

SEATTLE GENETICS INC /WA  
Form 10-K  
March 12, 2010  
Table of Contents

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

Washington, D.C. 20549

**Form 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2009

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 0-32405

## Seattle Genetics, Inc.

(Exact name of registrant as specified in its charter)

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

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

**21823 30<sup>th</sup> Drive SE**  
**Bothell, WA 98021**

(Address of principal executive offices, including zip code)

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

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

Title of class	Name of each exchange on which registered
<b>Common Stock, par value \$0.001</b>	<b>The NASDAQ Stock Market LLC</b>

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

**None**

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

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

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

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

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

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

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

Large accelerated filer

Non-accelerated filer  (Do not check if smaller reporting company)

Accelerated filer

Smaller reporting company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$696,136,787 million 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 Market reported for such date. Excludes an aggregate of 15,264,720 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 100,655,967 shares of the registrant's Common Stock issued and outstanding as of March 10, 2010.

### 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 2010 Annual Meeting of Stockholders.



**Table of Contents**

**SEATTLE GENETICS, INC.**

**FORM 10-K**

**FOR THE YEAR ENDED DECEMBER 31, 2009**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I</u></b>	
Item 1. <u>Business</u>	3
Item 1A. <u>Risk Factors</u>	22
Item 1B. <u>Unresolved Staff Comments</u>	37
Item 2. <u>Properties</u>	37
Item 3. <u>Legal Proceedings</u>	37
Item 4. <u>(Removed and Reserved)</u>	37
<b><u>PART II</u></b>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	38
Item 6. <u>Selected Financial Data</u>	40
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	41
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	54
Item 8. <u>Financial Statements and Supplementary Data</u>	55
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	82
Item 9A. <u>Controls and Procedures</u>	82
Item 9B. <u>Other Information</u>	82
<b><u>PART III</u></b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	83
Item 11. <u>Executive Compensation</u>	83
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	83
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	83
Item 14. <u>Principal Accounting Fees and Services</u>	83
<b><u>PART IV</u></b>	
Item 15. <u>Exhibits, Financial Statement Schedules</u>	84
<u>Signatures</u>	88

## **Table of Contents**

### **PART I**

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

#### **Item 1. Business.**

##### **Overview**

Seattle Genetics is a clinical stage biotechnology company focused on the development and commercialization of monoclonal antibody-based therapies for the treatment of cancer and autoimmune diseases. In August 2009, we completed enrollment to a pivotal trial of our lead product candidate, brentuximab vedotin (SGN-35), for patients with relapsed or refractory Hodgkin lymphoma under a special protocol assessment, or SPA, with the U.S. Food and Drug Administration, or FDA, and we expect to report data from the trial in the second half of 2010. Brentuximab vedotin is empowered by our proprietary antibody-drug conjugate, or ADC, technology comprising highly potent synthetic drugs and stable linkers for attaching the drugs to monoclonal antibodies. In December 2009, we entered into a collaboration agreement with Millennium: The Takeda Oncology Company, or Millennium, to develop and commercialize brentuximab vedotin, under which Seattle Genetics has United States and Canadian commercial rights and Millennium has commercial rights in the rest of the world. We are also expecting to report data from an ongoing phase IIb trial of lintuzumab (SGN-33) for patients with acute myeloid leukemia, or AML, during the second quarter of 2010. In addition, we have three other product candidates in ongoing clinical trials: dacetuzumab (SGN-40), SGN-70 and SGN-75. Our worldwide dacetuzumab collaboration with Genentech, Inc., a wholly-owned member of the Roche Group, or Genentech, will end in June 2010 and, as a result, we will be solely responsible for any continued development of that product candidate.

We have collaborations for our ADC technology with a number of leading biotechnology and pharmaceutical companies, including: Bayer Pharmaceuticals Corporation, or Bayer; Celldex Therapeutics, Inc., or Celldex; Daiichi Sankyo Co., Ltd., or Daiichi Sankyo; Genentech; GlaxoSmithKline LLC, or GSK; MedImmune, Inc., a subsidiary of AstraZeneca Biopharmaceuticals Inc., or MedImmune; Millennium; and PSMA Development Company LLC, a subsidiary of Progenics Pharmaceuticals, Inc., or Progenics; as well as an ADC co-development agreement with Agensys, Inc., an affiliate of Astellas Pharma Inc., or Agensys.

##### **Monoclonal Antibodies for Cancer Therapy**

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

Antibodies are proteins released by the immune system's B-cells, a type of white blood cell, in response to the presence of a foreign entity in the body, such as a virus or bacteria, or in some abnormal cases, during an autoimmune response. B-cells collectively produce millions of different kinds of antibodies, which have slightly different characteristics that enable them to bind to specific molecular targets. Once bound to the specific target,

## **Table of Contents**

the antibody may neutralize the target cell directly or recruit other parts of the immune system to neutralize the target cell. Antibodies that have identical molecular structures and bind to a specific target are called monoclonal antibodies. The inherent selectivity of monoclonal antibodies makes them ideally suited for targeting specific cells, such as cancer cells, while bypassing most normal tissue.

There are an increasing number of antibody-based products that have been approved for the treatment of cancer. These include six engineered monoclonal antibodies (Rituxan<sup>®</sup>, Herceptin<sup>®</sup>, Campath<sup>®</sup>, Avastin<sup>®</sup>, Erbitux<sup>®</sup> and Vectibix<sup>®</sup>), two radionuclide-conjugated monoclonal antibodies (Zevalin<sup>®</sup> and Bexxar<sup>®</sup>) and an antibody-drug conjugate (Mylotarg<sup>®</sup>). Together, these nine products generated worldwide sales of more than \$18 billion in 2009. Additionally, there are many monoclonal antibodies in preclinical and clinical development that are likely to increase the number of monoclonal antibody-based commercial products in the future.

Cancer is the second most common cause of death in the United States, resulting in over 560,000 deaths annually. The American Cancer Society estimated that more than 1.4 million new cases of cancer were diagnosed in the United States during 2009. The World Health Organization, or WHO, estimates that more than 11 million people worldwide are diagnosed with cancer each year, a rate that is expected to increase to an estimated 15 million people annually by the year 2030. Nearly eight million people die of cancer worldwide each year, and WHO projects that cancer deaths will increase 45 percent by 2030 to nearly twelve million deaths worldwide. According to the National Cancer Institute, approximately 35 percent of people with cancer will die within five years after being diagnosed.

## **Our Monoclonal Antibody Technologies**

Our pipeline of monoclonal antibody-based product candidates utilizes three technologies to maximize antitumor activity and reduce toxicity. The first technology is the use of genetic engineering to produce monoclonal antibodies that have intrinsic antitumor activity with lowered risk of adverse events or autoimmune response. The second involves attaching a highly potent cell-killing drug to an antibody, which delivers and releases the drug inside the tumor cell. The resulting hybrid molecule is called an antibody-drug conjugate, or ADC. The third technology 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. We also 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.

### *Engineered Monoclonal Antibodies*

Our antibodies are genetically engineered to reduce non-human protein sequences, thereby lowering the potential for patients to develop a neutralizing immune response to the antibodies and potentially extending the duration of their use in therapy. Our monoclonal antibody engineering activities are primarily focused on developing humanized monoclonal antibodies. We have substantial expertise in humanizing antibodies and have non-exclusive licenses to antibody humanization patents owned by PDL BioPharma, Inc., or PDL BioPharma. Through our ADC co-development agreement with Agensys, we also have the opportunity to co-develop ADCs incorporating fully-human antibodies.

Some monoclonal antibodies have intrinsic antitumor activity and can kill cancer cells on their own either by directly sending a cell-killing signal, by activating an immune response that leads to cell death and/or by inhibiting the growth of cancer cells. These antibodies can be effective in tumor regression and have the advantage of low systemic toxicity. For example, antibodies targeted to antigens such as CD20 (Rituxan), HER2 (Herceptin), CD52 (Campath), VEGF (Avastin) and EGFR (Erbitux) can kill tumor cells in this manner. Lintuzumab, dacetuzumab and SGN-70 fall into the category of engineered antibodies that have intrinsic antitumor activity without conjugation to a drug or further enhancement by modifying sugars.



*Antibody-Drug Conjugates (ADCs)*

ADCs are monoclonal antibodies that are linked to potent cell-killing drugs. Our ADCs utilize monoclonal antibodies that internalize within target cells after binding to their cell-surface receptors. Enzymes present inside

## **Table of Contents**

the cell cause the cell-killing drug to be released from the monoclonal antibody, allowing it to have the desired activity. A key component of our ADCs is the linker that attaches the drug to the monoclonal antibody. When the ADC is internalized within the target cell, the drug is released, thereby minimizing toxicity to normal tissues. Our ADCs use auristatins, which are highly potent cell-killing drugs. 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. Brentuximab vedotin, SGN-75, ASG-5ME and SGN-19A all utilize our proprietary, auristatin-based ADC technology, and this technology is also the basis of many 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 and potent, cell-killing drugs for use in our ADC programs.

### *Sugar Engineered Antibodies (SEA)*

Our proprietary SEA technology is a novel approach to increasing the potency of monoclonal antibodies through enhanced effector function. SEA technology comprises sugar analogs that inhibit the incorporation of fucose, a sugar, into monoclonal antibodies, resulting in minimal fucosylation and improved antibody-dependent cellular cytotoxicity, or ADCC, activity in preclinical models. ADCC functions by recruiting the body's immune system to attack and kill target cells and is an important contributor to the potency of many monoclonal antibodies.

A key feature of our SEA technology is that the sugar analogs can be readily added to standard cell culture media used in the production of monoclonal antibodies, without significantly modifying the underlying manufacturing processes, yields and product quality. We believe that the SEA approach is much simpler and more cost-effective to implement as compared to existing technologies for enhancing antibody effector function, most of which require genetic modifications to the antibody or cell lines. In model systems, SEA technology has been shown to be applicable across a wide range of antibodies and antibody-producing cell lines, and can also be readily applied when screening antibodies for the desired activity. We have filed patent applications covering our novel SEA technology and we intend to employ the SEA technology in our internal early-stage pipeline, providing an alternative approach to increasing the potency of antibodies, as well as to evaluate licensing opportunities.

