revenues</b>	<b>210,812</b>	<b>94,778</b>	<b>107,470</b>
<b>Costs and expenses</b>			
Cost of sales	11,546	3,115	0
Cost of royalty revenues	1,923	0	0
Research and development	170,297	163,396	146,410
Selling, general and administrative	84,300	72,659	29,258
<b>Total costs and expenses</b>	<b>268,066</b>	<b>239,170</b>	<b>175,668</b>
Loss from operations	(57,254)	(144,392)	(68,198)
Investment and other income (loss), net	3,472	(7,638)	1,933
Net loss	\$ (53,782)	\$ (152,030)	\$ (66,265)
Net loss per share - basic and diluted	\$ (0.46)	\$ (1.34)	\$ (0.66)
Shares used in computation of net loss per share - basic and diluted	117,851	113,098	101,055
<b>Comprehensive loss:</b>			
Net loss	\$ (53,782)	\$ (152,030)	\$ (66,265)
Other comprehensive gain (loss) unrealized gain (loss) on securities available for sale	17	1,393	(124)
Comprehensive loss	\$ (53,765)	\$ (150,637)	\$ (66,389)

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

**Table of Contents****Seattle Genetics, Inc.****Consolidated Statements of Stockholders Equity****(In thousands)**

	Common stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	paid-in	deficit	other	stockholders
			capital		comprehensive	equity
					income (loss)	
Balances at December 31, 2009	100,554	\$ 101	\$ 603,053	\$ (395,705)	\$ (1,249)	\$ 206,200
Net loss	0	0	0	(66,265)	0	(66,265)
Other comprehensive loss	0	0	0	0	(124)	(124)
Issuance of common stock for employee stock purchase plan	173	0	1,506	0	0	1,506
Stock option exercises	880	1	5,870	0	0	5,871
Share-based compensation	0	0	14,330	0	0	14,330
<b>Balances at December 31, 2010</b>	<b>101,607</b>	<b>102</b>	<b>624,759</b>	<b>(461,970)</b>	<b>(1,373)</b>	<b>161,518</b>
Net loss	0	0	0	(152,030)	0	(152,030)
Other comprehensive income	0	0	0	0	1,393	1,393
Issuance of common stock for employee stock purchase plan	229	0	2,526	0	0	2,526
Stock option exercises	1,670	2	12,325	0	0	12,327
Issuance of common stock	11,500	11	168,042	0	0	168,053
Warrant exercises	1,017	1	5,077	0	0	5,078
Share-based compensation	0	0	19,984	0	0	19,984
<b>Balances at December 31, 2011</b>	<b>116,023</b>	<b>116</b>	<b>832,713</b>	<b>(614,000)</b>	<b>20</b>	<b>218,849</b>
Net loss	0	0	0	(53,782)	0	(53,782)
Other comprehensive income	0	0	0	0	17	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
<b>Balances at December 31, 2012</b>	<b>119,710</b>	<b>\$ 120</b>	<b>\$ 893,773</b>	<b>\$ (667,782)</b>	<b>\$ 37</b>	<b>\$ 226,148</b>

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



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

	<b>Years ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
<b>Operating activities</b>			
Net loss	\$ (53,782)	\$ (152,030)	\$ (66,265)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities			
Share-based compensation expense	25,340	19,984	14,330
Depreciation and amortization	6,159	4,170	3,562
Amortization of premiums, accretion of discounts and gain (loss) on investments	2,574	12,474	3,429
Deferred rent and other long-term liabilities	716	2,247	198
Changes in operating assets and liabilities			
Interest receivable	(252)	141	568
Accounts receivable, net	21,512	(35,676)	60,843
Inventories	(28,278)	(9,469)	0
Prepaid expenses and other current assets	(699)	(1,574)	4,056
Accounts payable and accrued liabilities	3,082	27,265	6,287
Deferred revenue	35,109	8,437	(20,200)
Net cash provided by (used in) operating activities	11,481	(124,031)	6,808
<b>Investing activities</b>			
Purchases of securities available for sale	(505,066)	(479,389)	(453,599)
Proceeds from maturities of securities available for sale	425,151	498,959	443,256
Proceeds from sales of securities available for sale	10,824	0	2,321
Purchases of property and equipment	(10,485)	(11,252)	(3,548)
Investments in other non-current assets	(600)	(5,764)	26
Net cash provided by (used in) investing activities	(80,176)	2,554	(11,544)
<b>Financing activities</b>			
Net proceeds from issuance of common stock	0	168,053	0
Proceeds from exercise of stock options, warrants and employee stock purchase plan	35,724	19,931	7,377
Net cash provided by financing activities	35,724	187,984	7,377
Net increase (decrease) in cash and cash equivalents	(32,971)	66,507	2,641
Cash and cash equivalents at beginning of year	87,634	21,127	18,486
Cash and cash equivalents at end of year	\$ 54,663	\$ 87,634	\$ 21,127

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

**Table of Contents**

**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements**

**1. Nature of business and summary of significant accounting policies**

*Nature of business and 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 Company is a biotechnology company focused on the development and commercialization of monoclonal antibody-based therapies for cancer. The Company operates in one reporting segment: the development and commercialization of pharmaceutical products on its own behalf or in collaboration with others. The Company began to recognize product sales and cost of sales following the accelerated approval of ADCETRIS by the U.S Food and Drug Administration, or FDA, in August 2011.

*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 will 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.

*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.

*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 income 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 (loss), net. The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Amortization of premiums and accretion of discounts are included in investment and other income (loss), net. Interest and dividends earned on all securities are included in investment and other income (loss), 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

**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)**

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 (loss), 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. The Company began capitalizing ADCETRIS®, or brentuximab vedotin, production costs into inventory following its accelerated approval by the FDA in August 2011. 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 as follows:

	<b>Years</b>
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 deferred 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 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, 2012 as there have been no events warranting an impairment analysis.

