SEATTLE GENETICS INC /WA
Form 10-K
February 27, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 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	**91-1874389**
(State or other Jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

21823 30th Drive SE

Bothell, WA 98021

(Address of principal executive offices, including zip code)

Registrant s telephone number, including area code: **(425) 527-4000**

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

Title of class	**Name of each exchange on which registered**
Common Stock, par value $0.001	**The NASDAQ Stock Market LLC**

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

None

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES x NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $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.

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SEATTLE GENETICS, INC.

FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2012

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PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including those relating to future events or our future financial performance. 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®, 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.

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

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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

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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

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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.

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ADCETRIS and Product Candidate Development Pipeline

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

Name of Product or Product Candidate	Description	Commercial Rights	Status
ADCETRIS®	Anti-CD30 ADC	Seattle Genetics in United States and Canada; Millennium in rest of world	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.
			AETHERA phase III trial ongoing for patients with Hodgkin lymphoma at high risk of relapse following ASCT. Enrollment was completed in 2012.
			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.
			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.
			ALCANZA phase III trial ongoing for relapsed CD30-positive CTCL patients, comparing ADCETRIS versus investigator s choice of methotrexate or bexarotene.
			Phase II retreatment trial ongoing for patients with Hodgkin lymphoma or sALCL who have relapsed after previously responding to ADCETRIS.
			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

	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.

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Name of Product or Product Candidate	Description	Commercial Rights	Status
			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.

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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

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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

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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 patents 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.

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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.

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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.

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.

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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

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

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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:

Collaborator	Effective Date	Number of Targets	Development Status[1]
AbbVie	March 2011	Multiple[2]	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		