## **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:

*Advance our Five Lead Clinical Programs toward Regulatory Approval and Commercialization.* Our primary goal is to advance our five lead clinical product candidates, brentuximab vedotin, lintuzumab, dacetuzumab, SGN-70 and SGN-75, through clinical trials to regulatory approval and commercialization. During 2009, we continued to expand our clinical group and broaden our relationships with experts in hematology and oncology at leading cancer centers in the United States and Europe to support aggressive advancement of our ongoing and planned clinical trials. In late 2009, we advanced SGN-75 into a clinical trial for metastatic renal cell carcinoma and relapsed and refractory non-Hodgkin lymphoma. We also began building a commercial infrastructure to support sales and marketing of brentuximab vedotin in the United States and Canada, if approved for commercial sale. We expect to report top-line data from our pivotal trial of brentuximab vedotin in relapsed and refractory Hodgkin lymphoma in the second half of 2010, and, if the results from the trial are positive, we plan to submit a New Drug Application, or NDA, to the FDA in the first half of 2011. We also expect to receive top-line data from our lintuzumab phase IIb trial in the second quarter of 2010.

*Enter into Strategic Collaborations to Generate Capital and Supplement our Internal Resources.* We enter into collaborations at appropriate stages in our drug development process to broaden and accelerate clinical trials and commercialization of our product

candidates. Collaborations can generate significant capital, supplement our own internal expertise in key areas such as manufacturing, regulatory

**Table of Contents**

affairs and clinical development, and provide us with access to our collaborators' marketing, sales and distribution capabilities. When establishing strategic collaborations, we seek strong financial terms and endeavor to retain significant product rights, such as our brentuximab vedotin collaboration with Millennium, in which we retained commercial rights in the United States and Canada.

*Maintain a Strong Product Candidate Pipeline by Advancing our Preclinical Programs toward Clinical Trials.* 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 currently have two lead preclinical programs, ASG-5ME, which we and Agensys expect to advance into clinical trials in 2010, and SGN-19A, which is a future Investigational New Drug application, or IND, candidate. We also have several other preclinical programs at the research stage that employ either our SEA or ADC technologies. In addition, we have an ADC co-development agreement with Agensys that provides us with the opportunity to co-develop two additional ADCs.

*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 brentuximab vedotin, SGN-75, ASG-5ME and several other preclinical programs. We also license our ADC technology to leading biotechnology and pharmaceutical companies to generate near-term revenue and funding, as well as potential future milestones and royalties. Presently, we have active ADC collaborations with Bayer, Celldex, Daiichi Sankyo, Genentech, GSK, MedImmune, Millennium and Progenics, as well as an ADC co-development agreement with Agensys. Our ADC technology licensing deals have generated approximately \$110 million as of December 31, 2009 through a combination of upfront and research support fees, milestones 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 potent, 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, or Bristol-Myers Squibb, PDL BioPharma, Facet Biotech Corporation, or Facet, the University of Miami, Arizona State University, Mabtech AB, or Mabtech, and CLB Research and Development, among others. We also have active research collaborations with other biotechnology companies and academic institutions to help advance our ADC technology.

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

The following table summarizes our product candidate development pipeline:

<b>Commercial</b>			
<b>Product Candidate</b>	<b>Description</b>	<b>Rights</b>	<b>Status</b>
Brentuximab vedotin (SGN-35)	Anti-CD30 ADC	Seattle Genetics in United States & Canada; Millennium in rest of world	Pivotal phase II single-agent trial ongoing under an SPA with the FDA in relapsed and refractory Hodgkin lymphoma; enrollment completed and data expected to be reported in the second half of 2010  Phase II single-agent trial ongoing in relapsed and refractory systemic anaplastic large cell lymphoma, or sALCL; enrollment expected to be complete by mid-2010  Phase II retreatment trial ongoing for patients with Hodgkin lymphoma or sALCL who have relapsed after previously responding to brentuximab vedotin  Phase I trial ongoing in combination with adriamycin (doxorubicin), bleomycin, vinblastine and dacarbazine, or ABVD, for front-line treatment of patients with Hodgkin lymphoma
Lintuzumab (SGN-33)	Humanized anti-CD33 antibody	Seattle Genetics	Phase III trial planned to commence in first half of 2010 for patients with Hodgkin lymphoma at high risk of relapse following autologous stem cell transplant, or ASCT Randomized phase IIb trial ongoing in combination with low-dose cytarabine for acute myeloid leukemia, or AML; enrollment completed and data expected to be reported in the second quarter of 2010 Phase I investigator-sponsored trial ongoing in combination with Vidaza <sup>®</sup> for myelodysplastic syndromes, or MDS
Dacetuzumab (SGN-40)	Humanized anti-CD40 antibody	Seattle Genetics	Completing phase Ib trials in non-Hodgkin lymphoma and multiple myeloma; considering next steps for the program
SGN-70	Humanized anti-CD70 antibody	Seattle Genetics	Phase I trial ongoing for autoimmune disease
SGN-75	Anti-CD70 ADC	Seattle Genetics	Phase I trial ongoing for metastatic renal cell carcinoma and non-Hodgkin lymphoma
ASG-5ME	Anti-AGS-5 ADC	50:50 co-development and commercialization	INDs planned to be submitted to the FDA for prostate and pancreatic cancer during 2010

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

SGN-19A	Anti-CD19 ADC	with Agensys Seattle Genetics	Future IND candidate for CD19-positive hematologic malignancies
---------	---------------	----------------------------------	---

## **Table of Contents**

### ***Brentuximab vedotin***

Brentuximab vedotin is an ADC composed of an anti-CD30 monoclonal antibody attached by our proprietary, enzyme-cleavable linker to a compound of the highly potent class of cell-killing drugs called auristatins. The CD30 antigen is an attractive target for cancer therapy because it is expressed on hematologic malignancies including Hodgkin lymphoma and several types of T-cell lymphoma but has limited expression on normal tissues. In December 2009, we entered into a collaboration for brentuximab vedotin with Millennium under which we received a \$60 million upfront payment and retained commercialization rights in the United States and Canada. Millennium has rights to commercialize brentuximab vedotin in the rest of the world and will fund fifty percent of joint development costs, except in Japan where Millennium is fully responsible for funding development costs. Development funding provided by Millennium over the first three years of the collaboration is expected to be at least \$75 million. Seattle Genetics is entitled to receive milestone payments that could total more than \$230 million and tiered double-digit royalties based on net sales in Millennium's territories.

We are currently conducting a single-arm, open-label pivotal trial of brentuximab vedotin for patients with relapsed or refractory Hodgkin lymphoma under an SPA with the FDA. The SPA is an agreement between the FDA and Seattle Genetics regarding the design, including size and clinical endpoints, of the pivotal trial to support an efficacy claim in an NDA. We are also conducting a phase II single-arm, open-label trial for patients with sALCL, a phase II retreatment trial for patients who previously responded to brentuximab vedotin therapy, and a phase I combination study of brentuximab vedotin with ABVD, a common chemotherapy regimen, for the front-line treatment of patients with Hodgkin lymphoma. We have received orphan drug designations from the FDA and the European Medicines Agency, or EMEA, for brentuximab vedotin in Hodgkin lymphoma and sALCL. Our goal is to submit an NDA for brentuximab vedotin in the first half of 2011 under the accelerated approval regulations.

### ***Market Opportunities***

According to the American Cancer Society, approximately 8,500 cases of Hodgkin lymphoma were expected to be diagnosed in the United States during 2009, and an estimated 1,300 people were expected to die of the disease. An additional 2,000 to 3,000 patients per year in the United States are diagnosed with sALCL, a T-cell lymphoma that expresses the CD30 antigen. Advances made in the use of combination chemotherapy and novel treatments for malignant lymphomas have resulted in high remission rates from front-line therapy. However, a significant number of these patients relapse and require additional treatments including other chemotherapy regimens and autologous stem cell transplant, or ASCT. We believe there is a strong need for therapies that can maintain patients in remission after ASCT and provide a high rate of durable responses in post-ASCT relapses. According to a recognized cancer database and primary market research we conducted with physicians, we believe that there are several thousand newly relapsed or refractory Hodgkin lymphoma and sALCL patients in the United States each year who would be potentially eligible for treatment with brentuximab vedotin, and that the United States prevalence population of these patients is approximately 8,000 to 9,000 individuals.

### ***Clinical Results and Development Plan***

We have conducted two phase I clinical trials with brentuximab vedotin in patients with relapsed or refractory CD30-positive hematologic malignancies, primarily Hodgkin lymphoma. These single-agent, dose-escalation studies were designed to evaluate the safety, pharmacokinetic profile and antitumor activity of brentuximab vedotin administered either every three weeks or every week. In both trials, greater than 50 percent of patients treated at higher dose levels achieved a complete or partial remission, including greater than 30 percent achieving a complete remission. Brentuximab vedotin was generally well tolerated, with the majority of adverse events being Grade 1 or 2. The most common side effects included fatigue, fever, peripheral neuropathy, neutropenia, diarrhea and nausea.





## **Table of Contents**

In collaboration with Millennium, we are conducting a broad development plan that includes clinical trials of brentuximab vedotin both as a single agent and in combination with standard therapies for Hodgkin lymphoma and sALCL. These clinical trials include:

*Phase II Pivotal Study.* In February 2009, we initiated a pivotal, single-arm, open label trial of brentuximab vedotin in patients with relapsed or refractory Hodgkin lymphoma under an SPA with the FDA and completed enrollment in August 2009. The trial is assessing efficacy and safety of single-agent brentuximab vedotin in approximately 100 patients with relapsed or refractory Hodgkin lymphoma who previously received ASCT. Patients receive brentuximab vedotin every three weeks for up to approximately one year. The primary endpoint of the trial is objective response rate assessed by an independent radiographic facility. Secondary endpoints include duration of response, progression-free survival, overall survival and tolerability. The trial is being conducted at multiple centers in the United States and Europe. We expect to report data from this study in the second half of 2010. If the data from this trial are positive, we intend to use these data to seek regulatory approval through the submission of an NDA to the FDA under the accelerated approval guidelines.

*Phase II sALCL Study.* We are also conducting a phase II single-agent study of brentuximab vedotin in approximately 55 patients with relapsed or refractory sALCL. This trial is being conducted at multiple centers in the United States and Europe. We expect to complete enrollment to this trial in mid-2010. We believe sALCL may represent an additional registration pathway for brentuximab vedotin; however, we do not have a SPA with the FDA for this indication and additional clinical trials may be required.

*Phase II Retreatment Study.* In July 2009, we initiated a phase II trial of brentuximab vedotin for the 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 brentuximab vedotin. The trial is designed to enroll up to 50 patients at multiple centers in the United States and Europe.

