SEATTLE GENETICS INC /WA
Form 10-K
February 29, 2012
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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, 2011

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 $1,324,552,293 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 49,870,139 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 116,361,172 shares of the registrant s Common Stock issued and outstanding as of February 23, 2012.

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 2012 Annual Meeting of Stockholders.

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SEATTLE GENETICS, INC.

FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2011

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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. On August 19, 2011, the U.S. Food and Drug Administration, or FDA, granted accelerated approval of ADCETRIS™, or brentuximab vedotin, in 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 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 in patients with Hodgkin lymphoma and sALCL and other CD30-positive malignancies. In addition, we have three clinical-stage ADC programs, SGN-75, ASG-5ME, and ASG-22ME, as well as several preclinical product candidates, including SGN-CD19A.

In December 2009, we 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. In June 2011, Millennium s Marketing Authorization Application, or MAA, seeking regulatory approval to market ADCETRIS for the treatment of relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL in the European Union was accepted by the European Medicines Agency, or EMA, which is currently reviewing the application. We also have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including Abbott Biotechnology Ltd., or Abbott; 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.

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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 cell-killing drugs. 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 drug from the monoclonal antibody, which then results in the desired activity, specific killing of the target cancer cell. A key component of our ADCs is the linker that attaches the drug to the monoclonal antibody, which is designed to hold the drug to the monoclonal antibody until it binds to the cell surface receptor on the target cell and then to release the drug upon internalization within the target cell. This targeted delivery of the cell-killing drug is intended to maximize delivery of the drug to tumor cells while minimizing toxicity to normal tissues. Our ADCs use auristatins, which are anti-microtubulin agents, as the cell-killing drug. In contrast to natural product drugs 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 and SGN-CD19A all utilize our proprietary, auristatin-based ADC technology, and this technology is also the basis of all 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 drugs 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 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 autoimmune 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 and autoimmune diseases. Key elements of our strategy are to:

Successfully Commercialize ADCETRIS. Our most important near-term objective is to continue our efforts to successfully commercialize ADCETRIS. At the time of the ADCETRIS approval by the FDA in August 2011, we had our commercial and supply infrastructure in place to enable a prompt commercial launch of ADCETRIS. We continue to focus our efforts on commercializing ADCETRIS in the United States, including through the coordinated efforts of our sales, marketing, reimbursement and market planning groups. We are preparing our regulatory application for submission to Canadian Health authorities in the first half of 2012 under which we are seeking approval of ADCETRIS for the treatment of patients with relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL. In addition, in June 2011, Millennium s MAA seeking regulatory approval to market ADCETRIS in the European Union was accepted by the EMA. Millennium is currently working with the EMA toward potential marketing approvals for ADCETRIS in the treatment of relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL.

Expand the Therapeutic Potential of ADCETRIS. We believe ADCETRIS may have applications in many types of CD30-expressing cancers. We have ongoing or are planning to initiate clinical trials evaluating ADCETRIS in earlier lines of therapy for Hodgkin lymphoma and mature T-cell lymphoma and in other types of CD30-expressing lymphoma such as cutaneous T-cell lymphoma, peripheral T-cell lymphoma and some types of B-cell lymphomas including diffuse large B-cell lymphoma. In addition, we are conducting a phase II clinical trial of ADCETRIS for patients with CD30-positive

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non-lymphoma malignancies, including multiple myeloma, leukemia and solid tumors. We are also supporting investigator sponsored trials in different CD30-positive indications, including cutaneous T-cell lymphoma, front-line treatment of older patients with Hodgkin lymphoma, salvage therapy for patients with Hodgkin lymphoma prior to autologous hematopoietic cell transplant, 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 and ASG-22ME, as well as our preclinical programs, such as SGN-CD19A 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 and several preclinical programs, including SGN-CD19A. We also license our ADC technology to biotechnology and pharmaceutical companies to generate near-term collaboration revenue and funding, as well as potential future milestones and royalties. Presently, we have active ADC collaborations with Abbott, 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 cash payments of over $165 million as of December 31, 2011 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 drugs 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	Accelerated approval by the FDA for 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) for the treatment of patients with 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. We plan to initiate confirmatory trials required under the accelerated approval of ADCETRIS for these indications by late 2012 or early 2013.
			Phase III trial ongoing for patients with Hodgkin lymphoma at high risk of relapse following autologous stem cell transplant, or ASCT (the AETHERA trial).
			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 diffuse large B-cell lymphoma, 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 I safety trial ongoing in combination with Adriamycin, vinblastine, bleomycin and dacarbazine, or ABVD, or in combination with AVD, which removes bleomycin from the regimen, for front-line treatment of patients with Hodgkin lymphoma.

