SEATTLE GENETICS INC /WA
Form 10-K
February 28, 2014
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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, 2013

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 $1,782,964,197 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 64,803,406 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 122,982,860 shares of the registrant s Common Stock issued and outstanding as of February 24, 2014.

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 2014 Annual Meeting of Stockholders.

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SEATTLE GENETICS, INC.

FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2013

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PART I

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

Item 1. Business

Overview

Seattle Genetics is a biotechnology company focused on the development and commercialization of targeted therapies for the treatment of cancer. Our marketed product ADCETRIS®, or brentuximab vedotin, received accelerated approval in the United States in August 2011 and approval with conditions in Canada in February 2013 for patients with relapsed Hodgkin lymphoma or relapsed systemic anaplastic large cell lymphoma, or sALCL. ADCETRIS is 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, including sALCL, or MTCL, and in other CD30-positive malignancies.

We are collaborating with Takeda Pharmaceutical Company Limited, or Takeda, 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 Takeda has commercial rights in the rest of the world. ADCETRIS was granted conditional marketing authorization in the European Union in October 2012 for patients with relapsed Hodgkin lymphoma or relapsed sALCL. We and Takeda have received marketing authorizations by regulatory authorities in 39 countries, including those described above, as well as Japan, Australia, Switzerland, South Korea and Singapore, and Takeda continues to pursue marketing authorizations in multiple other countries. In addition, we have five clinical-stage ADC programs, which consist of SGN-CD19A, SGN-CD33A, SGN-LIV1A, ASG-22ME, and ASG-15ME. We recently announced plans to advance a novel ADC that targets CD70, SGN-CD70A, into phase 1 clinical development during the second half of 2014. In addition, we have multiple pre-clinical-stage programs that are being developed as potential candidates for future clinical-stage development. 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 Pharma AG, 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; Pfizer, Inc., or Pfizer, PSMA Development Company LLC, a subsidiary of Progenics Pharmaceuticals Inc., or Progenics; and Takeda; as well as ADC co-development agreements with Agensys, Inc., an affiliate of Astellas Pharma, Inc., or Agensys, Genmab A/S, or Genmab, and Oxford BioTherapeutics Ltd., or OBT.

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The commercial potential of ADCETRIS and the ability to realize that potential by us and Takeda remains uncertain. Our success in effectively commercializing ADCETRIS will continue to require, among other things, effective sales, marketing, manufacturing, distribution, information systems and pricing strategies, our ability to demonstrate in the medical community the safety and efficacy of ADCETRIS and its potential advantages, and our ability to comply with applicable laws and regulations. Our success could be unfavorably impacted by adverse events or competition. The U.S. Food and Drug Administration, or 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. Similarly, Takeda is required to conduct post-approval confirmatory studies as a condition to the conditional marketing authorization of ADCETRIS by the European Commission and regulatory authorities in other countries. In addition, we currently expect that future ADCETRIS sales growth, if any, will depend primarily on our ability to expand ADCETRIS labeled indications of use. Accordingly, we are exploring the use of ADCETRIS in earlier lines of therapy in patients with Hodgkin lymphoma and MTCL, 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 Takeda are conducting four phase 3 clinical trials of ADCETRIS, one in Hodgkin lymphoma patients at high risk of relapse following autologous stem cell transplant, or ASCT, called the AETHERA trial, one in relapsed cutaneous T-cell lymphoma, or CTCL, called the ALCANZA trial, one in front-line advanced classical Hodgkin lymphoma, called the ECHELON-1 trial, and one in front-line MTCL, including sALCL, called the ECHELON-2 trial. Based on current estimates of progression events from pooled, blinded data from the ongoing AETHERA trial, we have amended the trial design to enable a time point-driven progression-free survival analysis after patients have completed all required scans, which is anticipated to occur in the second half of 2014. The AETHERA trial is not being conducted under a Special Protocol Assessment, or SPA, agreement from the FDA and has not been designated as a confirmatory trial to convert either accelerated approval or conditional marketing authorization to regular approval; however, this trial will provide drug safety data analyses and fulfills one of our post-approval requirements with both the FDA and the European Medicines Agency, or EMA. We have entered into SPA agreements with the FDA for the ALCANZA, ECHELON-1 and ECHELON-2 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, or BLA, submission to the FDA if the trial achieves its primary endpoints. The primary end point in the ECHELON-1 and ECHELON-2 trials is progression-free survival per independent review facility assessment in patients treated with ADCETRIS compared to that achieved with therapy in the control arm. The primary endpoint in the ALCANZA trial is overall response rate, lasting at least four months, in patients treated with ADCETRIS compared to that achieved with therapy in the control arm.