*Phase I Frontline ABVD Combination Study.* In February 2010, we initiated a combination trial to evaluate brentuximab vedotin plus ABVD, a commonly used front-line chemotherapy regimen for Hodgkin lymphoma. The phase I dose-escalation trial will evaluate the safety of combining brentuximab vedotin and ABVD, as well as assess pharmacokinetics and antitumor activity of the combination. The study is expected to enroll approximately 40 patients at multiple centers in the United States and Canada.

*Phase III Relapse Prevention Study.* In the first half of 2010, we plan to initiate a phase III trial of brentuximab vedotin for post-transplant Hodgkin lymphoma patients. This trial will be a randomized, double-blind, placebo-controlled study to evaluate brentuximab vedotin 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 will be progression-free survival and secondary endpoints will include overall survival, safety and tolerability. Patients will receive brentuximab vedotin every three weeks for up to approximately one year. The trial will be conducted at multiple centers in the United States, Europe and Russia. This trial is designed to fulfill regulatory requirements in both the United States and Europe and will also provide data on the use of brentuximab vedotin in an earlier line of Hodgkin lymphoma therapy as part of an integrated second-line regimen with ASCT.

In collaboration with Millennium, we are also exploring additional potential trial designs to evaluate brentuximab vedotin more broadly as a treatment for lymphoma, which may include earlier lines of therapy, as well as patient subsets with high medical need and in chemotherapy-sparing regimens. Additionally, we look forward to initiating trials in other CD30-positive hematologic malignancies. We and Millennium are in discussions with multiple clinical investigators and cooperative groups around the world about additional clinical trials of brentuximab vedotin and internal planning activities are underway to evaluate these and other life cycle management opportunities for this program.



## **Table of Contents**

We believe the reported clinical data for brentuximab vedotin indicate the promising potential of our ADC technology to empower antibodies. We previously conducted clinical trials of an unconjugated anti-CD30 monoclonal antibody, SGN-30, which is the same antibody used in brentuximab vedotin. At the American Society of Hematology, or ASH, annual meeting in December 2005, we reported data from a phase II single agent trial of SGN-30, where the antibody was not sufficiently active as a single agent to demonstrate any objective responses in 35 patients with relapsed or refractory Hodgkin lymphoma treated at weekly doses up to twelve milligrams per kilogram (12 mg/kg). In contrast, brentuximab vedotin has demonstrated multiple objective responses in a similar patient population at much lower doses and at a less frequent dosing schedule.

### *Lintuzumab (SGN-33)*

Lintuzumab is a humanized monoclonal antibody that targets the CD33 antigen, which is highly expressed on myeloid malignancies and several myeloproliferative disorders. Phase II clinical development of lintuzumab in patients with AML or MDS is currently underway, and we have received orphan drug designation from the FDA for lintuzumab in both diseases. We have retained worldwide commercial rights to lintuzumab.

### *Market Opportunities*

*Acute Myeloid Leukemia.* AML, the most common type of acute leukemia in adults, results in uncontrolled growth and accumulation of malignant cells, or blasts, which fail to function normally and inhibit the production of normal blood cells. Progression of AML often leads to a deficiency of red cells, platelets and normal white cells in the blood, which can cause infections and bleeding. According to the American Cancer Society, approximately 12,800 cases of AML were expected to be diagnosed in the United States during 2009, and 9,000 people were expected to die of the disease. Approximately two-thirds of AML patients are over 60 years of age at diagnosis. Currently approved therapies for AML include chemotherapy drugs such as cytarabine, daunorubicin or mitoxantrone and Mylotarg, an ADC. However, these therapies have low cure rates, usually lead to relatively short disease remissions and can have life-threatening side effects such as severe neutropenia, especially in older patients. In addition, stem cell transplantation, which may offer a higher probability of cure, is not an option for many patients due to potential toxicity of this treatment or the absence of an appropriate stem cell donor. Median survival of older patients with AML who are unable to tolerate intensive chemotherapy or stem cell transplant is estimated at less than six months and less than 20 percent remain alive one year after diagnosis. As such, we believe there is a significant need for well-tolerated, targeted therapies for these patients.

*Myelodysplastic Syndromes.* MDS includes a heterogeneous group of hematologic myeloid malignancies that occur when blood cells remain in an immature stage within the bone marrow and never develop into mature cells capable of performing their necessary functions. Eventually, the bone marrow may be filled with immature cells, which suppresses normal cell development. According to the American Cancer Society, 10,000 to 15,000 new cases of MDS are diagnosed annually in the United States, with this number increasing each year. Mean survival rates range from approximately six months to six years for the different stages of MDS, with approximately 30 percent of MDS cases eventually transforming into AML. MDS patients must often rely on blood transfusions or growth factors to manage symptoms of fatigue, bleeding and frequent infections. Many MDS patients die from complications of the disease prior to developing AML, establishing a critical unmet medical need for new therapies targeting the cause of the condition and helping to restore normal blood cell production as well as delay the onset of leukemia. Recent data with hypomethylating agents such as Vidaza<sup>®</sup> and Dacogen<sup>®</sup> have demonstrated advantages over standard chemotherapy regimens among patients with intermediate-2 and high-risk MDS. However, these therapies are associated with significant toxicities, and MDS remains a largely incurable disease. Consequently, there remains a strong need for additional therapies in MDS that are well-tolerated and effective in reducing patient morbidity and mortality.

### *Clinical Results and Development Plan*

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

In June 2009, we reported data from our phase I single-agent dose escalation study of lintuzumab in patients with AML at the 14th Congress of the European Hematology Association. Data from 82 patients were presented, including 59 with AML, 19 with MDS and 4 with other myeloproliferative diseases. Ten of 59 patients with

## **Table of Contents**

AML achieved an objective response, including four complete remissions, two morphologic leukemia-free states and four partial remissions. Thirty-seven patients experienced treatment failure and 12 were not evaluable for response. Overall, 28 AML patients (47 percent) had reductions in tumor blasts compared to baseline. Of 23 patients with MDS or other myeloproliferative diseases, 15 patients achieved stable disease. Lintuzumab was generally well tolerated. The majority of adverse events were Grade 1 and 2, with the most common being chills and nausea.

In February 2009, we completed enrollment in a randomized, double blind, placebo-controlled, phase IIb study of low-dose cytarabine chemotherapy with or without lintuzumab in approximately 210 patients with AML. This study enrolled newly diagnosed AML patients age 60 years or older who declined or were ineligible for high-dose chemotherapy. Currently, a significant percentage of older AML patients do not receive treatment with any chemotherapy due to limited efficacy and toxicity concerns with existing therapies. Those who do receive low-dose chemotherapy have a median survival of less than six months. The primary goal of this study is to determine whether the addition of lintuzumab prolongs overall survival of older AML patients who do not receive aggressive chemotherapy. In addition, the trial will evaluate whether patients receiving lintuzumab experience reduced infections, transfusion independence, fewer hospitalizations and improved quality of life. We believe there is an opportunity in this patient population to combine a well-tolerated antibody with low-dose cytarabine to potentially prolong survival without meaningful added toxicity. We expect data from this study, which is event-driven, to be available in the second quarter of 2010.

In addition to treatment of older AML patients, we are pursuing opportunities for lintuzumab in MDS. Enrollment in our phase Ib study evaluating the combination of lintuzumab and Revlimid for patients with intermediate and high-risk MDS is complete, and we plan to report the results at an appropriate conference. We are also evaluating the combination of lintuzumab and Vidaza for patients with MDS in an investigator-sponsored phase II trial.

### ***Dacetuzumab (SGN-40)***

Dacetuzumab is a humanized monoclonal antibody that has been evaluated in phase I and phase II clinical trials for non-Hodgkin lymphoma and multiple myeloma. Dacetuzumab targets the CD40 antigen, which is expressed on B-cell lineage hematologic malignancies, as well as solid tumors such as bladder, renal and ovarian cancer. We also believe dacetuzumab may have applications in the treatment of autoimmune disease. We have received orphan drug designations from the FDA for dacetuzumab in multiple myeloma and chronic lymphocytic leukemia.

In January 2007, we entered into an exclusive worldwide collaboration agreement with Genentech for the development and commercialization of dacetuzumab. Under this collaboration, we and Genentech evaluated dacetuzumab in five clinical trials combined with other therapies for non-Hodgkin lymphoma and multiple myeloma. In October 2009, we discontinued a phase IIb combination clinical trial for diffuse large B-cell lymphoma, or DLBCL, based on a determination by the Independent Data Monitoring Committee, or IDMC, that the trial would be unlikely to meet its primary endpoint of superior complete response rate in the dacetuzumab combination arm as compared to the placebo combination arm. We reported data from two phase Ib clinical trials of dacetuzumab, one in combination with Rituxan and Gemzar<sup>®</sup> for DLBCL and the other in combination with Revlimid<sup>®</sup> for multiple myeloma at the ASH annual meeting in December 2009. After the December 2009 ASH annual meeting, Genentech provided notice of termination of the collaboration agreement, and the collaboration will end in June 2010. We are completing patient treatment in the four remaining phase Ib trials, evaluating available clinical and preclinical data and considering potential next steps for the program. As a result of such evaluation or other factors, we may determine to discontinue the development of dacetuzumab. If we decide to continue the development of dacetuzumab, we will be responsible for and will be required to solely fund any new dacetuzumab development and clinical trial activities undertaken after June 2010.

### ***SGN-70***

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

SGN-70 is a humanized anti-CD70 monoclonal antibody that we believe may have application for the treatment of autoimmune diseases, a condition where the body's immune system malfunctions and attacks its

## **Table of Contents**

own healthy cells. Many therapies for autoimmune diseases rely on suppressing the immune system to prevent further damage to normal tissues, but have the unwanted side effect of making the patient more susceptible to infection or cancer. The CD70 antigen is expressed on activated T- and B-cells, but is absent on these cells when in a resting state. Since resting T- and B-cells make up the majority of immune cells circulating in the body, SGN-70 may be able to prevent or reduce a damaging immune response without globally suppressing the patient's immune system. We have presented preclinical data demonstrating that SGN-70 inhibits T- and B-cell functions, selectively depletes CD70-positive activated T-cells and limits expansion of CD70- positive lymphocytes. We conducted a phase I dose-escalation trial of SGN-70 to assess the safety, tolerability and pharmacokinetics of SGN-70 in healthy volunteers and amended the trial design to add patients with autoimmune disease. We expect to complete enrollment to this phase I trial in 2010.