*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.

---

**Table of Contents**

**Seattle Genetics, Inc.**

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

*Net product sales*

The Company began selling ADCETRIS in August 2011 following its accelerated approval by the U.S. Food and Drug Administration, or FDA, in two indications. The Company sells ADCETRIS through a limited number of pharmaceutical distributors. Healthcare providers order ADCETRIS through these distributors. The Company receives orders from distributors and ships product directly to the customer. The Company records product sales when title and risk of loss pass. This 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. Reserves are established for these deductions and actual amounts incurred are offset against applicable reserves. The Company reflects these reserves 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 reserves 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 to participating states based on covered purchases of ADCETRIS. Medicaid rebates are invoiced to the Company by participating states. The Company estimated 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 an interim Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on their purchases of ADCETRIS. The Company has entered into a Pharmaceutical Pricing Agreement, or PPA, with the Secretary of Health and Human Services, which enables certain private 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 discounted price for entities entitled to FSS discounts and PHS pricing. 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 fee for distribution services that they perform on behalf of the Company. The Company is able to calculate the amount due for each distributor based on the amount of sales to each distributor. The Company allows for the return of product that is within 30 days of its expiration date or that is damaged. The Company estimated product returns based on historical industry information of return rates for other specialty pharmaceutical products. In addition, the Company considered 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 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 need criteria. Estimated contributions for commercial coinsurance 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*

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

The Company uses a time-based proportional performance model to recognize revenue over the Company's performance period and adopted ASU 2009-13 entitled Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force in 2011. Under this standard, payments received by the

**Table of Contents**

**Seattle Genetics, Inc.**

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

Company are recognized as revenue over the performance period of the collaboration. 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 deliverables under the Company's collaboration and license agreements have not qualified as separate units of accounting. Accordingly, all amounts received or due, including any upfront payments, maintenance fees, milestone payments and reimbursement payments, are recognized as revenue over the performance obligation periods of each agreement, which range from two to fourteen years for the Company's current agreements. Following the completion of the performance obligation period, such amounts will be recognized as revenue when collectibility is reasonably assured. 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 period used in each agreement is a reasonable estimate of the performance obligation period of such agreement.

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 I clinical trial. Generally, phase I clinical trials may take one to two years to complete.

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

Initiation or completion of a phase III clinical trial. Generally, phase III 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 or Japan. Generally it may take up to three years after a marketing application is submitted to obtain full approval for marketing and pricing from the applicable regulatory agency.



## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

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 or Europe.

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.

**Table of Contents**

**Seattle Genetics, Inc.**

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

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 of between two and fourteen years. 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 other collaboration and license agreements, such as the Company's ADCETRIS collaboration with Millennium: The Takeda Oncology Company, or Millennium, or its co-development agreement with Agensys, Inc., an affiliate of Astellas Pharma, Inc., or Agensys, the Company's proprietary products or product candidates may be covered by the collaboration or the Company may be involved in certain development activities; however, the achievement of milestone events under these agreements is based on activities undertaken by the collaborator.

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 Millennium, 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 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 reflect amounts earned under the ADCETRIS collaboration with Millennium. Royalties are based on a percentage of Millennium's net sales in its territory at rates that range from the mid-teens to the mid-twenties based on sales volume. Millennium bears a portion of third party royalty costs owed on sales of ADCETRIS in its territory. This amount is included in royalty revenue in our consolidated financial statements. Cost of royalty revenues reflects amounts owed to the Company's third party licensors related to the sale of ADCETRIS in Millennium's territory. These amounts are recognized in the quarter in which Millennium reports its sales activity to the Company, which is the quarter following the related sales.

*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. 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

**Table of Contents**

**Seattle Genetics, Inc.**

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

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 \$13.0 million and \$10.7 million in advertising expense during 2012 and 2011, 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. The fair value of Level 3 investments in 2011 was determined based on a probability-weighted discounted cash flow analysis and other market-based inputs. These investments were sold in the first quarter of 2012 at their approximate carrying values.

*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*

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

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 revenues and greater than 10% of accounts receivable as noted below. In addition, certain of the Company's collaborators have accounted for greater than 10% of total revenues or accounts receivable for certain periods as noted below. Revenues generated outside the United States 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,		
	2012	2011	2010
Distributor A	22%	16%	NA
Distributor B	21%	10%	NA
Distributor C	19%	17%	NA
Collaborator A	19%	29%	15%
Collaborator B	NA	NA	77%

**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)**

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

	Percent of total accounts receivable at December 31,	
	2012	2011
Distributor A	25%	30%
Distributor B	20%	18%
Distributor C	16%	31%
Collaborator A	31%	14%

*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 each component of ADCETRIS and 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*

Other non-current assets include milestone payments due upon the approval of ADCETRIS related to certain in-licensed technology. These amounts are amortized to cost of sales over the estimated life of the related licenses which range from six to ten years. Other non-current assets also include \$0.3 million of investments pledged as security on an operating lease.

*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. 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.

**Table of Contents**

**Seattle Genetics, Inc.**

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

*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, Health Canada in Canada and the European Commission in the European Union and 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 are terminable by the Company's collaborators. 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 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.

*Guarantees*

In the normal course of business, the Company indemnifies 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 since the Company has not had any prior indemnification claims on which to base the calculation. 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 restricted stock units, warrants 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,**



Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

	2012	2011	2010
Warrants to purchase common stock	0	991	1,113
Stock options and restricted stock units	13,483	13,236	11,395
<b>Total</b>	<b>13,483</b>	<b>14,227</b>	<b>12,508</b>

*Recent accounting pronouncements*

In July 2012, the Financial Accounting Standards Board completed an accounting standards update entitled ASU 2012-02, Intangibles – Goodwill and Other that revises the requirements around how entities test indefinite-lived intangible assets, other than goodwill, for impairment. The guidance will allow entities to first assess qualitative factors to determine whether it is necessary to perform a quantitative impairment test. If entities determine, on the basis of qualitative factors, that the fair value of the indefinite-lived intangible asset is more

**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)**

likely than not greater than the carrying amount, a quantitative calculation would not be needed. The Company will adopt this standard in the first quarter of 2013 and does not expect the adoption of this standard to have an impact on its consolidated financial statements.