We have an agreement with Ventana Medical Systems, Inc., a member of the Roche Group, or Ventana, under which Ventana is working to develop, manufacture and commercialize a molecular companion diagnostic test with the goal of identifying patients who might respond to treatment with ADCETRIS based on CD30 expression levels in their tissue specimens. A molecular companion diagnostic is not required for the current approved indications for ADCETRIS; however, we are utilizing a molecular companion diagnostic to screen patients for inclusion in our ECHELON-2 and ALCANZA trials, and we expect that a molecular companion diagnostic may be required by regulatory authorities to support regulatory approval of ADCETRIS in other CD30-positive malignancies.

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

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antibody until it binds to the cell surface receptor on the target cell and then to release the cytotoxic agent upon internalization within the target cell. This targeted delivery of the cell-killing agent is intended to maximize delivery of the cytotoxic agent to targeted cells while minimizing toxicity to normal tissues. Our ADCs use proprietary auristatins, which are microtubule disrupting agents, or pyrrolobenzodiazepine, or PBD, dimers, which are DNA cross-linkers, as cell-killing agents. The PBD dimer cell killing agent is stably linked to an antibody using our proprietary, site-specific conjugation technology, resulting in uniform drug-loading of two PBD dimers per antibody. We call this engineered antibody an EC-mAb. In contrast to natural products that are often more difficult to produce and link to antibodies, our drugs are synthetically produced and easier to scale for manufacturing. ADCETRIS, SGN-CD19A, SGN-CD33A, SGN-LIV1A, ASG-22ME, and ASG-15ME all utilize our proprietary, auristatin-based or PBD-based ADC technology, and this technology is also the basis of our corporate collaborations. We own or hold exclusive or partially-exclusive licenses to multiple issued patents and patent applications covering our ADC technology. We continue to evaluate new linkers, antibody formats, and cell-killing agents for use in our ADC programs.

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 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, specifically fucose. 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 targeted therapies for cancer. Key elements of our strategy are to:

Successfully Execute ADCETRIS Commercial Plan. An important near-term objective is to continue to execute our ADCETRIS commercial plan by maintaining or increasing market penetration and continuing to drive duration of therapy, consistent with the current ADCETRIS label. We continue to focus 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. As of January 31, 2014, ADCETRIS had received marketing authorizations in relapsed Hodgkin lymphoma and sALCL by regulatory authorities in 39 countries, and we are continuing to support Takeda s efforts to obtain regulatory approvals and conduct commercial launches in many other countries worldwide.

Expand the Therapeutic Potential of ADCETRIS. We believe ADCETRIS may have applications in earlier lines of therapy for Hodgkin lymphoma and MTCL and in other types of CD30-positive cancers. We are conducting a phase 3 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. Based on current estimates of progression events from pooled, blinded data from the ongoing AETHERA trial, the AETHERA trial has been amended to enable a time point-driven progression-free survival analysis after patients have completed all required scans, which is anticipated to occur in the second half of 2014. We have reported encouraging data and we also have ongoing clinical trials evaluating ADCETRIS in earlier lines of therapy for Hodgkin lymphoma (the ECHELON-1 trial), MTCL (the ECHELON-2 trial), and in other types of CD30-positive lymphoma such as CTCL, peripheral T-cell lymphoma and some types of B-cell lymphomas including diffuse large B-cell lymphoma, or DLBCL. We are also supporting both corporate and investigator sponsored trials in different CD30-positive indications, including CTCL, salvage therapy for patients with Hodgkin

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lymphoma prior to autologous hematopoietic cell transplant, novel combinations of ADCETRIS plus other anticancer agents, graft versus host disease and other areas of medical and scientific interest.