### ***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. We presented data at the American Association for Cancer Research, or AACR, annual meeting in April 2009 demonstrating that the CD70 antigen has a broad expression profile on a variety of solid tumors, including pancreatic, larynx/pharynx, ovarian, skin, lung and colon cancer. This presentation adds to data we previously reported at AACR meetings indicating that CD70 is expressed in multiple hematologic malignancies, renal cancer and glioblastoma and demonstrating that SGN-75 has potent antitumor activity at well-tolerated doses in preclinical models of renal cell cancer.

In November 2009, we initiated a phase I clinical trial of SGN-75 for CD70-positive relapsed or refractory non-Hodgkin lymphoma and metastatic renal cell carcinoma. The single-agent phase I study is designed to enroll up to 80 patients at multiple centers in the United States. The trial will evaluate the safety, tolerability, pharmacokinetic profile and antitumor activity of SGN-75 in order to identify a dose and schedule for potential future clinical trials.

### ***Market Opportunities***

*Non-Hodgkin lymphoma.* Non-Hodgkin lymphoma is the most common form of hematologic malignancy. According to the American Cancer Society, during 2009 approximately 66,000 cases of non-Hodgkin lymphoma were expected to be diagnosed in the United States and approximately 19,500 people were expected to die from the disease. Advances made with combined chemotherapy and the use of Rituxan, a monoclonal antibody, have resulted in high remission rates for front-line therapy in early stage disease. However, therapeutic options for refractory or relapsed patients are still limited, and there are significant opportunities for new treatments in this patient population, especially in aggressive lymphoma subtypes such as DLBCL.

*Renal Cell Carcinoma.* Renal cell carcinoma, or RCC, forms in the kidney, which filters and cleans the blood. Metastatic RCC occurs when the cancer has spread to other parts of the body. RCC is the most common type of kidney cancer in adults, representing approximately 90 percent of cases. The American Cancer Society estimates that during 2009 there were more than 57,700 new cases of kidney cancer diagnosed in the United States, and about 13,000 people died from the disease.

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

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

ASG-5ME, an ADC targeting the AGS-5 antigen, is a preclinical ADC product candidate for the treatment of solid tumors that we are co-developing under our collaboration with Agensys. The target of ASG-5ME is expressed in high density in multiple types of solid tumors, including pancreatic and prostate cancer. We and Agensys expect to submit two INDs for ASG-5ME during 2010, one for prostate cancer and one for pancreatic cancer.

### ***SGN-19A***

SGN-19A is a preclinical ADC product candidate for the treatment of hematologic malignancies. SGN-19A targets CD19, which is a B-cell antigen that is expressed in non-Hodgkin lymphoma, chronic lymphocytic



## **Table of Contents**

leukemia and acute lymphocytic leukemia. We have previously reported preclinical data demonstrating that an anti-CD19 ADC effectively 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.

## **Research Programs**

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

*Novel Antigen Targets and Monoclonal Antibodies.* 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 proteins that are highly expressed in cancer to identify those proteins that are located 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 collaboration with Agensys.

*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.

*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.

## **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, 2009, 2008 and 2007, we recorded \$119.1 million, \$110.9 million and \$64.8 million, respectively, in research and development expenses.

## **Corporate Collaborations**

We seek collaborations with leading 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 empower their

own antibodies. These ADC collaborations benefit us in many ways, including generating 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 Brentuximab Vedotin Collaboration***

In December 2009, we entered into a collaboration agreement with Millennium to develop and commercialize brentuximab vedotin, under which Seattle Genetics has United States and Canadian commercial rights and Millennium has commercial rights in the rest of the world. Under the collaboration, we received an upfront payment of \$60 million and retain full commercialization rights for brentuximab vedotin in the United States and Canada. Millennium and its Takeda affiliates have exclusive rights to commercialize the product candidate in all countries other than the United States and Canada. We are entitled to receive progress- and sales-

## **Table of Contents**

dependent milestone payments in addition to tiered double-digit royalties based on net sales of brentuximab vedotin within Millennium's licensed territories. Milestone payments to us could total more than \$230 million. Millennium is funding half of joint worldwide development costs under the collaboration, excluding costs solely related to development in Japan, which Millennium is funding. Development funding from Millennium over the first three years of the collaboration is expected to be at least \$75 million. 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.

### ***Genentech Dacetuzumab Collaboration***

In January 2007, we entered into an exclusive worldwide collaboration agreement with Genentech for the development and commercialization of dacetuzumab. Under the terms of the agreement, we received an upfront payment of \$60 million and \$20 million in progress-dependent milestone payments, as well as reimbursement for development costs totaling \$63.8 million through December 31, 2009. Genentech elected to terminate the collaboration in December 2009 and as a result, the collaboration will end in June 2010. If we decide to continue development of dacetuzumab, we will be responsible for and will be required to solely fund any new dacetuzumab development and clinical trial activities undertaken after June 2010.

### ***ADC Collaborations***

We have active collaborations with eight companies to allow them to use our proprietary ADC technology with their monoclonal antibodies:

*GlaxoSmithKline.* In December 2009, we entered into an ADC collaboration with GSK. Under the terms of the multi-year agreement, we received a \$12 million upfront payment for rights to utilize our ADC technology with multiple antigens to be named by GSK. GSK is paying service and reagent fees and has agreed to make milestone payments and pay royalties on net sales of any resulting ADC products. GSK is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated as a result of this collaboration.

*Millennium.* In March 2009, we entered into an ADC collaboration with Millennium. Under the terms of the multi-year agreement, we received a \$4 million upfront payment for exclusive rights to utilize our ADC technology with a single antigen and granted Millennium options to exercise exclusive licenses to our ADC technology for two other antigens upon payment of additional fees. Millennium is paying service and reagent fees and has agreed to make milestone payments and pay royalties on net sales of any resulting ADC products. Millennium is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated as a result of this collaboration.

*Daiichi Sankyo.* In July 2008, we entered into an ADC collaboration with Daiichi Sankyo Co., Ltd. Under the terms of the multi-year agreement, we received a \$4 million upfront payment in exchange for an exclusive license to our technology for a single antigen found on multiple types of solid tumors. Daiichi Sankyo is paying service and reagent fees and has agreed to make milestone payments and pay royalties on net sales of any resulting products. Daiichi Sankyo is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated as a result of this collaboration.

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

*Progenics.* In June 2005, we entered into an ADC collaboration with Progenics. Under the terms of the multi-year agreement, we received a \$2 million upfront fee for an exclusive license to our technology for a single antigen. Progenics is paying service and reagent fees and has agreed to make milestone payments and pay royalties on net sales of any resulting products. Progenics is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated as a result of this collaboration.

## **Table of Contents**

Progenics initiated a phase I clinical trial for an ADC product candidate during 2008 for which we received a milestone payment.

*MedImmune.* In April 2005, we entered into an ADC collaboration with MedImmune. Under the terms of the multi-year agreement, MedImmune paid us a \$2 million upfront fee for an exclusive license to our technology for a single antigen. In October 2007, MedImmune paid us an additional \$1.5 million fee for an exclusive license to a second antigen. MedImmune is paying service and reagent fees and has agreed to make milestone payments and pay royalties on net sales of any resulting products. MedImmune is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated as a result of this collaboration. MedImmune initiated a phase I clinical trial for an ADC product candidate during 2009 for which we received a milestone payment.

*Bayer.* In September 2004, we entered into an ADC collaboration with Bayer. Under the terms of the multi-year agreement, Bayer paid us a \$2 million upfront fee for an exclusive license to our technology for a single antigen. In May 2008, Bayer paid us an additional fee to amend the collaboration agreement and expand the research conducted pursuant to the collaboration. Bayer is also paying service and reagent fees and has agreed to make milestone payments and pay royalties on net sales of any resulting products. Bayer is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated as a result of this collaboration. Bayer submitted an IND for an ADC product candidate during 2009 for which we received a milestone payment.

*Celldex.* In June 2004, we entered into an ADC collaboration with Celldex. Under the terms of the multi-year agreement, Celldex paid us a \$2 million upfront fee for an exclusive license to our technology for a single antigen. In February 2005, Celldex paid us an additional fee for an exclusive license to a second antigen. Celldex is also paying service and reagent fees and has agreed to make milestone payments to us, certain of which milestone payments have been made in connection with the initiation of phase I and II trials of an ADC product candidate. Celldex has further agreed to pay royalties to us on net sales of any resulting ADC products. Celldex is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated as a result of this collaboration.

*Genentech.* In April 2002, we entered into an ADC collaboration with Genentech. Since entering into the multi-year agreement, Genentech has paid us more than \$33 million in upfront fees, milestones, access fees and equity purchases, including \$7.3 million during 2009. Additionally, Genentech is also paying service and reagent fees. Genentech has also agreed to pay future progress-dependent milestone payments, support fees and royalties on net sales of any resulting ADC products. Genentech is responsible for research, product development, manufacturing and commercialization of any products resulting from the collaboration.

### ***Agensys Co-Development Agreement***

*Agensys.* In January 2007, we entered into an agreement with Agensys to jointly research, develop and commercialize ADCs for cancer. The collaboration encompasses combinations of our ADC technology with fully-human antibodies developed by Agensys to proprietary cancer targets. Under the terms of the multi-year agreement, we and Agensys will jointly screen and select ADC product candidates to an initial target, AGS-5, co-fund all preclinical and clinical development and share equally in any profits. 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 will conduct preclinical studies aimed at identifying ADC product candidates for additional designated antigens. We have the right to exercise a co-development option for two additional ADC product candidates 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. As part of the modified agreement, we are eligible to receive up to \$250 million in potential development milestones and \$100 million in potential sales milestones. 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



## **Table of Contents**

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. We and Agensys are currently co-developing ASG-5ME for the treatment of solid tumors, and expect to initiate clinical trials for the treatment of prostate and pancreatic cancer in 2010.

## ***License Agreements***

We have in-licensed antibodies, targets and enabling technologies from pharmaceutical and biotechnology companies and academic institutions for use in our pipeline programs and ADC technology, including the following:

*Bristol-Myers Squibb.* In March 1998, we obtained rights to some of our technologies and product candidates, portions of which are exclusive, through a license agreement with Bristol-Myers Squibb. Through this license, we secured rights to monoclonal antibody-based cancer targeting technologies, including patents, monoclonal antibodies, chemical linkers, a ribosome-inactivating protein and enabling technologies. Under the terms of the license agreement, we are required to pay royalties on net sales of future products incorporating technology licensed from Bristol-Myers Squibb.

*PDL BioPharma.* In January 2004, as part of the expansion of our then-existing ADC collaboration, PDL BioPharma granted us one license and options for two additional licenses under PDL BioPharma's antibody humanization patents. We used the initial antibody humanization license for our dacetuzumab product candidate. Under the terms of the license agreements, we are required to pay annual maintenance fees and royalties on net sales of products using PDL BioPharma's humanization technology.