**2. 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
<b>December 31, 2012</b>				
U.S. Treasury securities	\$ 309,558	\$ 42	\$ (5)	\$ 309,595
<b>Contractual Maturities</b>				
Due in one year or less	\$ 309,558			\$ 309,595
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
<b>December 31, 2011</b>				
U.S. Treasury securities	\$ 227,697	\$ 24	\$ (3)	\$ 227,718
Corporate obligations	9,565	0	(1)	9,564
Auction rate securities	5,780	0	0	5,780
<b>Total</b>	<b>\$ 243,042</b>	<b>\$ 24</b>	<b>\$ (4)</b>	<b>\$ 243,062</b>
<b>Contractual Maturities</b>				
Due in one year or less	\$ 237,262			\$ 237,282
Due in 2017	5,780			5,780
<b>Total</b>	<b>\$ 243,042</b>			<b>\$ 243,062</b>

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
--	---	------------------------

Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

	Fair value	Gross unrealized losses	Fair value	Gross unrealized losses
December 31, 2012				
U.S. Treasury securities	\$ 76,015	\$ (5)	\$ NA	\$ NA
December 31, 2011				
U.S. Treasury securities	\$ 80,234	\$ (3)	\$ NA	\$ NA
Corporate obligations	4,571	(1)	NA	NA
Total	\$ 84,805	\$ (4)	\$ NA	\$ NA

### 3. 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

**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)**

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.

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. Level 2 investments, which include investments that are valued based on quoted prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency, consisted of high-grade corporate obligations at December 31, 2011. Level 3 investments consisted of auction rate securities at December 31, 2011 that were sold in March 2012. The Company did not hold any Level 2 or 3 investments as of December 31, 2012 and did not transfer any investments in or out of Levels 1, 2 and 3 during the years ended December 31, 2012 or 2011.

The following table presents the Company's available-for-sale securities by level within the fair value hierarchy (in thousands):

	Quoted prices in active markets for identical assets (Level 1)	Fair value measurement using:		Total
		Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
As of December 31, 2012				
Cash equivalents U.S. Treasury securities	\$ 10,016	\$ 0	\$ 0	\$ 10,016
Short-term investments U.S. Treasury securities	309,595	0	0	309,595
Total	\$ 319,611	\$ 0	\$ 0	\$ 319,611

Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

	Quoted prices in active markets for identical assets (Level 1)	Fair value measurement using:		Total
		Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
As of December 31, 2011				
Cash equivalents money market funds	\$ 66	\$ 0	\$ 0	\$ 66
Short-term investments:				
U.S. Treasury securities	227,718	0	0	227,718
Corporate obligations	0	9,564	0	9,564
Auction rate securities	0	0	5,780	5,780
<b>Total</b>	<b>\$ 227,784</b>	<b>\$ 9,564</b>	<b>\$ 5,780</b>	<b>\$ 243,128</b>

**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)**

In 2011, the Company recorded an \$8.7 million realized loss related to an other-than-temporary impairment in the value of its auction rate securities. This resulted in a new carrying value of \$5.8 million as of December 31, 2011. The Company sold these securities in 2012 for \$5.8 million.

The following table contains a roll-forward of the fair value of the Company's auction rate securities where fair value was determined using Level 3 inputs (in thousands):

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
Balance, beginning of year	\$ 5,780	\$ 13,031
Unrealized loss included in other comprehensive income (loss)	0	(240)
Losses deemed other than temporary reclassified from other comprehensive income (loss)	0	1,659
Impairment losses included in investment and other income (loss), net	0	(8,670)
Sale of auction rate securities	(5,825)	0
Realized gain on auction rate securities	45	0
Balance, end of year	\$ 0	\$ 5,780

**4. Inventories**

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

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
Raw materials	\$ 32,293	\$ 9,275
Work in process	4,605	173
Finished goods	849	21
Total	\$ 37,747	\$ 9,469

The Company began capitalizing ADCETRIS inventory costs following accelerated approval by the FDA in August 2011. Prior to FDA approval, the Company expensed ADCETRIS production costs as a research and development expense. The Company does not capitalize manufacturing costs for any of its other product candidates. 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.

**5. Property and equipment**

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

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
Leasehold improvements	\$ 25,650	\$ 18,818
Laboratory equipment	16,768	15,377
Computers and office equipment	7,158	5,590
Furniture and fixtures	5,040	4,691
	54,616	44,476
Less: accumulated depreciation and amortization	(29,864)	(24,824)
<b>Total</b>	<b>\$ 24,752</b>	<b>\$ 19,652</b>

**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)**

Depreciation and amortization expenses on property and equipment totaled \$5.4 million, \$3.9 million and \$3.6 million for the years ended December 31, 2012, 2011 and 2010, respectively. Leasehold improvements included \$6.3 million of construction in process at December 31, 2012.

**6. Accounts payable and accrued liabilities**

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

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
Compensation and benefits	\$ 16,228	\$ 16,345
Trade accounts payable	12,864	15,650
Clinical trial and companion diagnostic costs	10,442	9,516
Contract manufacturing	8,371	7,305
Third-party royalties and government rebates	5,000	2,960
Other	3,225	1,272
<b>Total</b>	<b>\$ 56,130</b>	<b>\$ 53,048</b>

**7. 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, 2012 or 2011.

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, 2012, the Company has NOL carryforwards of \$400.9 million expiring from 2018 to 2032 if not utilized, and tax credit carryforwards of \$33.0 million expiring from 2021 to 2032.