Continue to Develop our Other Pipeline Programs. We believe that it is important to maintain a diverse pipeline of product candidates to sustain our future growth. To accomplish this, we are continuing to advance the development of our other clinical product candidates, particularly SGN-CD19A, SGN-CD33A, SGN-LIV1A, ASG-22ME, and ASG-15ME, as well as our preclinical programs, such as SGN-CD70A, and research-stage programs that employ our proprietary technologies. In addition, we have ADC co-development agreements with Genmab and OBT that provide us with future ADC product opportunities.

Continue to Leverage our Industry-Leading ADC Technology. We have developed proprietary ADC technology designed to empower monoclonal antibodies. We are currently developing multiple product candidates that employ our ADC technology, including SGN-CD19A, SGN-CD33A, SGN-LIV1A, ASG-22ME, and ASG-15ME and several preclinical programs, including SGN-CD70A. 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, Takeda, Pfizer and Progenics, as well as ADC co-development agreements with Agensys, Genmab and OBT. Our ADC technology licensing deals have generated over $250 million as of December 31, 2013 through a combination of upfront payments, research support, and other fees, milestone payments and equity purchases.

Support Future Growth of our Pipeline through Internal Research Efforts and Strategic In-Licensing. We have internal research programs directed toward identifying novel antigen targets, monoclonal antibodies and other targeting molecules, creating new antibody engineering techniques and developing new classes of stable linkers and cell-killing agents for our ADC technology. In addition, we supplement these internal efforts through ongoing initiatives to identify product candidates, products and technologies to in-license from biotechnology and pharmaceutical companies and academic institutions. We have license agreements with Bristol-Myers Squibb Corporation and the University of Miami, among others, which provide us with access to technology used in our development programs. We also have active research collaborations with other biotechnology companies and academic institutions to help advance our technology.

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, including seeking to retain product rights in the United States and Europe.

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ADCETRIS and Product Candidate Development Pipeline

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

Name of Product or Product Candidate	Description	Commercial Rights	Status
ADCETRIS®	Anti-CD30 ADC	Seattle Genetics in United States and Canada; Takeda in rest of world	ADCETRIS received accelerated approval in the United States in 2011, conditional approval in the European Union in 2012, approval with conditions in Canada in 2013 and marketing authorization in Japan in 2014, among other countries, for patients with relapsed Hodgkin lymphoma or relapsed sALCL. As of January 31, 2014, ADCETRIS had received marketing authorizations in relapsed Hodgkin lymphoma or relapsed sALCL by regulatory authorities in 39 countries.
			AETHERA phase 3 randomized trial ongoing for patients with Hodgkin lymphoma at high risk of relapse following ASCT. Enrollment was completed in 2012. The AETHERA trial was recently amended to enable a time point-driven progression-free survival analysis after patients have completed all required scans, which is anticipated to occur in the second half of 2014.
			ECHELON-1 phase 3 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 3 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 3 randomized trial ongoing for relapsed CD30-positive CTCL patients, comparing ADCETRIS versus investigator s choice of methotrexate or bexarotene.
			Phase 2 trial ongoing for patients with relapsed or refractory CD30-positive non-Hodgkin lymphomas, including DLBCL, peripheral T-cell lymphoma and other less common lymphoma subtypes (but excluding sALCL).

	Phase 2 CD30-screening and treatment trial ongoing for patients with CD30-positive non-lymphoma malignancies, including multiple myeloma, leukemia and solid tumors.