*Facet Biotech Corporation.* In April 2005, we in-licensed lintuzumab from PDL BioPharma. In December 2008, Facet spun out of PDL BioPharma with Facet being assigned all of PDL's rights and interest in the lintuzumab license, as well as its rights in our ADC collaboration with PDL BioPharma. We paid PDL BioPharma an upfront fee and have agreed to pay progress-dependent milestones and royalties on net sales of anti-CD33 products incorporating technology in-licensed, which includes an antibody humanization license for the CD33 antigen. As part of the agreement, we also agreed to reduce the royalties payable by Facet to us with respect to one target under the ADC collaboration. We and Facet have also granted each other a co-development option for second generation versions of lintuzumab with improved therapeutic characteristics developed by either party.

*CMC ICOS Biologics, Inc.* In October 2000, we entered into a license agreement with ICOS Corporation, now a wholly-owned subsidiary of Eli Lilly, for non-exclusive rights to use ICOS' CHEF expression system. In December 2007, CMC Biologics A/S acquired the biologics manufacturing site and all related intellectual property of ICOS from Eli Lilly, including the rights to the CHEF expression system. We use this system to manufacture the antibody components of brentuximab vedotin, SGN-70 and SGN-75 and we may also use it for other monoclonal antibodies in the future. Under the terms of this agreement, we are required to make progress-dependent milestone payments and pay royalties on net sales of products manufactured using the CHEF expression system to CMC ICOS Biologics.

*University of Miami.* In September 1999, we entered into an exclusive license agreement with the University of Miami, Florida, covering an anti-CD30 monoclonal antibody that is the basis for the antibody component of brentuximab vedotin. Under the terms of this license, we made an upfront payment and are required to pay annual maintenance fees, progress-dependent milestone payments and royalties on net sales of products incorporating technology licensed from the University of Miami.





## **Table of Contents**

*Mabtech AB.* In June 1998, we obtained exclusive, worldwide rights to a monoclonal antibody targeting the CD40 antigen, which is the basis for dacetuzumab, from Mabtech, located in Sweden. Under the terms of this license, we made an up-front payment, are required to make progress-dependent milestone payments and pay royalties on net sales of products incorporating technology licensed from Mabtech.

*CLB-Research and Development.* Pursuant to a license agreement we entered into in July 2001, we obtained an exclusive license to specific monoclonal antibodies that target cancer and autoimmune disease targets from CLB-Research and Development, a division of Sanquin Blood Supply Foundation, located in the Netherlands. One of these antibodies is the basis for SGN-70 and the antibody component of SGN-75. Under the terms of this agreement, we have made upfront and option exercise payments and are required to make progress-dependent milestone payments and pay royalties on net sales of products incorporating technology licensed from CLB-Research and Development.

*Arizona State University.* In February 2000, we entered into a license agreement with Arizona State University for a worldwide, exclusive license to the cell-killing agent Auristatin E. We subsequently amended this agreement in August 2004. Under the terms of the amended agreement, we are required to pay annual maintenance fees to Arizona State University until expiration of their patents covering Auristatin E. We are not, however, required to pay any milestone payments or royalties on net sales of products incorporating the auristatins currently used in our ADC technology, and thus we do not expect to pay any milestones or royalties to Arizona State University with respect to products employing our current ADC technology.

## **Patents and Proprietary Technology**

For brentuximab vedotin and our ADC technology, our issued patents will expire between 2020 and 2025 in the United States and Europe, and additional patent applications are pending that, if issued, could increase the patent term to 2030 for certain methods of treatment using brentuximab vedotin. For lintuzumab, our issued patents will expire in 2014 in the United States and additional patent applications are pending that, if issued, could increase the patent term until at least 2027. In some cases, our U.S. patents may be eligible for additional patent term adjustment or extension, and our European patents may be eligible for supplemental protection in one or more countries. The length of any such adjustment or extension would vary by country.

Our owned and licensed patents and patent applications are directed to product candidates, monoclonal antibodies, ADC product candidates, our ADC and SEA technologies and other antibody-based and/or enabling technologies. We commonly seek claims directed to compositions of matter, including antibodies, ADCs, and drug-linkers containing highly potent cell-killing drugs, as well as methods of using such compositions. When appropriate, we also seek claims to related technologies, such as methods of using certain sugar analogs utilized in our SEA technology. For each of our product candidates, we have filed or expect to file multiple patent applications. We maintain patents and prosecute applications worldwide for technologies that we have outlicensed, such as our ADC technology. Similarly, for partnered product development candidates, such as brentuximab vedotin and ASG-5ME, we seek to work closely with our development partners to coordinate patent efforts, including patent application filings, prosecution, term extension, defense and enforcement. As our development product candidates advance through research and development, we seek to diligently identify and protect new inventions, such as combinations, improvements to methods of manufacturing, and methods of treatment. We also work closely with our scientist personnel to identify and protect new inventions that could eventually add to our development pipeline.

Patents expire, on a country by country basis, at various times depending on various factors, including the filing date of the corresponding patent application(s), the availability of patent term extension and supplemental protection certificates and terminal disclaimers. Although we believe our owned and licensed patents and patent applications provide us with a competitive advantage, the patent positions of biotechnology and pharmaceutical companies can be uncertain and involve complex legal and factual questions. We and our corporate collaborators may not be able to develop patentable products or processes or obtain patents from pending patent applications. Even if patent claims are allowed, the claims may not issue. In the event of issuance, the patents may not be



## **Table of Contents**

sufficient to protect the proprietary technology owned by or licensed to us or our corporate collaborators. Our or our corporate collaborators current patents, or patents that issue on pending applications, may be challenged, invalidated, infringed or circumvented. Our patents may be challenged by third parties in post-issuance administrative proceedings or in litigation as invalid or unenforceable under U.S. or foreign laws or they may be infringed by third parties. The costs of defending our patents or enforcing our proprietary rights in litigation may be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our proprietary technologies without a license from us or our collaborators. Ours and our collaborators patents may also be circumvented, which may allow third parties to use similar technologies without a license from us or our collaborators.

Our commercial success depends significantly on our ability to operate without infringing patents and proprietary rights of third parties. A number of pharmaceutical and biotechnology companies, universities and research institutions may have filed patent applications or may have been granted patents that cover technologies similar to the technologies owned, optioned by or licensed to us or to our collaborators. We cannot determine with certainty whether patents or patent applications of other parties may materially affect our or our collaborators ability to make, use or sell any products.

We require our scientific personnel to maintain laboratory notebooks and other research records in accordance with our policies, which are designed to strengthen and support our patent efforts. In addition to our patented intellectual property, we also rely on trade secrets and other proprietary information, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a propriety information and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. These agreements provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of their relationship with us except in limited circumstances. These agreements also provide that we shall own all inventions conceived by the individual in the course of rendering services to us. Our agreements with collaborators require them to have a similar policy and agreements with their employees, consultants and advisors. Our policy and agreements and those of our collaborators may not sufficiently protect our confidential information, or third parties may independently develop equivalent information.

## **Government Regulation**

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, pre-market approval, manufacture, marketing and distribution of biopharmaceutical products. These agencies and other regulatory agencies regulate research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, recordkeeping, advertising and promotion of product candidates. Failure to comply with applicable FDA or other requirements may result in Warning Letters, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market. The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. We must obtain approval of our product candidates from the FDA before we can begin marketing them in the United States. Similar approvals are also required in other countries.

Product development and approval within this regulatory framework is uncertain, can take many years and requires the expenditure of substantial resources. The nature and extent of the governmental review process for our product candidates will vary, depending on the regulatory categorization of particular product candidates and various other factors.

The necessary steps before a new biopharmaceutical product may be sold in the United States ordinarily include:

preclinical *in vitro* and *in vivo* tests, which must comply with Good Laboratory Practices, or GLP;

## **Table of Contents**

submission to the FDA of an IND which must become effective before clinical trials may commence, and which must be updated annually with a report on development;

completion of adequate and well controlled human clinical trials to establish the safety and efficacy of the product candidate for its intended use;

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

FDA pre-approval inspection of manufacturing facilities for current Good Manufacturing Practices, or GMP, compliance and FDA inspection of select clinical trial sites for Good Clinical Practice, or GCP, compliance; and

FDA review and approval of the marketing authorization application and product label prior to any commercial sale.

The results of preclinical tests (which include laboratory evaluation as well as preclinical GLP studies to evaluate toxicity) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30 day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP regulations and regulations for informed consent and privacy of individually-identifiable information.

Clinical trials generally are conducted in three sequential phases that may overlap or in some instances, be skipped. In phase I, the initial introduction of the product into humans, the product is tested to assess safety, metabolism, pharmacokinetics and pharmacological actions associated with increasing doses. Phase II usually involves trials in a limited patient population to evaluate the efficacy of the potential product for specific, targeted indications, determine dosage tolerance and optimum dosage and further identify possible adverse reactions and safety risks. Phase III and pivotal trials are undertaken to evaluate further clinical efficacy often in comparison to standard therapies within a broader patient population, generally at geographically dispersed clinical sites. Phase IV, or postmarketing, trials may be required as a condition of commercial approval by the FDA and may also be voluntarily initiated by us or our collaborators. In limited circumstances, the FDA may allow a company to conduct a pivotal trial prior to completing phase II trials. The FDA has agreed, through the use of a special protocol assessment, or SPA, to allow us to conduct a pivotal trial of brentuximab vedotin prior to completing phase II studies. In addition, we plan to use the accelerated approval regulations, which provide for the submission of an NDA or BLA based on surrogate markers, such as objective response rate, if we submit an NDA for brentuximab vedotin. Phase I, phase II or phase III testing may not be completed successfully within any specific period of time, if at all, with respect to any of our product candidates. Similarly, suggestions of safety, tolerability or efficacy in earlier stage trials do not necessarily predict findings of safety and effectiveness in subsequent trials. Furthermore, the FDA, an IRB or we may suspend a clinical trial at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical trials are subject to central registration requirements, such as on [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

The results of preclinical studies, pharmaceutical development and clinical trials, together with information on a product's chemistry, manufacturing, and controls, are submitted to the FDA in the form of an NDA or BLA, for approval of the manufacture, marketing and commercial shipment of the pharmaceutical product. Data from



## **Table of Contents**

clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. The submission of an NDA or BLA is required to be accompanied by a substantial user fee, with few exceptions or waivers. The testing and approval process is likely to require substantial time, effort and resources, and there can be no assurance that any approval will be granted on a timely basis, if at all. The FDA may deny review of an application or not approve an application by issuance of a complete response letter if applicable regulatory criteria are not satisfied, require additional testing or information, or require risk management programs and post-market testing and surveillance to monitor the safety or efficacy of the product. Approval may occur with significant Risk Evaluation and Mitigation Strategies, or REMS, that limit the labeling, distribution or promotion of a product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including manufacture, labeling, advertising, distribution, advertising, promotion, recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. Manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Warning Letters that could cause us to modify certain activities. A Form 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. Failure to adequately and promptly correct the observations(s) can result in regulatory action. In addition to Form 483 notices and Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a product from distribution or withdraw approval of the BLA or NDA for that product. Failure to comply with ongoing regulatory obligations can result in warning letters, product seizures, criminal penalties, and withdrawal of approved products, among other enforcement remedies.