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. It is possible that there has been, or in the future will be, a change in ownership, which would limit the amount of NOL available to be used in the future. Any limitation may result in the expiration of the NOL and



tax credit carryforwards before utilization.

**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)**

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

	December 31,	
	2012	2011
Deferred tax assets		
Net operating loss carryforwards	\$ 123,672	\$ 106,269
Deferred revenue	51,128	48,434
Tax credit carryforwards	33,043	31,365
Capitalized research and development	16,311	21,390
Share-based compensation	12,722	10,813
Depreciation and amortization	2,424	2,227
Other	11,274	11,437
<b>Total deferred tax assets</b>	<b>250,574</b>	<b>231,935</b>
Less: valuation allowance	(250,574)	(231,935)
<b>Net deferred tax assets</b>	<b>\$ 0</b>	<b>\$ 0</b>

Increases in the valuation allowance were \$18.6 million in 2012 and \$49.1 million in 2011. Certain amounts in the summary of deferred tax assets as of December 31, 2011 have been updated to conform to the treatment of various items in the Company's tax return, including research and development expenses and related tax credits. These include a decrease in total deferred tax assets and an offsetting reduction in the valuation allowance as of December 31, 2011 by \$12.6 million. There was no change in the Company's net deferred tax assets.

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

	Years ended December 31,		
	2012	2011	2010
Statutory federal income tax rate	(35%)	(35%)	(35%)
Tax credits	(3)	(3)	(6)
State income taxes and other	3	1	3
Valuation allowance	35	37	38
<b>Effective tax rate</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

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 2012 remain subject to future examination for federal income taxes.



**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)****8. 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,		
	2012	2011	2010
Millennium	\$ 36,021	\$ 27,914	\$ 16,040
AbbVie	9,839	3,721	219
Genentech	6,174	5,302	82,819
Agensys	4,834	3,957	2,256
Other	10,679	10,643	6,136
Total	\$ 67,547	\$ 51,537	\$ 107,470

*Product collaboration agreements*

In December 2009, the Company entered into a collaboration agreement with Millennium: The Takeda Oncology Company, or Millennium, to develop and commercialize ADCETRIS. Under this collaboration, Seattle Genetics has retained commercial rights for ADCETRIS in the United States and its territories and in Canada, and Millennium has commercial rights in the rest of the world. Under the collaboration, the Company received an upfront payment of \$60 million and is entitled to receive progress- and sales-dependent milestone payments based on the achievement by Millennium of specific events. As of December 31, 2012, the Company had received \$30 million in milestone payments under the collaboration related to Millennium achieving specific regulatory and approval milestones for ADCETRIS in its territory. The Company and Millennium will each fund 50% of worldwide joint development costs performed under the collaboration. In Japan, Millennium 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 upfront fee and other payments received were deferred and are being recognized as revenue over the performance obligation period of the collaboration agreement, currently estimated as ten years, using a time-based approach. The Company is also entitled to receive royalties based on a percentage of Millennium's net sales of ADCETRIS in its territory ranging from the mid-teens to the mid-twenties based on sales volume. Millennium also bears a portion of third party royalty costs owed on sales of ADCETRIS in its territory. Either party may terminate the collaboration agreement if the other party materially breaches the agreement and such breach remains uncured. Millennium 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.

In January 2007, the Company entered into a collaboration agreement with Genentech, Inc., a member of the Roche Group, or Genentech, for the development and commercialization of dacetuzumab. Genentech ended the collaboration effective June 2010. All deferred revenue, representing payments received in advance of the culmination of the earnings process was fully recognized as revenue using a time-based

method over the remaining term of the agreement following Genentech's election to end the collaboration. During the first half of 2010, the Company recorded \$70 million in collaboration revenue related to this collaboration. All product rights to dacetuzumab were returned to the Company upon completion of the collaboration.

**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)***Collaboration and co-development agreement with Agensys*

The Company is party to an agreement with Agensys, Inc., an affiliate of Astellas Pharma Inc., or Agensys, to jointly research, develop and commercialize ADCs for cancer. The collaboration encompasses combinations of the Company's ADC technology with antibodies developed by Agensys to proprietary cancer targets. Under the co-development provisions of the collaboration agreement, the companies co-fund development and commercialization costs and share equally in any profits. The agreement was expanded and modified in November 2009 to provide for additional antigen licenses to Agensys. The Company received a \$12 million upfront payment in 2009 and is entitled to future milestone payments, royalties and support fees for research and development services and material provided under the agreement. Under the amended agreement, Agensys is conducting preclinical studies aimed at identifying ADC product candidates for additional targets. The Company has the right to exercise a co-development option for two ADC product candidates upon submission of an IND to the FDA. The Company exercised one of these options in 2011 and began co-developing ASG-22ME. Agensys has the right to develop and commercialize the other ADC product candidates on its own, subject to paying the Company fees, milestones and royalties. Either party may opt out of co-development and profit-sharing in return for receiving milestones and royalties from the continuing party. Amounts received for product candidates being developed solely by Agensys will be recognized as revenue over the seventy-eight month performance obligation period of the collaboration agreement using a time-based approach.

The Company and Agensys are currently collaborating on the development of ASG-5ME and ASG-22ME for the treatment of solid tumors. 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,		
	2012	2011	2010
Research and development expense using contractual rates	\$ 4,885	\$ 6,404	\$ 4,654
Co-development funding due to Agensys	5,484	6,844	360
<b>Total</b>	<b>\$ 10,369</b>	<b>\$ 13,248</b>	<b>\$ 5,014</b>

*ADC collaboration agreements*

The Company has entered into collaborations for its ADC technology with a number of biotechnology and pharmaceutical companies, including AbbVie Biotechnology Ltd (formerly part of Abbott Laboratories), or AbbVie, Genentech, Inc., a member of the Roche Group, or Genentech, and Millennium. Under these collaborations, 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 collaborators during the performance obligation period of the collaboration. The Company receives upfront fees, progress- and sales-dependent milestones for the achievement by its collaborators of certain events, annual maintenance fees and support fees for

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

research and development services and material provided under the agreements. The Company is also entitled to receive royalties on net sales of any resulting ADC products. The upfront fee and other payments received are deferred and recognized as revenue over the performance obligation period of the related collaboration agreement using a time-based approach. The Company's collaboration partners are solely responsible for research, product development, manufacturing and commercialization of all products under the agreements.