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Name of Product or Product Candidate	Description	Commercial Rights	Status
			Phase 2 trial ongoing for patients age 60 or older with newly diagnosed Hodgkin lymphoma evaluating ADCETRIS as a front-line monotherapy. In addition, the trial was recently amended to include the administration of ADCETRIS in combination with dacarbazine.
			Phase 1/2 second-line trial ongoing for patients with relapsed Hodgkin lymphoma evaluating ADCETRIS in combination with bendamustine.
			Phase 2 front-line trial ongoing for patients with DLBCL evaluating ADCETRIS in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone, or R-CHOP.
SGN-CD19A	Anti-CD19 ADC	Seattle Genetics	Two phase 1 trials ongoing for relapsed or refractory B-cell acute lymphoblastic leukemia, or ALL, and relapsed or refractory B-cell non-Hodgkin lymphomas.
SGN-CD33A	Anti-CD33 ADC	Seattle Genetics	Phase 1 trial ongoing for patients with acute myeloid leukemia, or AML.
SGN-LIV1A	Anti-LIV1 ADC	Seattle Genetics	Phase 1 trial ongoing for patients with LIV-1-positive metastatic breast cancer.
ASG-22ME	Anti-Nectin-4 ADC	50:50 co-development and commercialization with Agensys	Phase 1 trial ongoing for Nectin-4-positive solid tumors.
ASG-15ME	Anti-SLITRK6 ADC	50:50 co-development and commercialization with Agensys	Phase 1 trial ongoing for patients with bladder cancer.

ADCETRIS

ADCETRIS is an ADC comprising an anti-CD30 monoclonal antibody attached by a protease-cleavable linker to a proprietary microtubule disrupting agent, monomethyl auristatin E (MMAE). ADCETRIS employs a linker system that is designed to be stable in the bloodstream and to release MMAE upon internalization into CD30-positive cells. We believe that the CD30 antigen is an attractive target for cancer therapy because it is expressed on multiple types of cancer, but has limited expression on normal tissues. We are collaborating with Takeda on the global development and commercialization of ADCETRIS. Under this collaboration, we retain commercial rights in the United States and Canada. Takeda has exclusive rights to commercialize ADCETRIS in the rest of the world. ADCETRIS has received regulatory approvals as follows:

United States. In August 2011, the FDA granted accelerated approval of ADCETRIS in two indications: (1) the treatment of patients with Hodgkin lymphoma after failure of ASCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates and (2) the treatment of patients with sALCL, after failure of at least one prior multi-agent chemotherapy regimen. These indications are based on response rate. There are no data available demonstrating

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improvement in patient-reported outcomes or survival with ADCETRIS. In July 2013 we received notification from the FDA approving a supplemental Biologics License Application, or sBLA, to remove the 16-cycle limitation on duration of use of ADCETRIS from the U.S. prescribing information. However, a requested label claim for retreatment that we submitted as part of the sBLA was not approved.

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

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

Worldwide. As of January 31, 2014, ADCETRIS had received marketing authorization in relapsed Hodgkin lymphoma and relapsed sALCL by regulatory authorities in 39 countries, including those described above as well as Japan, Australia, Switzerland, South Korea and Singapore.

Required ADCETRIS Post-approval Clinical Studies

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

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

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

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

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Market Opportunities

According to the American Cancer Society, more than 9,200 cases of Hodgkin lymphoma were diagnosed in the United States during 2013, and an estimated 1,180 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. In addition to lymphoma, CD30 is also expressed in leukemia, multiple myeloma and solid tumors, which may provide additional market opportunities in the future. For the reasons discussed in Item 1A Risk Factors , we may not be able to obtain regulatory approvals to market ADCETRIS for front-line Hodgkin lymphoma or MTCL, or otherwise expand its labeled indications of use.

Clinical Development Plan

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

Phase 3 Hodgkin Lymphoma Post-ASCT Relapse Prevention. In April 2010, we initiated a phase 3 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 were required to be at high risk for residual Hodgkin lymphoma, defined as those with a history of refractory Hodgkin lymphoma, those who relapsed or progress within one year from receiving front-line chemotherapy and/or those who had disease outside of the lymph nodes at the time of pre-ASCT relapse. We completed enrollment of the AETHERA trial during 2012. Patients received ADCETRIS every three weeks for up to approximately one year. The primary endpoint of the study is progression-free survival and secondary endpoints include overall survival, safety and tolerability. Based on current estimates of progression events from pooled, blinded data from the ongoing AETHERA trial, the AETHERA trial has been amended to enable a time point-driven progression-free survival analysis after patients have completed all required scans, which is anticipated to occur in the second half of 2014. The AETHERA trial is not being conducted under a SPA agreement from the FDA and has not been designated as a confirmatory trial to convert either accelerated approval or conditional marketing authorization to regular approval. 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.