	Phase I safety trial ongoing sequentially with or in combination with chemotherapy for front-line treatment of patients with mature T-cell lymphomas, including sALCL.

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Name of Product or Product Candidate	Description	Commercial Rights	Status
SGN-75	Anti-CD70 ADC	Seattle Genetics	Completed enrollment in a single-agent phase I trial of SGN-75 for relapsed or refractory non-Hodgkin lymphoma and renal cell carcinoma.
			Planning to initiate during 2012 a phase Ib clinical trial to evaluate SGN-75 in combination with everolimus for renal cell carcinoma.
ASG-5ME	Anti-SLC44A4 ADC	50:50 co-development and commercialization with Agensys	Phase I trial ongoing for metastatic pancreatic cancer
			Phase I trial ongoing for 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	Investigational new drug application, or IND, submission planned in 2012 for CD19-positive hematologic malignancies

ADCETRIS

ADCETRIS is an ADC comprising an anti-CD30 monoclonal antibody attached by a protease-cleavable linker to a microtubule disrupting agent, monomethyl auristatin E (MMAE), utilizing our proprietary technology. ADCETRIS employs a linker system that is designed to be stable in the bloodstream but to release MMAE upon internalization into CD30-expressing tumor 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. In December 2009, we entered into a collaboration agreement for the development and commercialization of ADCETRIS with Millennium under which we received a $60 million upfront payment. 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 and will fund fifty percent of joint development costs under the collaboration, except in Japan where Millennium is fully responsible for funding development costs. We are entitled to receive milestone payments for significant events that Millennium achieves under the collaboration, including EMA approval of ADCETRIS, that could total more than $230 million, and tiered royalties with percentages beginning in the mid-teens and escalating to the mid-twenties based on net sales of ADCETRIS in Millennium s territories, subject to offsets for third party royalties paid by Millennium.

On August 19, 2011, the FDA granted accelerated approval of ADCETRIS in two indications: (1) the treatment of patients with Hodgkin lymphoma after failure of ASCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates, and (2) the treatment of patients with sALCL after failure of at least one prior multi-agent chemotherapy regimen. There are no data available demonstrating improvement in patient-reported outcomes or survival with ADCETRIS. Following accelerated approval of ADCETRIS by the FDA, we commercially launched ADCETRIS in the United States and began to recognize product sales in the third quarter of 2011. In January 2012, the FDA approved updates to the ADCETRIS label to include a boxed warning related to the risk that JC virus infection resulting in progressive multifocal leukoencephalopathy, or PML, a serious brain infection, and death can occur in patients receiving ADCETRIS, as well as to include a patient discussion relating to PML and to add a contraindication warning relating to the concomitant use of ADCETRIS and bleomycin due to pulmonary toxicity.

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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 data 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 have agreed to conduct 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. As a condition of accelerated approval, we are required to conduct the following post-approval studies that are intended to verify and describe ADCETRIS clinical benefit. Successful completion of either of these two trials could result in conversion to regular approval for both indications:

A phase III randomized trial evaluating ADCETRIS plus AVD versus ABVD as front-line therapy in advanced-stage Hodgkin lymphoma patients. The primary endpoint will be progression free survival, with overall survival as a key secondary endpoint. We plan to initiate this trial by late 2012 or early 2013.