**Table of Contents**

**Seattle Genetics, Inc.**

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

**9. 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 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.

**10. Commitments and contingencies**

The Company is obligated to make future minimum payments under three operating leases for approximately 195,000 square feet of space used for general office and research and development purposes. The leases expire in 2018 and include options to renew at the then fair market rental for the facilities. The Company also has an early termination option on one facility, totaling approximately 50,000 square feet, in 2014, subject to payment of a termination fee.

The lease agreements contain scheduled rent increases and provide for tenant improvement allowances. Accordingly, the Company has recorded a deferred rent liability of \$5.7 million at December 31, 2012 and \$4.5 million at December 31, 2011. This deferred rent liability is amortized over the term of the related lease.



## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

Future minimum lease payments under all noncancelable operating leases, and not assuming the exercise by the Company of any termination options or extensions and noncancelable obligations under other agreements are as follows (in thousands):

	<b>Leases</b>	<b>Other Agreements</b>
Years ending December 31,		
2013	\$ 4,071	\$ 40,395
2014	4,208	16,462
2015	4,348	12,629
2016	4,495	12,358
2017	4,639	1,677
Thereafter	2,279	54,803
	\$ 24,040	\$ 138,324

**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)**

Rent expense attributable to noncancelable operating leases totaled approximately \$3.6 million, \$3.5 million and \$2.7 million for the years ended December 31, 2012, 2011 and 2010, respectively. Minimum contractual payments to be made by the Company under other agreements do not include up to approximately \$10.0 million in additional payments that are contingent upon achievement of certain progress-dependent milestones, as well as the payment of royalties based on net sales of commercial products. These amounts have been excluded because the events triggering the obligations have not occurred and the occurrence of such events cannot be reasonably estimated.

**11. Stockholders' equity***Common stock*

In February 2011, the Company completed an underwritten public offering of 11,500,000 shares of its common stock. The public offering price of \$15.50 per share resulted in net proceeds to the Company of approximately \$168.1 million, after deducting underwriting discounts and commissions and offering expenses.

In May 2011, following stockholder approval, the Company amended its Certificate of Incorporation to increase the number of authorized shares of the Company's common stock from 150,000,000 shares to 250,000,000 shares.

At December 31, 2012, shares of common stock reserved for future issuance are as follows (in thousands):

Stock options and RSUs outstanding	13,021
Stock options and RSUs available for grant	3,681
Employee stock purchase plan shares available for issuance	511
Total	17,213

*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 511,000 shares of common stock available for issuance as of December 31, 2012. Activity under the Stock Purchase Plan for the years ended December 31, was as follows:

	Shares Purchased	Weighted-average purchase price per share
2012	287,841	\$ 14.88
2011	229,014	\$ 11.03
2010	173,379	\$ 8.68

Prior to 2011, shares were purchased at 85 percent of the fair market value of the Company's common stock on either the first day of an offering period or the last day of each six month purchase period, whichever was lower. An offering period could last for up to two years. 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.

## 12. Stock option plans

### *2007 Equity Incentive Plan*

In 2007, the Company adopted the 2007 Equity Incentive Plan, or the Option Plan, that provides for the issuance of the Company's common stock to employees, including officers, directors and consultants of the

**Table of Contents**

**Seattle Genetics, Inc.**

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

Company and its affiliates. The Option Plan was amended and restated in May 2010 to reserve an additional 7,500,000 shares and in May 2012 to reserve an additional 4,000,000 shares thereunder, such that an aggregate of 16,500,000 shares of the Company's common stock were reserved for issuance under the Option Plan at December 31, 2012. Under the Option Plan, the Company may issue stock options (including incentive stock options and nonstatutory stock options), restricted stock, restricted stock units, stock appreciation rights and other similar types of awards. No awardee may be granted, in any calendar year under the Option Plan, options or stock awards covering more than 1,000,000 shares. The Option Plan was also amended and restated in May 2012 to extend the term such that it will terminate in May 2022 unless it is terminated earlier pursuant to its terms.

Incentive stock options under the Option 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 Option Plan. Generally, options granted under the Option Plan vest 25% one year after the beginning of the vesting period and thereafter ratably each month over the following thirty-six months. The Plan provides for (i) the full acceleration of vesting of stock awards, including stock options, upon a change in control (as defined in the Plans) 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 stock awards, including stock options held by a holder of such stock awards, if at the time of, immediately prior to or within twelve months after a change in control of the Company, the holder of such stock 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.

Stock awards under the Option Plan may be restricted stock grants, restricted stock units, stock appreciation rights or other similar stock awards (including awards 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). Restricted stock grants are awards of a specific number of shares of the Company's common stock. Restricted stock units 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 restricted stock units under the Option Plan.

Each stock award agreement under the Option Plan contains provisions regarding (i) the number of shares subject to the stock award, (ii) the purchase price of the shares, if any, and the means of payment for the shares, (iii) 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, (iv) 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 Company's Board of Directors, (v) restrictions on the transferability of the stock award or the shares, and (vi) such further terms and conditions, in each case not inconsistent with the Option 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. Stock awards were granted in the form of restricted stock units, or RSUs, for the first time in 2011. During 2012, the Company increased the



**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)**

relative weighting of RSUs as a component of total stock awards. RSUs granted in 2011 vest 100% on the second or third anniversary of the date of grant, as applicable, whereas all 2012 RSU awards vest on the third anniversary of the date of grant.