Phase 3 Front-line Hodgkin Lymphoma. In November 2012, we and Takeda announced a randomized, open-label, phase 3 trial investigating ADCETRIS plus AVD versus ABVD as frontline therapy in patients with advanced classical Hodgkin lymphoma, or the ECHELON-1 trial. The primary endpoint is modified 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 a SPA agreement with the FDA and also received scientific advice from the EMA. We are required to conduct this trial as part of our ADCETRIS post-marketing requirement, and the trial is designed to be confirmatory in the United States, Canada and European Union. At the December 2012 American Society of Hematology, or ASH, meeting we announced results from a phase 1 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. Grade 3 or higher adverse events occurring in more than one patient overall noted in the ABVD and AVD cohorts, respectively, were neutropenia (80 percent, 77 percent), anemia (20 percent,

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12 percent), febrile neutropenia (20 percent, 8 percent) and pulmonary toxicity (24 percent, 0 percent). One patient experienced a Grade 3 peripheral neuropathy event. Data from this phase 1 trial supported initiation of the ECHELON-1 trial.

Phase 3 Front-line Mature T-Cell Lymphoma. In January 2013, we and Takeda initiated a global randomized, double-blind, placebo-controlled multi-center phase 3 clinical trial evaluating ADCETRIS in combination with CHP versus CHOP for the treatment of newly diagnosed CD30-positive MTCL patients, including patients with sALCL and other types of peripheral T-cell lymphomas, or the ECHELON-2 trial. The primary endpoint is 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 is being used in this trial to identify eligible patients based on CD30-expression. We are developing a companion diagnostic under a collaboration agreement with Ventana and Takeda. The trial is being conducted under a SPA agreement with the FDA and also received scientific advice from the EMA. We are required to conduct this trial as part of our ADCETRIS post-marketing requirement, and the trial is designed to be confirmatory in the United States, Canada and European Union. At the December 2013 ASH meeting, we announced updated results from a phase 1 dose-escalation combination trial to evaluate ADCETRIS plus chemotherapy for sALCL, which was subsequently amended to include patients with any CD30-positive MTCL. After completing combination therapy, 26 of 26 patients treated with ADCETRIS plus CHP had an objective response, including 23 patients with a complete remission. The most common treatment-emergent adverse events of any grade occurring in more than 40 percent of patients were peripheral sensory neuropathy (69 percent), nausea (65 percent), diarrhea (58 percent), fatigue (58 percent), shortness of breath (46 percent) and constipation (38 percent). Data from this trial supported initiation of the ECHELON-2 trial. In addition, we recently reported that ADCETRIS has been added to the National Comprehensive Cancer Network, or NCCN, guidelines for the treatment of relapsed CD30-positive peripheral T-cell lymphoma.

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

Relapsed or Refractory CD30-Positive Non-Hodgkin Lymphoma, including DLBCL and other B-cell Lymphomas. In August 2011, we initiated a phase 2 trial for patients with relapsed or refractory CD30-positive non-Hodgkin lymphomas, including DLBCL, peripheral T-cell lymphoma and other less common lymphoma subtypes, but excluding sALCL. The primary endpoint of this trial is to determine the antitumor activity of ADCETRIS as measured by objective response rate. In addition, the trial will assess safety and characterize the relationship of CD30 expression with potential antitumor activity. Interim data were reported at the December 2013 ASH meeting from 50 patients with relapsed DLBCL. Of these patients, 42 percent achieved an objective response, including 16 percent complete remissions and 26 percent partial remissions. At the time of data analysis, the median duration of response for DLBCL was 5.8 months. For DLBCL patients who achieved a complete remission, the median duration of response was 11.5 months. Objective responses were observed across a broad range of CD30 expression, from DLBCL patients with undetectable CD30 by standard immunohistochemistry testing to those with CD30 expression up to 90 percent. The most common treatment-emergent adverse events of any grade in patients with DLBCL and other B-cell lymphomas occurring in more