## **Competition**

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many third parties compete with us in developing various approaches to cancer and autoimmune disease therapy. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approval and marketing than we do. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to our programs.

---

## **Table of Contents**

We expect that competition among products approved for sale will be based, among other things, on efficacy, reliability, product safety, price and patent position. Our ability to compete effectively and develop products that can be manufactured cost-effectively and marketed successfully will depend on our ability to:

advance our technology platforms;

license additional technology;

maintain a proprietary position in our technologies and products;

obtain required government and other public and private approvals on a timely basis;

attract and retain key personnel; and

enter into additional collaborations to advance the development and commercialization of our product candidates.

We are aware of specific companies that have technologies that may be competitive with ours, including Wyeth, now wholly-owned by Pfizer, ImmunoGen and Medarex, a subsidiary of Bristol-Myers Squibb, all of which have ADC technology. Wyeth markets Mylotarg, an ADC, for patients with acute myeloid leukemia, which targets the same antigen as our lintuzumab product candidate. ImmunoGen has several ADCs in development that may compete with our product candidates if approved for commercial sale. ImmunoGen has also established partnerships with other pharmaceutical and biotechnology companies to allow those other companies to utilize ImmunoGen's technology, including Sanofi-Aventis and Genentech. In addition, Medarex has developed its own technology for linking antibodies to cytotoxic payloads. We are also aware of a number of companies developing monoclonal antibodies directed at the same antigen targets or for the treatment of the same diseases as our product candidates. For example, Novartis is developing an anti-CD40 antibody, Medarex has anti-CD30 and anti-CD70 antibody programs, Micromet AG and Wyeth have anti-CD19 programs and Xencor has anti-CD30 and anti-CD40 antibody programs that may be competitive with our product candidates if approved for commercial sale. In addition, many other pharmaceutical and biotechnology companies are developing and/or marketing therapies for the same types of cancer and autoimmune diseases that our product candidates are designed and being developed to treat. These include antibodies such as Genentech's Rituxan, proteasome inhibitors such as Millennium's Velcade, HDAC inhibitors such as Novartis' panobinostat, immunomodulatory agents such as Celgene's Revlimid, small molecule drugs such as Bayer's/Onyx's Nexavar, and a variety of cytotoxic drugs such as Genzyme's Clolar, Celgene's Vidaza, Eisai's Dacogen and Cephalon's Treanda.

## **Manufacturing**

We rely on corporate collaborators and contract manufacturing organizations to supply drug product for our IND-enabling studies and clinical trials. For the monoclonal antibody used in brentuximab vedotin, we have contracted with Abbott Laboratories for clinical and potential future commercial supplies and we recently entered into a manufacturing and supply agreement with Pierre Fabre Medicament Production, S.A.S., or PFMP, for the cGMP fill/finish manufacture of commercial quantities of brentuximab vedotin. For brentuximab vedotin and other ADCs, several contract manufacturers, including Albany Molecular and Sigma Aldrich Fine Chemicals, or SAFC, perform drug-linker manufacturing and several other contract manufacturers, including Piramal Healthcare, perform conjugation of the drug-linker to the antibody. For dacetuzumab, we have an ongoing manufacturing agreement with Abbott Laboratories to supplement our clinical and, if needed, future commercial supplies. For lintuzumab, we have contracted with Laureate Pharma for clinical drug supply. We have also contracted with Laureate Pharma to manufacture the antibody component of SGN-70 and SGN-75 for clinical trials. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including vialing and storage of our product candidates.



We believe that our existing supplies of drug product and our contract manufacturing relationships with Abbott Laboratories, PFMP, Laureate Pharma, Albany Molecular, SAFC, Piramal, and our other existing and potential contract manufacturers with whom we are in discussions, will be sufficient to accommodate clinical

## **Table of Contents**

trials through phase II, and in some cases into phase III, trials of our current product candidates. We are in the process of establishing our commercial scale supply chain for brentuximab vedotin to position us for a potential NDA submission in 2011 and potential commercial launch. However, we may need to obtain additional manufacturing arrangements or increase our own manufacturing capability to meet our future commercial needs, both of which would require significant capital investment. In addition, we have committed to provide Millennium with their needs of brentuximab vedotin for a limited period of time, which may require us to arrange for additional manufacturing supply. We may also enter into collaborations with pharmaceutical or larger biotechnology companies to enhance the manufacturing capabilities for our product candidates.

## **Employees**

As of December 31, 2009, we had 289 employees. Of these employees, 240 were engaged in or support research, development and clinical activities, and 49 were in administrative and business related positions. Each of our employees has signed confidentiality and inventions assignment agreements and none are covered by a collective bargaining agreement. We have never experienced employment-related work stoppages and consider our employee relations to be good.

## **Corporate Information**

We were incorporated in Delaware on July 15, 1997. Our principal executive offices are located at 21823 30<sup>th</sup> Drive SE, Bothell, Washington 98021. Our telephone number is (425) 527-4000. Seattle Genetics<sup>®</sup> and <sup>®</sup> are our registered trademarks in the United States. All other trademarks, tradenames and service marks included in this Annual Report on Form 10-K are the property of their respective owners.

We file electronically with the Securities and Exchange Commission our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at [www.seattlegenetics.com](http://www.seattlegenetics.com), free of charge, through a hyperlink on our website, copies of these reports, as soon as reasonably practicable after electronically filing such reports with, or furnishing them to, the Securities and Exchange Commission. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this Annual Report on Form 10-K.

## **Item 1A. Risk Factors.**

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

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

**Risks Related to Our Business**

*Our near-term prospects are substantially dependent on our lead product candidate, brentuximab vedotin. If we are unable to successfully develop and obtain regulatory approval for brentuximab vedotin for the treatment of patients with relapsed or refractory Hodgkin lymphoma, our ability to generate revenue from product sales will be significantly delayed.*

We currently have no products that are approved for commercial sale. Our product candidates are in various stages of development, and significant research and development, financial resources and personnel will be required to develop commercially viable products and obtain regulatory approvals for them. A substantial portion of our efforts and expenditures over the next few years will be devoted to brentuximab vedotin, which is the subject of an ongoing pivotal clinical trial under a special protocol assessment, or SPA, with the FDA.

## **Table of Contents**

Accordingly, our future prospects are substantially dependent on the successful development, regulatory approval and commercialization of brentuximab vedotin for the treatment of patients with relapsed or refractory Hodgkin lymphoma. In addition, in December 2009 we entered into an agreement with Millennium to develop and commercialize brentuximab vedotin, under which Seattle Genetics has United States and Canadian commercial rights and Millennium has commercial rights in the rest of the world. The success of this collaboration and the activities of Millennium will significantly impact the commercialization of brentuximab vedotin in countries other than the United States and Canada. Brentuximab vedotin is not expected to be commercially available for this or any other indication until at least the second half of 2011, if at all. Further, the commercial success of brentuximab vedotin will depend upon its acceptance by physicians, patients, third party payors and other key decision-makers as a therapeutic and cost-effective alternative to currently available products. In addition, the indications that we and Millennium are pursuing for brentuximab vedotin have relatively low incidence rates, including Hodgkin lymphoma and sALCL, which may limit the revenue potential of brentuximab vedotin. If we and Millennium are unable to successfully develop, obtain regulatory approval for and commercialize brentuximab vedotin for the treatment of relapsed or refractory Hodgkin lymphoma and other indications, our ability to generate revenue from product sales will be significantly delayed and our business would be materially affected and we may not be able to earn sufficient revenues to continue as a going concern.

***Although we have reached agreement with the FDA on an SPA relating to our brentuximab vedotin pivotal trial, this agreement does not guarantee any particular outcome with respect to regulatory review of the pivotal trial or with respect to regulatory approval of brentuximab vedotin.***

The protocol for the brentuximab vedotin pivotal trial was reviewed by the FDA under the SPA process, which allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of an NDA, and provides an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA. Reaching agreement with the FDA on an SPA is not an indication of approvability. Even if we believe that the data from the pivotal trial are positive, an SPA agreement is not a guarantee of approval, and we cannot be certain that the design of, or data collected from, the pivotal trial will be adequate to demonstrate the safety and efficacy of brentuximab vedotin for the treatment of patients with relapsed or refractory Hodgkin lymphoma, or will otherwise be sufficient to support FDA or any foreign regulatory approvals. Further, the SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement is entered into become evident, other new scientific concerns regarding product safety or efficacy arise or if we fail to comply with the agreed upon trial protocols. In addition, the SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from the pivotal trial. As a result, we do not know how the FDA will interpret the parties' respective commitments under the SPA agreement, how it will interpret the data and results from the pivotal trial or whether brentuximab vedotin will receive any regulatory approvals. Therefore, despite the potential benefits of the SPA agreement, significant uncertainty remains regarding the clinical development of and regulatory approval process for brentuximab vedotin for the treatment of relapsed or refractory Hodgkin lymphoma, and it is possible that we might never receive any regulatory approvals for brentuximab vedotin.

***Other than brentuximab vedotin, our product candidates are at an early stage of development, and it is possible that none of our product candidates will ever become commercial products.***

Other than brentuximab vedotin, our product candidates are in relatively early stages of development. These product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all. Currently, lintuzumab, dacetuzumab, SGN-70 and SGN-75 are in clinical trials, and ASG-5ME and SGN-19A are in preclinical development. We expect that much of our effort and many of our expenditures over the next few years will be devoted to registration and commercialization activities associated with brentuximab vedotin, which may restrict or delay our ability to develop our other clinical and preclinical product candidates.