*Share-based compensation expense*

The impact on the Company's net loss resulting from share-based payment awards was as follows (in thousands):

	Years ended December 31,		
	2012	2011	2010
Research and development	\$ 12,010	\$ 9,820	\$ 8,230
Selling, general and administrative	13,330	10,164	6,100
<b>Total</b>	<b>\$ 25,340</b>	<b>\$ 19,984</b>	<b>\$ 14,330</b>

No tax benefit was recognized related to share-based compensation expense since the Company has never reported taxable income and has established a full valuation allowance to offset all of the potential tax benefits associated with its deferred tax assets. During 2012 and 2011, \$1.1 million and \$0.3 million were capitalized as part of the cost of inventory, respectively. No amounts were capitalized as part of inventory cost in 2010.

*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:

	Option plan Years ended December 31,			Employee stock purchase plan Years ended December 31,		
	2012	2011	2010	2012	2011	2010
Risk-free interest rate	0.8%	1.3%	1.6%	0.1%	0.2%	0.5%
Expected lives in years	5.7	5.6	5.7	0.5	0.5	1.3
Expected dividends	0%	0%	0%	0%	0%	0%
Expected volatility	52%	52%	54%	42%	36%	47%

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

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.

**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)***Stock option activity*

A summary of stock option activity is as follows:

	<b>Shares</b>	<b>Weighted- average exercise price per share</b>	<b>Weighted-average remaining contractual term (in years)</b>	<b>Aggregate intrinsic value (in thousands)</b>
Balances at December 31, 2011	13,754,568	\$ 11.55		
Granted	1,908,688	24.82		
Exercised	(3,398,947)	9.25		
Forfeited/expired	(372,142)	14.64		
Balances at December 31, 2012	11,892,167	\$ 14.25	7.11	\$ 110,549
Expected to vest	11,500,542	\$ 14.05	7.04	\$ 108,859
Options exercisable	7,040,595	\$ 11.30	6.06	\$ 83,582

The weighted average grant-date fair values of options granted with exercise prices equal to market were \$11.92, \$7.94 and \$6.27 for the years ended December 31, 2012, 2011 and 2010, 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, 2012. The aggregate intrinsic value of options exercised was \$48.3 million during 2012, \$16.9 million during 2011 and \$6.0 million during 2010, determined as of the date of option exercise. As of December 31, 2012, there was approximately \$21.6 million of total unrecognized compensation cost related to unvested option arrangements, as adjusted for expected forfeitures, granted under the Option Plan. That cost is expected to be recognized over a weighted-average period of 1.3 years. The Company utilizes newly issued shares to satisfy option exercises.

*RSU activity*

During 2011, the Company began granting a mix of stock options and RSUs to employees under the Option Plan. The fair value of RSUs is determined based on the closing price of the Company's common stock on the date of grant.



## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

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

<b>Non-vested RSUs</b>	<b>Share equivalent</b>	<b>Weighted- average grant date fair value</b>
Non-vested at December 31, 2011	511,167	\$ 15.62
Changes during the period:		
Granted	672,781	25.45
Vested	0	0
Forfeited	(54,848)	16.76
Non-vested at December 31, 2012	1,129,100	\$ 21.42

As of December 31, 2012, there was \$15.6 million of total unrecognized compensation cost related to non-vested awards of RSUs that will be recognized as expense over a weighted-average period of 2.11 years. The

**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)**

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. No RSUs have vested to date. The Company will utilize newly issued shares to satisfy the vesting of RSUs.

**13. 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 50% 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. Under this matching program, the Company contributed a total of approximately \$2.1 million in 2012, \$1.4 million in 2011 and \$0.8 million in 2010.

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

The following table contains selected unaudited financial data for each quarter of 2012 and 2011. 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):**

	March 31,	Three months ended		December 31,
	March 31,	June 30,	September 30,	December 31,
<b>2012</b>				
Total revenues	\$ 48,245	\$ 48,823	\$ 49,832	\$ 63,912
Net loss	\$ (12,298)	\$ (17,236)	\$ (13,652)	\$ (10,596)
Net loss per share - basic and diluted	\$ (0.11)	\$ (0.15)	\$ (0.12)	\$ (0.09)
<b>2011</b>				
Total revenues	\$ 12,171	\$ 13,054	\$ 20,666	\$ 48,887
Net loss	\$ (32,674)	\$ (51,506)	\$ (40,685)	\$ (27,165)
Net loss per share - basic and diluted	\$ (0.30)	\$ (0.45)	\$ (0.35)	\$ (0.24)

---

**Table of Contents**

**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 Rules 13a-15(e) and 15d-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, 2012 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 Exchange Act Rule 13a-15(f). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 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, 2012.

The effectiveness of our internal control over financial reporting as of December 31, 2012 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**

On February 1, 2013, the Compensation Committee of the Board of Directors of the Company (the "Compensation Committee"), approved the 2013 Senior Executive Annual Bonus Plan (the "Plan"), an incentive compensation program, which is designed to motivate, retain and reward the Company's executive officers based on the achievement of specified Company and individual goals. The Compensation Committee administers the Plan. Participants eligible under the Plan are those executives at the Vice President level or higher (each a "Participant"), including the following named executive officers (as defined under applicable securities laws): Clay Siegall, Todd Simpson, Eric Dobmeier, Vaughn Himes and Chris Boerner. The amount of a Participant's bonus is based on a target percentage of such Participant's annual base pay as of the date of payment of the bonus, which target percentages have been determined by the Compensation Committee. The target percentage for Dr. Siegall is seventy-five percent (75%), Mr. Dobmeier's is fifty percent (50%), Mr. Simpson's and Dr. Himes' target percentage is forty-five percent (45%) and Mr. Boerner's is forty percent (40%). Under the Plan, this target percentage is then adjusted, generally based 50% on the Company's performance and 50% on the individual Participant's performance as determined by the Compensation Committee, except for members of the Company's Executive Committee (which include Mr. Simpson, Dr. Himes and Mr. Boerner), in which case the percentage adjustment is based 60% on the Company's performance and 40% on the individual Participant's performance. Additionally, Mr. Dobmeier's percentage adjustment is based 80% on the Company's performance and 20% on individual performance, and Dr. Siegall's final performance percentage will be

## Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

determined by the Compensation Committee at its sole discretion. The corporate performance measures under the Plan for 2013 are primarily based on the achievement of commercial objectives, enrollment objectives of ongoing clinical trials of ADCETRIS, submission of an sBLA for ADCETRIS, obtaining Canadian approval for ADCETRIS, as well as development and clinical activities related to our other product candidates. Additional goals include hiring and retention goals, strategic objectives and stock performance. The Company's achieved performance percentage and/or the individual achieved Participant performance percentage may exceed 100% in the event the Company and/or the Participant exceed the predetermined goals (provided that neither percentage may exceed 150%), which could result in the payment of cash bonuses under the Plan at a level above target. The Plan is effective for the Company's 2013 calendar year and expires on December 31, 2013 (with any bonus payments under the Plan to be made by February 15, 2014). The above description of the terms of the Plan is a summary and is qualified in its entirety by the terms of the Plan, which is filed as an exhibit to this annual report on Form 10-K for the year ending December 31, 2012 as Exhibit 10.19.

**Table of Contents**

**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 2012 fiscal year pursuant to Regulation 14A for our 2013 Annual Meeting of Stockholders, or the 2013 Proxy Statement, and the information to be included in the 2013 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 2013 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 2013 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 2013 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 2013 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 2013 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 2013 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 2013 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 2013 Proxy Statement. Such information is incorporated herein by reference.

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

The information required by this Item may be found under the section entitled Proposal No. 2 Ratification of Appointment of Independent Registered Public Accounting Firm appearing in the 2013 Proxy Statement. Such information is incorporated herein by reference.

**Table of Contents****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**

<b>Number</b>	<b>Description</b>
3.1(8)	Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.
3.2(7)	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.
3.3(3)	Amended and Restated Bylaws of Seattle Genetics, Inc.
4.1(1)	Specimen Stock Certificate.
4.2(2)	Investor Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders.
10.1(4)	License Agreement dated March 30, 1998 between Seattle Genetics, Inc. and Bristol-Myers Squibb Company.
10.2(4)	Amendment Letter to the Bristol-Myers Squibb Company License Agreement dated July 29, 1999 between Seattle Genetics, Inc. and Bristol-Myers Squibb Company.
10.3(1)	Amendment Agreement to the Bristol-Myers Squibb Company License Agreement dated July 26, 2000 between Seattle Genetics, Inc. and Bristol-Myers Squibb Company.
10.4(4)	License Agreement dated September 20, 1999 between Seattle Genetics, Inc. and the University of Miami.
10.5(4)	Amendment No. 1 to the University of Miami License Agreement dated August 4, 2000 between Seattle Genetics, Inc. and the University of Miami.
10.6 (1)	Lease Agreement dated December 1, 2000 between Seattle Genetics, Inc. and WCM132-302, LLC.
10.7(11)*	Amended and Restated 1998 Stock Option Plan, effective as of August 4, 2009.
10.8(5)*	Form Notice of Grant and Stock Option Agreement under Seattle Genetics, Inc. Amended and Restated 1998 Stock Option Plan.
10.9(5)*	Form Notice of Grant and Stock Option Agreement under Seattle Genetics, Inc. 2000 Directors Stock Option Plan.
10.10(12)*	2000 Directors Stock Option Plan, as amended February 5, 2010.
10.11(18)*	Amended and Restated 2000 Employee Stock Purchase Plan, effective February 1, 2011.
10.12(1)*	Form of Indemnification Agreement between Seattle Genetics, Inc. and each of its officers and directors.

Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

10.13 (3) First Amendment to Lease dated May 28, 2003 between Seattle Genetics, Inc. and B&N 141-302, LLC.