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than 25 percent of all patients enrolled were fatigue (49 percent), neutropenia (40 percent), nausea (38 percent), diarrhea (37 percent) and fever (29 percent). The most common Grade 3 treatment-emergent adverse events in patients with DLBCL and other B-cell lymphomas were neutropenia and anemia. The only Grade 4 treatment-emergent event was neutropenia. Serious adverse events considered related to treatment and occurring in more than one patient were pneumonia (three patients), anemia, febrile neutropenia, neutropenia and thrombocytopenia (two patients each). Enrollment is ongoing and the study is expected to enroll more than 150 patients at multiple centers in the United States.

Front-line Therapy for Hodgkin Lymphoma Patients Age 60 and Over. In October 2012, we initiated a phase 2 clinical trial evaluating ADCETRIS monotherapy as a front-line therapy for patients age 60 or older with newly diagnosed Hodgkin lymphoma. The phase 2 single-arm, open-label clinical trial will evaluate the efficacy and tolerability of ADCETRIS in patients age 60 or older with Hodgkin lymphoma. The primary endpoint of the trial is 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 50 patients at multiple centers in the United States. In addition, we recently amended the trial to include the administration of ADCETRIS in combination with dacarbazine.

Second-line Therapy for Relapsed or Refractory Hodgkin Lymphoma Patients. In June 2013, we initiated a phase 1/2 single-arm, open-label clinical trial to evaluate the efficacy and tolerability of ADCETRIS in combination with bendamustine in Hodgkin lymphoma patients after first relapse. The multi-phase study is divided into two cohorts to determine the recommended dose and tolerability of ADCETRIS in combination with bendamustine and to assess the complete remission rate associated with combination use. Bendamustine is an alkylating agent used in the treatment of chronic lymphocytic leukemias and lymphomas. Patients are eligible to receive up to six cycles of ADCETRIS in combination with bendamustine followed by additional single-agent ADCETRIS for a total of 16 cycles. As a part of the trial design, after patients receive ADCETRIS plus bendamustine combination therapy, they have the option to pause therapy to receive an ASCT and then resume treatment with single-agent ADCETRIS as consolidation. At the February 2014 American Medical Association Bone Marrow Transplant Tandem Meetings, we presented interim data that included 23 patients who were evaluable for safety and 13 patients who were evaluable for response at the time of data analysis. After a median of two cycles of therapy, 92 percent of patients evaluable for response (12 of 13 patients) achieved an objective response, including 77 percent (ten patients) with complete remissions and 15 percent (two patients) with partial remissions. At the time of analysis, the two patients with partial remissions had each received two cycles of therapy and treatment was ongoing. The most common adverse events were nausea (57 percent), rash (39 percent), fever (35 percent), fatigue (30 percent) and vomiting (30 percent). The most common Grade 3 or 4 adverse event was lymphopenia (13 percent Grade 3; nine percent Grade 4). Infusion reactions considered related to combination therapy were reported as serious adverse events in six patients and led to treatment discontinuation for three patients. As a result, the protocol is being amended to require premedication with corticosteroids and antihistamines. Enrollment is ongoing and expected to include up to 50 patients at multiple centers in the United States.

Front-line Therapy for DLBCL Patients. In August 2013, we initiated a phase 2 study of ADCETRIS in combination with R-CHOP as front-line therapy in patients with DLBCL. This study will evaluate the safety and antitumor activity of adding ADCETRIS to standard front-line therapy for DLBCL. The study is expected to enroll up to 50 patients at multiple centers in the United States.

Investigator-Sponsored Studies. As of December 31, 2013, there were 24 ongoing investigator sponsored trials of ADCETRIS in the U.S. In addition, we and Takeda are reviewing proposals from multiple clinical investigators and cooperative groups in the United States, Canada and Europe about potential clinical trials of ADCETRIS. The investigator sponsored trials 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

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of ADCETRIS in other CD30-positive and select CD30-undetectable settings, such as novel combinations of therapy and graft versus host disease.