A phase III randomized, double-blind clinical trial comparing ADCETRIS in combination with cyclophosphamide, hydroxydaunorubicin, and prednisone, or CH-P, to cyclophosphamide, hydroxydaunorubicin, Oncovin (vincristine), and prednisone, or CHOP, as front-line therapy in patients with CD30-positive mature T-cell lymphomas, including sALCL. The primary endpoint will be progression free survival, with overall survival as a key secondary endpoint. We plan to initiate this trial by late 2012 or early 2013.

Both of these studies are described in greater detail below under Clinical Development Plan below. 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.

Pivotal Clinical Trials

FDA approval of ADCETRIS was based on the results of two single-arm pivotal phase II trials in relapsed or refractory Hodgkin lymphoma and sALCL. Both trials evaluated single-agent ADCETRIS administered on an every three week basis for up to approximately one year, and were conducted at multiple centers in the United States, Canada and Europe. The primary endpoint of both trials was response rate as assessed by independent central review, with key secondary endpoints of duration of response, progression-free survival and overall survival.

Phase II Hodgkin Lymphoma Study. This study evaluated ADCETRIS in 102 relapsed or refractory Hodgkin lymphoma patients who had previously received ASCT and was conducted under a special protocol assessment, or SPA, with the FDA. Seventy-five percent of patients achieved an objective response with a median duration of response of 29 weeks. In addition, 34 percent of patients achieved a complete remission. The median duration of response for patients who achieved a complete remission was 20.5 months. Tumor reductions were achieved in 94 percent of patients. ADCETRIS was generally well tolerated, with the majority of adverse events being Grade 1 or 2. The most common adverse events were peripheral sensory neuropathy, fatigue, nausea, upper respiratory tract infection and diarrhea. The most common Grade 3 or higher adverse events were neutropenia, peripheral sensory neuropathy, thrombocytopenia and anemia.

Phase II sALCL Study. This study evaluated ADCETRIS in 58 patients with relapsed or refractory sALCL. Eighty-six percent of patients achieved an objective response with a median duration of response of 13.2 months. In addition, 59 percent of patients achieved a complete remission. The median

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duration of response of patients who achieved a complete remission had not yet been reached at a median follow up on study of approximately 15 months. Tumor reductions were achieved in 97 percent of patients. ADCETRIS was generally well tolerated, with the majority of adverse events being Grade 1 or 2. The most common adverse events were peripheral sensory neuropathy, fatigue, nausea, diarrhea, neutropenia and myalgia. The most common Grade 3 or higher adverse events were neutropenia, peripheral sensory neuropathy and diarrhea.

Market Opportunities

According to the American Cancer Society, approximately 8,800 cases of Hodgkin lymphoma were diagnosed in the United States during 2011, and an estimated 1,300 people died of the disease. Approximately 2,000 additional patients per year in the United States are diagnosed with sALCL, a type of mature T-cell 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-expressing cancers. These ongoing and planned clinical trials include:

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 approximately 325 Hodgkin lymphoma patients following ASCT. Patients must be at high risk for residual Hodgkin lymphoma, defined as 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 expect to complete enrollment of the AETHERA trial during 2012.

Front-line Hodgkin Lymphoma. In February 2010, we initiated a phase I dose-escalation combination trial in front-line Hodgkin lymphoma to evaluate ADCETRIS combined with ABVD or combined with AVD. This trial is evaluating the safety, pharmacokinetics and antitumor activity of these combination regimens. The study is being conducted at multiple centers in the United States and Canada, and enrollment was completed in 2011. Interim data were reported at the American Society of Hematology, or ASH, meeting in December 2011 from 44 patients, including 25 in the ADCETRIS plus ABVD cohorts and 19 in the ADCETRIS plus AVD cohorts. At that time, no dose-limiting toxicity had been observed at the maximum planned dose of ADCETRIS and no pulmonary toxicity events had been observed in the ADCETRIS plus AVD cohorts. Ten out of 25 patients, or 40 percent, in the ADCETRIS plus ABVD cohorts had an event of pulmonary toxicity, including three Grade 3 and two Grade 4 events. This compares to an overall rate of pulmonary toxicity with bleomycin-based regimens reported in published literature of 10 to 25 percent. Due to this increased incidence of pulmonary adverse events, concomitant use of ADCETRIS with bleomycin is not recommended, and patients are no longer being treated on the ABVD cohorts of the study. In January 2012, the FDA approved changes to the ADCETRIS label to add a contraindication warning relating to the concomitant use of ADCETRIS and bleomycin due to pulmonary