Our ability to commercialize any of our product candidates, including brentuximab vedotin, depends on first receiving required regulatory approvals, and it is possible that we may never receive regulatory approval for any



## Table of Contents

of our product candidates. Even if a product candidate receives regulatory approval, the resulting product may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Assuming that brentuximab vedotin receives the required regulatory approvals, commercial success outside of the United States and Canada will depend on Millennium's commercialization efforts. The degree of commercial success of any approved product will depend on a number of factors, including:

- establishment and demonstration of clinical efficacy and safety;
- cost-effectiveness of the product;
- the product's potential advantage over alternative treatment methods;
- whether the product can be produced in commercial quantities at acceptable costs; and
- marketing and distribution support for the product.

We do not expect any of our current product candidates to be commercially available until at least the second half of 2011, if at all. If we and/or our collaborators are unable to develop and commercialize any of our product candidates, if development is delayed or if sales revenue from any product candidate that receives marketing approval is insufficient, we may never be profitable.

***If we or our collaborators are not able to obtain or maintain required regulatory approvals, we or our collaborators will not be able to commercialize our product candidates, our ability to generate revenue will be materially impaired and our business will not be successful.***

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor our collaborators are permitted to market our product candidates in the United States or foreign countries until we obtain marketing approval from the FDA or other foreign regulatory authorities, and we or our collaborators may never receive regulatory approval for the commercial sale of any of our product candidates. Obtaining marketing approval is a lengthy, expensive and uncertain process and approval is never assured, and we have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. Further, the FDA has substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any product candidate we develop. In this regard, even if we believe the data collected from clinical trials of our product candidates are promising, such data, including data from our pivotal trial of brentuximab vedotin, may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory authority. In addition, the FDA or their advisors may disagree with our interpretations of data from preclinical studies and clinical trials. Regulatory agencies also may approve a product candidate for fewer conditions than requested or may grant approval subject to the performance of post-approval studies for a product candidate. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards, or IRBs, for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors, our current product candidates or any of our other future product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain regulatory approval, which could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

If we or our collaborators receive regulatory approval for our product candidates, we will also be subject to ongoing FDA obligations and oversight, including adverse event reporting requirements, marketing restrictions and potential post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such products. The FDA's policies may also change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate

## **Table of Contents**

post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we may be subject to civil and criminal penalties, we may not be permitted to market our products and our business could suffer. Any delay in or failure to receive or maintain regulatory approval for any of our product candidates could harm our business and prevent us from ever generating meaningful revenues or achieving profitability.

We and our collaborators will need to obtain regulatory approval from authorities in foreign countries to market our product candidates in those countries. Neither we nor our collaborative partners have filed for regulatory approval to market our product candidates in any foreign jurisdictions. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. If we or our collaborative partners fail to obtain approvals from foreign jurisdictions, the geographic market for our product candidates would be limited.

***Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.***

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate, through extensive preclinical studies and clinical trials, that the product candidate is safe and effective in humans. Ongoing and future clinical trials of our product candidates may not show sufficient safety or efficacy to obtain requisite regulatory approvals. The clinical data from our phase I trials of brentuximab vedotin are limited, and the results of our brentuximab vedotin pivotal trial, which was initiated in the first quarter of 2009 and for which we completed patient enrollment in August 2009, will be blinded to us until completion of the trial. In addition, we still only have limited data from our phase I and phase II clinical trials of lintuzumab and dacetuzumab, and our phase I trials of SGN-75 and SGN-70. Phase I and phase II clinical trials are not primarily designed to test the efficacy of a product candidate but rather are designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the product candidate's side effects at various doses and dosing schedules. Furthermore, success in preclinical and early clinical trials does not ensure that later large-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be repeated in later trials. The pivotal trial of brentuximab vedotin required the enrollment of 100 patients and we believe that any clinical trial designed to test the efficacy of lintuzumab, dacetuzumab, SGN-70 or SGN-75, whether phase II or phase III, will likely involve a large number of patients to achieve statistical significance, will be expensive and will take a substantial amount of time to complete. As a result, we may conduct lengthy and expensive clinical trials of our product candidates, only to learn that the product candidate is not an effective treatment or is not superior to existing approved therapies or has an unacceptable safety profile, which could prevent or significantly delay regulatory approval for such product candidate. For example, in October 2009 we discontinued our phase IIb clinical trial of dacetuzumab in combination with Rituxan plus ifosfamide, carboplatin and etoposide, or R-ICE, chemotherapy for patients with relapsed or refractory DLBCL based on a determination by the IDMC that the trial would be unlikely to meet its primary endpoint of superior complete response rate in the dacetuzumab combination arm as compared to the placebo combination arm.

***Clinical trials for our product candidates are expensive and time consuming, may take longer than we expect or may not be completed at all, and their outcome is uncertain.***

We are currently conducting multiple clinical trials for our clinical product candidates, including a pivotal trial under an SPA with the FDA for brentuximab vedotin, and we expect to commence additional trials of these and other product candidates in the future. Each of our clinical trials requires the investment of substantial expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delay or failure to obtain IRB approval to conduct a clinical trial at a prospective site, and shortages of available drug supply. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility





## Table of Contents

criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. In addition, many of our future and ongoing brentuximab vedotin clinical trials will be coordinated with Millennium, which may delay the commencement or affect the continuation or completion of these trials. We have experienced enrollment-related delays in certain of our current and previous clinical trials and will likely experience similar delays in our future trials, particularly as we attempt to significantly increase patient size as may be required for phase III studies. We depend on medical institutions and clinical research organizations, or CROs, to conduct our clinical trials in compliance with Good Clinical Practice or GCP, and to the extent they fail to enroll patients for our clinical trials or are delayed for a significant time in achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign CROs, as well as expose us to risks associated with less experienced clinical investigators who are unknown to the FDA, different standards of medical care, and foreign currency transactions insofar as we might desire to use U.S. dollars to make contract payments denominated in the foreign currency where the trial is being conducted.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under GMP and other requirements in foreign countries, and may require large numbers of test patients. We, the FDA or other foreign governmental agencies could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including:

deficiencies in the conduct of the clinical trial, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;

deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;

the product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;

the time required to determine whether the product candidate is effective may be longer than expected;

fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;

the product candidate may not appear to be more effective than current therapies;

the quality or stability of the product candidate may fall below acceptable standards;

our inability to produce or obtain sufficient quantities of the product candidate to complete the trials;

our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

our inability to obtain IRB approval to conduct a clinical trial at a prospective site;

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

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;

our inability to recruit and enroll patients to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or

our inability to retain patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with

---

**Table of Contents**

other therapies, which often occurs in later-stage clinical trials. For example, in October 2009 we announced that our phase IIb clinical trial of dacetuzumab in combination with R-ICE chemotherapy for patients with DLBCL was discontinued based on a determination by the IDMC that the trial would be unlikely to meet its primary endpoint of superior complete response rate in the dacetuzumab combination arm as compared to the placebo combination arm. We are also conducting a phase IIb clinical trial of lintuzumab combined with low-dose cytarabine, and may experience unexpected adverse events as a result of this combination or for other reasons. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events, including patient fatalities that may be attributable to our product candidates, during a clinical trial could cause it to be redone or terminated. Further, some of our clinical trials may be overseen by an IDMC, and an IDMC may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial.

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

We have established and intend to continue to establish collaborations with third parties to develop and market some of our current and future product candidates. We entered into an exclusive worldwide collaboration agreement with Millennium in December 2009 for the development and commercialization of our brentuximab vedotin product candidate. We also have ADC collaborations with Bayer, Celldex, Daiichi Sankyo, GSK, Genentech, MedImmune, Millennium and Progenics, and an ADC co-development agreement with Agensys.

Under certain conditions, our collaborators may terminate their agreements with us and discontinue use of our technologies. For example, in December 2009, Genentech notified us that it has elected to terminate our collaboration agreement for dacetuzumab effective June 8, 2010 and, as a result, we will not receive any milestone payments, cost reimbursements or royalties for the development or sale of dacetuzumab from Genentech. If we decide to continue development of dacetuzumab, we will be responsible for and will be required to solely fund any new dacetuzumab development and clinical trial activities undertaken after June 8, 2010, which could result in a significant delay in the dacetuzumab development process. If we determine instead to discontinue the development of dacetuzumab, we will not receive any future return on our investment from that product candidate. In addition, we cannot control the amount and timing of resources our collaborators may devote to products incorporating our technology. Moreover, our relationships with our collaborators divert significant time and effort of our scientific staff and management team and require effective allocation of our resources to multiple internal and collaborative projects. Our collaborators may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborators. Even if our collaborators continue their contributions to the collaborative arrangements, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Our collaborators may fail to perform their obligations under the collaboration agreements or may be slow in performing their obligations. If any of our collaborators terminate or breach our agreements with them, or otherwise fail to complete their obligations in a timely manner, it may have a detrimental effect on our financial position by reducing or eliminating the potential for us to receive technology access and license fees, milestones and royalties, reimbursement of development costs, as well as possibly requiring us to devote additional efforts and incur costs associated with pursuing internal development of product candidates. In particular, if Millennium were to terminate the collaboration at its election, we would not receive milestone payments, co-funded development payments or royalties for sale of brentuximab vedotin. As a result of such termination, we may have to engage another collaborator to complete the brentuximab vedotin development process or complete the process ourselves internally, either of which could significantly delay the development process and increase our costs. In turn, this could significantly harm our financial position, adversely affect our stock price and require us to incur all the costs of developing and commercializing brentuximab vedotin, which are now being co-funded by Millennium. Furthermore, if our collaborators do not prioritize and commit substantial resources to programs associated with our product candidates, we may be unable to commercialize our product candidates, which would

## **Table of Contents**

limit our ability to generate revenue and become profitable. In the future, we may not be able to locate third-party collaborators to develop and market our product candidates and we may lack the capital and resources necessary to develop all our product candidates alone.

*We have no experience in commercializing products on our own and, to the extent we do not develop this ability or contract with a third party to assist us, we may not be able to successfully commercialize our product candidates that may be approved for commercial sale.*

We do not have a sales and marketing force and may not be able to develop this capacity. If we are unable to establish sales and marketing capabilities, we will need to enter into sales and marketing agreements to market any of our product candidates that may be approved for commercial sale. If we are unable to establish sales and marketing capabilities or successful distribution relationships with biotechnology or pharmaceutical companies, we may fail to realize the full sales potential of some of our product candidates. Even if we are able to establish distribution agreements with biotechnology or pharmaceutical companies, we generally would not have control over the resources or degree of effort that any of these third parties may devote to our collaborations, and if they fail to devote sufficient time and resources to the marketing of our product candidates, or if their performance is substandard, it will adversely affect the sale of our product candidates.