SGN-CD19A

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

At the December 2013 ASH annual meeting, we announced interim data from 16 adult patients and four pediatric patients with relapsed or refractory B-lineage ALL and highly aggressive lymphoma, including B-cell lymphoblastic lymphoma, or B-LBL, and Burkitt lymphoma. At the time of interim data analysis, the maximum tolerated dose had not yet been reached and enrollment and dose escalation was ongoing. Of the 16 adult patients treated across all dose levels, three achieved a complete remission or complete remission with incomplete platelet recovery, eight had resistant disease with clinical benefit or stable disease, and five had progressive disease. At dose levels greater than 1.0 milligram per kilogram (mg/kg), eight of 10 adult patients had clinical benefit, consisting of complete remission, complete remission with incomplete platelet recovery, resistant disease with clinical benefit or stable disease. Of the four pediatric patients, one patient had resistant disease with clinical benefit, one had resistant disease without clinical benefit, one had progressive disease and one was unevaluable. The most common adverse events of any grade occurring in adult patients were fever, nausea, chills, fatigue, blurred vision and vomiting. Adverse events seen in at least two pediatric patients were vomiting and abdominal pain, cough, shortness of breath, nausea and fever. We plan to report additional data from both phase 1 trials of SGN-CD19A during 2014.

SGN-CD33A

SGN-CD33A is an ADC composed of an anti-CD33 monoclonal antibody linked to a potent PBD dimer using our proprietary ADC technology, and is a product candidate for the treatment of AML. SGN-33A targets CD33, a protein that is expressed on most AML cells. SGN-CD33A employs our newest proprietary ADC technology. This technology is comprised of a PBD dimer, which is a potent cell-killing agent that works by a different mechanism than auristatins, linked to an engineered antibody called EC-mAb, resulting in uniform drug-loading of two PBD dimers per antibody.

In July 2013 we initiated a phase 1, open-label, multi-center, dose-escalation clinical trial of SGN-CD33A. The primary endpoints of the study are the estimation of the maximum tolerated dose and evaluation of the safety of SGN-CD33A. In addition, the trial will evaluate anti-leukemia activity, pharmacokinetics, progression-free survival and overall survival in patients with CD33-positive AML. The dose escalation portion of the study is designed to evaluate SGN-CD33A administered every three weeks and will enroll up to approximately 90 patients at multiple centers in the United States. Patients who achieve a complete remission are eligible to continue to receive SGN-CD33A at a lower, maintenance

dose given every three weeks. Dose escalation cohorts that show evidence of anti-leukemia activity may be expanded to allow for a more comprehensive evaluation of safety and clinical activity. We expect to report data from this phase 1 trial of SGN-CD33A during 2014.

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SGN-LIV1A

SGN-LIV1A is an ADC composed of an anti-LIV-1 monoclonal antibody linked to a potent auristatin compound using our proprietary ADC technology, and is a product candidate for the treatment of LIV-1-positive metastatic breast cancer. In October 2013 we initiated a phase 1, open-label, dose-escalation clinical trial to evaluate the safety and antitumor activity of SGN-LIV1A in patients with LIV-1-positive metastatic breast cancer. The trial is enrolling patients with triple negative disease who have previously been treated with at least two prior cytotoxic regimens in the metastatic setting, or patients with ER-positive and/or PR-positive and HER2-negative disease who have previously been treated with at least two prior cytotoxic regimens in the metastatic setting, and at least three prior hormonal therapies. The primary endpoint of the trial is safety, with key secondary endpoints of objective response, duration of response and progression-free survival. The study is expected to enroll up to 70 patients at multiple centers in the United States.

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 1 clinical trial of ASG-22ME for the treatment of Nectin-4-positive solid tumors was initiated in July 2011. This trial is evaluating 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.

ASG-15ME

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

SGN-70A

SGN-CD70A is an ADC composed of an anti-CD70 EC-mAb linked to a potent PBD dimer using our proprietary ADC technology, and is a product candidate for the treatment of CD70-positive renal cell carcinoma and non-Hodgkin lymphoma. We plan to initiate a phase 1, open-label, multi-center, dose escalation clinical trial of SGN-CD70A during 2014.