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toxicity. Among 25 patients in the ADCETRIS plus ABVD cohorts, all 15 patients who completed front-line therapy on study achieved a complete remission. Five patients were unevaluable because they withdrew from the study prior to completing a full course of therapy and five patients were in ongoing treatment at the time the data was reported. In addition, we reported that 36 of 37 evaluable patients in both study arms had negative interim positron emission tomography, or PET, scans after cycle 2 as assessed by central review, including 22 out of 22 in the ABVD cohorts and 14 out of 15 in the AVD cohorts. PET scans are frequently used to assess tumor burden in Hodgkin lymphoma patients. Across all treatment cohorts, the most common adverse events were neutropenia, nausea, peripheral sensory neuropathy, fatigue and vomiting and Grade 3 or higher adverse events were neutropenia, anemia, febrile neutropenia and pulmonary toxicity, all of which occurred in the ABVD cohorts. In addition, we reported that no Grade 3 or 4 adverse events of peripheral neuropathy had been observed and we reported that all patients in the ADCETRIS plus AVD cohorts were in ongoing treatment and response results were therefore not yet available. We expect to report additional data from this trial during 2012.

Based on the interim phase I results, we are planning a phase III, randomized trial in front-line advanced-stage Hodgkin lymphoma comparing ADCETRIS plus AVD versus ABVD alone. Our goal with this planned trial is to redefine the standard front-line regimen for Hodgkin lymphoma by potentially increasing the efficacy and decreasing treatment associated toxicities. The primary endpoint of this trial is expected to be progression-free survival with secondary endpoints including overall survival, safety and tolerability. As noted above, we are required to conduct this trial as part of our ADCETRIS post-marketing requirement, and the trial is being designed to be confirmatory in both the United States and European Union. We plan to initiate this trial by late 2012 or early 2013.

Front-line Mature T-Cell Lymphoma. In March 2011, we initiated 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 mature T-cell lymphoma. This trial is evaluating the safety profile, pharmacokinetics and antitumor activity of ADCETRIS when administered sequentially or in combination with multi-agent front-line chemotherapy regimens. The standard front-line therapy for mature T-cell lymphomas is CHOP. In this study we are combining ADCETRIS either concurrently or sequentially with CHOP or CH-P, which removes Oncovin (vincristine) from the regimen. The study is expected to enroll up to approximately 60 patients at multiple centers in the United States and Europe. Interim data from the first 32 patients treated in this study, including 12 who received the sequential regimen and 20 who received the concurrent regimen, were reported at the T-cell Lymphoma Forum in January 2012. All 12 patients treated with the sequential regimen achieved an objective response after two cycles of single-agent ADCETRIS. Among 20 patients treated with the concurrent regimen, all five patients who had completed the full course of six cycles of multi-agent induction treatment and were evaluable for response at the time of data analysis achieved a complete remission. The most common adverse events regardless of severity or relationship to study drug were nausea, fatigue and peripheral sensory neuropathy.

Based on the interim phase I results, we are planning a phase III, randomized trial in front-line mature T-cell lymphomas comparing ADCETRIS combined with CH-P versus CHOP alone. Our goal with this planned trial is to redefine the standard front-line regimen for mature T-cell lymphoma. The primary endpoint of this trial is expected to be progression-free survival with secondary endpoints including overall survival, safety and tolerability. As noted above, we are required to conduct this trial as part of our ADCETRIS post-marketing requirement with the FDA, and the trial is being designed to be confirmatory in both the United States and European Union. We plan to initiate this trial by late 2012 or early 2013.

Cutaneous T-Cell Lymphoma.