**Table of Contents**

<b>Number</b>	<b>Description</b>
10.14 (6)	Collaboration and License Agreement dated January 7, 2007 between Seattle Genetics, Inc. and Agensys, Inc.
10.15(9)*	Seattle Genetics, Inc. 2012 Senior Executive Annual Bonus Plan.
10.16 (8)	Second Amendment to Lease dated July 1, 2008 between Seattle Genetics, Inc. and B&N 141-302, LLC.
10.17(19)*	Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan, effective as of May 18, 2012.
10.18(10)*	Form Stock Option Agreement under Seattle Genetics, Inc. 2007 Equity Incentive Plan.
10.19+*	Seattle Genetics, Inc. 2013 Senior Executive Annual Bonus Plan.
10.20(10)*	Amended and Restated Employment Agreement, dated December 15, 2008, between Seattle Genetics, Inc. and Clay B. Siegall.
10.21(10)*	Amended and Restated Employment Agreement, dated December 15, 2008, between Seattle Genetics, Inc. and Todd E. Simpson.
10.22(10)*	Amended and Restated Employment Agreement, dated December 15, 2008, between Seattle Genetics, Inc. and Eric L. Dobmeier.
10.23(10)*	Amended and Restated Employment Agreement, dated December 15, 2008, between Seattle Genetics, Inc. and Thomas C. Reynolds.
10.24(12)*	Employment Agreement, dated April 1, 2009, between Seattle Genetics, Inc. and Vaughn Himes.
10.25(19)*	Employment Agreement, dated April 16, 2012 between Seattle Genetics, Inc. and Chris Boerner.
10.26+*	Compensation Information for Executive Officers and Directors.
10.27(9)*	Severance and Release Agreement by and between Seattle Genetics, Inc. and Bruce J. Seeley effective February 23, 2012.
10.28(12)	Amendment to the Collaboration and License Agreement between Seattle Genetics, Inc. and Agensys, Inc. dated November 9, 2009.
10.29(12)	Collaboration Agreement between Seattle Genetics, Inc. and Millennium Pharmaceuticals dated December 14, 2009.
10.30(13)	Office Lease dated May 9, 2011 between Seattle Genetics, Inc. and WCM Highlands II, LLC.
10.31(13)	Third Amendment to Lease dated May 9, 2011 between Seattle Genetics, Inc. and B&N 141-302, LLC.
10.32(13)*	Amended and Restated 2000 Employee Stock Purchase Plan, effective May 20, 2011.
10.33(13)*	Form of Notice of Stock Option Grant and Stock Option Agreement for non-employee directors under the Amended and Restated 2007 Equity Incentive Plan.
10.34(14)	Commercial Supply Agreement dated December 1, 2010 between Seattle Genetics, Inc. and SAFC, an operating division of Sigma-Aldrich, Inc.
10.35(15)	Development and Supply Agreement dated February 23, 2004 between Seattle Genetics, Inc. and Abbott Laboratories.
10.36(16)	First Amendment to Development and Supply Agreement dated April 17, 2008 between Seattle Genetics, Inc. and Abbott Laboratories, Inc.
10.37(14)	Second Amendment to Development and Supply Agreement dated June 15, 2009 between Seattle Genetics, Inc. and Abbott Laboratories, Inc.
10.38(14)	Third Amendment to Development and Supply Agreement dated November 5, 2009 between Seattle Genetics, Inc. and Abbott Laboratories, Inc.

**Table of Contents**

<b>Number</b>	<b>Description</b>
10.39(14)	Fourth Amendment to Development and Supply Agreement dated April 18, 2010 between Seattle Genetics, Inc. and Abbott Laboratories, Inc.
10.40(14)	Fifth Amendment to Development and Supply Agreement dated August 24, 2010 between Seattle Genetics, Inc. and Abbott Laboratories, Inc.
10.41(14)	Sixth Amendment to Development and Supply Agreement dated November 18, 2010 between Seattle Genetics, Inc. and Abbott Laboratories, Inc.
10.42*	Seventh Amendment to Development and Supply Agreement dated January 2, 2013 between Seattle Genetics, Inc. and Abbott Laboratories, Inc.
10.43 (17)*	Form of Stock Unit Grant Notice and Stock Unit Agreement under Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan.
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+(20)	XBRL Instance Document
101.SCH+(20)	XBRL Taxonomy Extension Schema Document.
101.CAL+(20)	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF+(20)	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+(20)	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE+(20)	XBRL Taxonomy Extension Presentation Linkbase Document.

- (1) Previously filed as an exhibit to Registrant's registration statement on Form S-1, File No. 333-50266, originally filed with the Commission on November 20, 2000, as subsequently amended, and incorporated herein by reference.
- (2) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on May 15, 2003, and incorporated herein by reference.
- (3) Previously filed as an exhibit to Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2003 and incorporated herein by reference.
- (4) Previously filed as an exhibit to the Registrant's annual report on Form 10-K/A filed with the Commission on November 26, 2010 and incorporated herein by reference.
- (5) Previously filed as an exhibit to Registrant's annual report on Form 10-K for the year ended December 31, 2004 and incorporated herein by reference.
- (6) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2007 and incorporated herein by reference.
- (7) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on May 26, 2011 and incorporated herein by reference.

Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

- (8) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2008 and incorporated herein by reference.
- (9) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on February 23, 2012 and incorporated herein by reference.

**Table of Contents**

- (10) Previously filed as an exhibit to the Registrant's annual report on Form 10-K filed with the Commission on March 13, 2009 and incorporated herein by reference.
- (11) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2009 and incorporated herein by reference.
- (12) Previously filed as an exhibit to the Registrant's annual report on Form 10-K filed with the Commission on March 12, 2010 and incorporated herein by reference.
- (13) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2011 and incorporated herein by reference.
- (14) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011 and incorporated herein by reference.
- (15) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2004 and incorporated herein by reference.
- (16) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference.
- (17) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on August 30, 2011 and incorporated herein by reference.
- (18) Previously filed as an exhibit to the Registrant's annual report on Form 10-K filed with the Commission on February 28, 2011 and incorporated herein by reference.
- (19) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2012 and incorporated herein by reference.
- (20) Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, are deemed not filed for purposes of section 18 of the Exchange Act and otherwise are not subject to liability under these sections.

+ 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.

**Table of Contents****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, 2013

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

*President & Chief Executive Officer*

*(Principal Executive Officer)*

Date: February 27, 2013

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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ CLAY B. SIEGALL Clay B. Siegall	Director, President & CEO (Principal Executive Officer)	February 27, 2013
/s/ TODD E. SIMPSON Todd E. Simpson	Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2013
/s/ FRANKLIN M. BERGER Franklin M. Berger	Director	February 27, 2013
/s/ DAVID W. GRYSKA David W. Gryska	Director	February 27, 2013
/s/ MARC E. LIPPMAN Marc E. Lippman	Director	February 27, 2013

Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-K

/s/ SRINIVAS AKKARAJU	Director	February 27, 2013
Srinivas Akkaraju		
/s/ FELIX BAKER	Director	February 27, 2013
Felix Baker		
/s/ JOHN P. McLAUGHLIN	Director	February 27, 2013
John P. McLaughlin		
/s/ DANIEL G. WELCH	Director	February 27, 2013
Daniel G. Welch		
/s/ NANCY A. SIMONIAN	Director	February 27, 2013
Nancy A. Simonian		