Research Programs

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

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

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 other targeting molecules and ADCs with novel specificities and activities against selected antigen targets. We focus on antigen targets that are highly expressed on the surface of cancer cells that may serve as targets for monoclonal antibodies or ADCs. We then create and screen panels of cancer-reactive monoclonal antibodies in our laboratories to identify those with the desired specificity. We supplement these internal efforts by evaluating opportunities to in-license targets and antibodies from academic groups and other biotechnology and pharmaceutical companies, such as our ongoing co-development collaborations with Genmab and OBT.

Antibody Engineering. We have substantial internal expertise in antibody engineering, both for antibody humanization and defucosylation, as well as engineering of antibodies to improve drug linkage sites for use with our ADC technology. By modifying the number and type of drug-linkage sites found on our antibodies, we believe that we can improve the robustness and cost-effectiveness of our manufacturing processes for conjugation of ADCs.

Research and Development Expense

Since inception, we have devoted a significant amount of resources to develop our product candidates and our antibody-based technologies. For the years ended December 31, 2013, 2012, and 2011, we recorded $218.6 million, $170.3 million, and $163.4 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.

Takeda ADCETRIS Collaboration

In December 2009, we entered into a collaboration agreement with Takeda to develop and commercialize ADCETRIS, under which Seattle Genetics retains commercial rights in the United States and its territories and in Canada, and Takeda and its Takeda affiliates have commercial rights in the rest of the world. As of December 31, 2013, we had received an upfront payment of $60 million and had achieved 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 Takeda s achievement of significant events under the collaboration in addition to tiered royalties with percentages starting in the mid-teens and escalating to the mid-twenties based on net sales of ADCETRIS within Takeda s licensed territories. Takeda also bears a portion of third party royalty costs owed on sales of ADCETRIS in its territory. Takeda is funding half of joint worldwide development costs under the collaboration, excluding costs solely related to development in Japan, which Takeda is solely responsible for funding. Although we are funding half of joint worldwide development costs, Takeda is responsible for the achievement of the progress- and sales-dependent milestone payments that we may receive. Either party may terminate the collaboration agreement if the other party materially breaches the agreement and such breach remains uncured. Takeda may terminate the collaboration agreement for any reason upon prior written notice to us and we may terminate the collaboration agreement in 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. Under this collaboration, Agensys is conducting research and development aimed at identifying ADC product candidates for multiple designated antigens as well as clinical trials on various ADC product candidates.

The co-development provisions of the collaboration agreement included an initial co-development product candidate, ASG-5ME, and provided us with two options to co-develop additional product candidates. We have exercised all of our co-development options and are currently co-developing ASG-22ME and ASG-15ME. Development of ASG-5ME has been discontinued. We and Agensys are co-funding all development and commercialization costs for both ASG-22ME and ASG-15ME, and will share equally in any profits for these product candidates. We and Agensys initiated a phase 1 clinical trial of ASG-22ME for the treatment of Nectin-4 positive solid tumors in July 2011. A phase 1 clinical trial of ASG-15ME for the treatment of bladder cancer was initiated in October 2013.

Agensys has the right to develop and commercialize the other ADC product candidates on its own, subject to paying us annual maintenance fees, milestones, royalties and support fees for research and development services and material provided under the collaboration agreement. We are entitled to receive progress- and sales-dependent milestone payments of up to approximately $195 million based on Agensys achievement of significant events under the collaboration in addition to mid-single digit royalties on net sales of any of these other ADC product candidates by Agensys. Either party may opt out of co-development and profit-sharing in return for receiving milestones and royalties from the continuing party. Either party may terminate the collaboration agreement if the other party becomes insolvent or the other party materially breaches the agreement and such breach remains uncured. Subject to certain restrictions, either party may terminate the collaboration agreement for any reason upon prior written notice to the other party. The collaboration agreement can also be terminated by mutual written consent of the parties. If neither party exercises its option to terminate the collaboration agreement, then the agreement will automatically terminate on the later of: (a) the expiration of all payment obligations pursuant to the collaboration agreement, or (b) the day upon which we and Agensys cease to develop and commercialize products under the agreement.

Genmab Co-Development Collaboration

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

ADC Collaborations