According to published literature, CD30 is expressed in up to 50 percent of cutaneous T-cell lymphomas, including cutaneous ALCL, mycosis fungoides and lymphomatoid papulosis. In our phase II sALCL trial, 14 out of 15 patients with cutaneous involvement of their lymphoma experienced complete regression of their skin lesions. There are also currently two investigator-sponsored trials of ADCETRIS ongoing in patients with CD30-positive cutaneous T-cell lymphoma, and interim data from one of these studies was reported at the T-cell

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Lymphoma Forum in January 2012, indicating that 65 percent (or eleven of 17) evaluable patients achieved an objective response. The most common adverse events were Grade 1.

Based on these data, we are planning a phase III, randomized trial in cutaneous T-cell lymphoma. This trial is being designed to compare ADCETRIS to standard treatments for cutaneous T-cell lymphoma patients who have failed at least one prior systemic therapy for their disease. The primary endpoint of this trial is expected to be overall response rate. This trial is planned to initiate by mid-2012.

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 diffuse large B-cell lymphoma, 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. The study is expected to enroll up to approximately 55 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 40 patients at multiple centers in the United States.

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 response to therapy 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 2010, we reported preliminary data demonstrating that objective responses were achieved in seven out of 11 retreatment experiences and that ADCETRIS was well-tolerated in the retreatment setting. We expect to report additional data from this study during 2012.

Investigator-Sponsored Studies. As of December 31, 2011, there were four ongoing investigator sponsored trials of ADCETRIS. In addition, we and Millennium are in discussions with multiple clinical investigators and cooperative groups in the United States, Canada and Europe about potential additional clinical trials of ADCETRIS. The investigator sponsored trials we have supported to date include the use of ADCETRIS in different CD30-positive 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 various settings, including other CD30-positive indications, novel combinations of therapy and graft versus host disease. We expect multiple additional investigator-sponsored trials of ADCETRIS to initiate during 2012.

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,

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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. We are not planning further single-agent trials of SGN-75 and instead plan to initiate a phase Ib clinical trial to evaluate SGN-75 in combination with everolimus for renal cell carcinoma during 2012.

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 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 are continuing to dose-escalate and enroll additional patients in the castration-resistant prostate clinical trial.

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 a preclinical ADC product candidate for the treatment of hematologic malignancies. SGN-CD19A targets CD19, which is a B-cell antigen that is expressed in non-Hodgkin lymphoma, chronic lymphocytic leukemia and acute lymphocytic 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. We are planning a 2012 IND submission for SGN-CD19A in CD19-positive hematologic malignancies.

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 drugs and stable linkers, and identifying novel antigen targets and monoclonal antibodies and advancing our antibody engineering initiatives.

New Cell-Killing Drugs. We continue to study new cell-killing drugs that can be linked to antibodies, such as the auristatins that we currently use in our ADC technology. We are evaluating multiple new auristatins, as well as other classes of cell-killing drugs, for potential applications as ADCs.

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.

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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.

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, 2011, 2010, and 2009, we recorded $163.4 million, $146.4 million, and $119.1 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. We are also entitled to receive progress- and sales-dependent milestone payments based on Millennium s achievement of significant events under the collaboration, including approval of ADCETRIS by the EMA, 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, subject to offsets for royalties paid by Millennium to third parties. 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.

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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 treatment of metastatic pancreatic cancer in July 2010 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.

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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]
Abbott	March 2011	One	Preclinical
Bayer	September 2004	One	Phase I
Celldex	June 2004	Two	Phase II
Daiichi Sankyo	July 2008	One	Preclinical
Genentech	April 2002	Multiple	Phase I
GlaxoSmithKline	December 2009	Multiple	Preclinical
Millennium	March 2009	Two [2]	Preclinical
Pfizer	December 2010	One	Preclinical
Progenics	June 2005	One	Phase I

[1] For collaborations involving multiple targets, development status denotes the most advanced program under the collaboration.

[2] In March 2011, Millennium paid us an additional fee to exercise an option to license our ADC technology for a second antigen. Millennium has the option to exercise an exclusive license to our ADC technology for one additional target upon payment of an additional fee.