Moreover, government health administrative authorities, private health insurers and other organizations are increasingly challenging both the need for and the price of new medical products and services. Significant changes in the U.S. healthcare system are intended in the near future, including the potential for increased use of cost-effectiveness measures and the possibility of generic biologics. Consequently, uncertainty exists as to the reimbursement status of newly approved therapeutics and diagnostics. For these and other reasons, physicians, patients, third-party payors and the medical community may not accept and utilize any product candidates that we develop and even if they do, reimbursement may not be available for our products to enable us to maintain price levels sufficient to realize an appropriate return on our investment in research and product development. Similarly, even if we do receive reimbursement, the target market for any approved products may be small or the focus of intense competition and we may not realize an appropriate return on our investment in research and product development.

*We depend on a small number of collaborators for most of our current revenue. The loss of any one of these collaborators could result in a substantial decline in our revenue.*

We have collaborations with a limited number of companies. To date, almost all of our revenue has resulted from payments made under agreements with our corporate collaborators, and we expect that most of our future revenue and substantial amounts of cash used to fund our operations will continue to come from corporate collaborations until the approval and commercialization of one or more of our product candidates and even then we may still be highly dependent on the activities of a collaborator to derive revenue from the approved product. For example, if brentuximab vedotin receives regulatory approval, our revenues will still depend in part on Millennium's ability and willingness to market the approved product outside of the United States and Canada. The loss of our collaborators, especially Millennium, or the failure of our collaborators to perform their obligations under their agreements with us, including paying license or technology fees, milestone payments, royalties or reimbursements, could have a material adverse effect on our financial performance. Payments under our existing and future collaboration agreements are also subject to significant fluctuations in both timing and amount, which could cause our revenue to fall below the expectations of securities analysts and investors and cause a decrease in our stock price.

*We currently rely on third-party manufacturers and other third parties for production of our drug products and our dependence on these manufacturers may impair the development of our product candidates.*

We do not currently have the internal ability to manufacture the drug products that we need to conduct our clinical trials and we rely upon a limited number of manufacturers to supply our drug products. For the monoclonal antibody used in brentuximab vedotin, we have contracted

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

with Abbott Laboratories for clinical and potential future commercial supplies and we recently entered into a manufacturing and supply agreement with

## **Table of Contents**

PFMP for the cGMP fill/finish manufacture of commercial quantities of brentuximab vedotin. For brentuximab vedotin and other ADCs, several contract manufacturers, including Albany Molecular and SAFC, supply us with drug-linker and other contract manufacturers, including Piramal, perform conjugation of the drug-linker to the antibody. For dacetuzumab, we have also contracted with Abbott Laboratories for clinical and potential future commercial supplies. For lintuzumab, we entered into a contract manufacturing arrangement with Laureate Pharma to provide later-stage clinical supplies. We have also contracted with Laureate Pharma to manufacture the antibody component of SGN-70 and SGN-75 for clinical trials. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including vialing and storage of our product candidates. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce, vial and store sufficient quantities of our product candidates for use in our clinical trials. If our contract manufacturers or other third parties fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our product candidates. In addition, we depend on outside vendors for the supply of raw materials used to produce our product candidates. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have our product candidates manufactured and to conduct preclinical testing and clinical trials of our product candidates would be adversely affected.

Although we are currently establishing our commercial scale supply chain for brentuximab vedotin, we do not yet have all of the agreements necessary for the supply of our product candidates in quantities sufficient for commercial sale and we may not be able to establish or maintain sufficient commercial manufacturing arrangements on commercially reasonable terms. In addition, we have committed to provide Millennium with their needs of brentuximab vedotin for a limited period of time, which may require us to arrange for additional manufacturing supply. Securing commercial quantities of our product candidates from contract manufacturers will require us to commit significant capital and resources. We may also be required to enter into long-term manufacturing agreements that contain exclusivity provisions and/or substantial termination penalties. In addition, contract manufacturers have a limited number of facilities in which our product candidates can be produced and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available product candidates.

Our contract manufacturers are required to produce our clinical product candidates under GMP in order to meet acceptable standards for our clinical trials. If such standards change, the ability of contract manufacturers to produce our product candidates on the schedule we require for our clinical trials may be affected. In addition, contract manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to successfully produce and market our product candidates. We and our contract manufacturers are subject to periodic unannounced inspection by the FDA and corresponding state and foreign authorities to ensure strict compliance with GMP and other applicable government regulations and corresponding foreign standards. We do not have control over a third-party manufacturer's compliance with these regulations and standards. Any difficulties or delays in our contractors' manufacturing and supply of product candidates or any failure of our contractors to maintain compliance with the applicable regulations and standards could increase our costs, cause us to lose revenue, make us postpone or cancel clinical trials, or cause our products to be recalled or withdrawn.

The FDA requires that we demonstrate structural and functional comparability between the same product candidates manufactured by different organizations. Because we have used or intend to use multiple sources to manufacture many of our product candidates, we will need to conduct comparability studies to assess whether manufacturing changes have affected the product safety, identity, purity or potency of any recently manufactured product candidate compared to the product candidate used in prior clinical trials. If we are unable to demonstrate comparability, the FDA could require us to conduct additional clinical trials, which would be expensive and may significantly delay our clinical progress and the possible commercialization of such product candidates.

## **Table of Contents**

Similarly, if we believe there may be comparability issues with any one of our product candidates, we may postpone or suspend manufacture of the product candidate to conduct further process development of such product candidate in order to alleviate such product comparability concerns, which may significantly delay the clinical progress of such product candidate or increase its manufacturing costs.

***We rely on third parties to provide services in connection with our preclinical and clinical development programs. The inadequate performance by or loss of any of these service providers could affect our product candidate development.***

Several third parties provide services in connection with our preclinical and clinical development programs, including *in vitro* and *in vivo* studies, assay and reagent development, immunohistochemistry, toxicology, pharmacokinetics and other outsourced activities. If these service providers do not adequately perform the services for which we have contracted or cease to continue operations and we are not able to quickly find a replacement provider or we lose information or items associated with our product candidates, our development programs may be delayed.

***Our ADC technology has not been incorporated into a commercial product and is still at a relatively early stage of development.***

Our ADC technology, utilizing proprietary stable linkers and highly potent cell-killing drugs, has not been incorporated into a commercial product and is still at a relatively early stage of development. This ADC technology is used in our brentuximab vedotin, SGN-75, ASG-5ME and SGN-19A product candidates and is the basis of our collaborations with Agensys, Bayer, Celldex, Daiichi Sankyo, Genentech, GSK, MedImmune, Millennium and Progenics. We and our corporate collaborators are conducting toxicology, pharmacology, pharmacokinetics and other preclinical studies and, although we and our collaborators have initiated clinical trials of ADC product candidates, additional studies may be required before other ADC product candidates enter human clinical trials. In addition, preclinical models to study patient toxicity and anti-cancer activity of compounds are not necessarily predictive of toxicity or efficacy of these compounds in the treatment of human cancer and there may be substantially different results in clinical trials from the results obtained in preclinical studies. Any failures or setbacks in our ADC program, including adverse effects resulting from the use of this technology in humans, could have a detrimental impact on our internal product candidate pipeline and our ability to maintain and/or enter into new corporate collaborations regarding these technologies, which would negatively affect our business and financial position.

***We have a history of net losses. We expect to continue to incur net losses and may not achieve or maintain profitability for some time, if at all.***

We have incurred substantial net losses in each of our years of operation and, as of December 31, 2009, we had an accumulated deficit of approximately \$396 million. We expect to make substantial expenditures to further develop and commercialize our product candidates, and we anticipate that our rate of spending will accelerate as the result of the increased costs and expenses associated with research, development, clinical trials, manufacturing, regulatory approvals and commercialization of our product candidates. In the near term, we expect our revenues to be derived from technology licensing fees, sponsored research fees and milestone payments under existing and future collaborative arrangements. In the longer term, our revenues may also include royalties from collaborations with current and future strategic partners and commercial product sales if any of our product candidates are approved for commercial sale. However, our revenue and profit potential is unproven and our limited operating history makes our future operating results difficult to predict. We have never been profitable and may never achieve profitability and if we do achieve profitability, it may not be sustainable.

***We will continue to need significant amounts of additional capital that may not be available to us.***



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

We expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees and support our preclinical development, manufacturing and clinical trial activities, as well as position our product candidates, specifically brentuximab vedotin, for potential regulatory

**Table of Contents**

approval and commercial sale. Although some of these expenditures are expected to be shared with Millennium as part of our brentuximab vedotin collaboration, we will continue to need significant amounts of additional capital. We may seek additional funding through public or private financings, including equity financings, and through other means, such as collaborations and license agreements. However, the global credit markets and the financial services industry have recently experienced a period of unusual volatility and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the U.S. government. These events have generally made equity and debt financing more difficult to obtain. As a result of these recent events and other factors, we do not know whether additional financing will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If adequate funds are not available to us, we will be required to delay, reduce the scope of or eliminate one or more of our development programs, which may adversely affect our business and operations. Our future capital requirements will depend upon a number of factors, including:

the time and costs involved in obtaining regulatory approvals, including the preparation for product commercialization;

the size, complexity, timing, and number of clinical programs;

our receipt of milestone-based payments or other revenue from our collaborations or license arrangements;

the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or our collaborators may develop;

progress with clinical trials;

the costs associated with acquisitions or licenses of additional products, including licenses we may need to commercialize our products;

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

the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;

the potential costs associated with state and federal taxes;

the timing and cost of milestone payment obligations as our product candidates progress towards commercialization; and

competing technological and market developments.

In addition, changes in our business may occur that would consume available capital resources sooner than we expect. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

*We rely on license agreements for certain aspects of our product candidates and technology. Failure to maintain these license agreements or to secure any required new licenses could prevent us from developing or commercializing our product candidates and technology.*

We have entered into agreements with third-party commercial and academic institutions to license technology for use in our product candidates and ADC technology. Currently, we have license agreements with Bristol-Myers Squibb, Arizona State University, Genentech, PDL BioPharma, Facet, CLB Research and Development, CMC ICOS Biologics, Mabtech, and the University of Miami, among others. Some of these license agreements contain diligence and milestone-based termination provisions, in which case our failure to meet any agreed upon diligence requirements or milestones may allow the licensor to terminate the agreement. Many of our license agreements grant us exclusive licenses to the underlying technologies. If our licensors

## **Table of Contents**

terminate our license agreements or if we are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize our product candidates. In addition, continued development and commercialization of our product candidates will likely require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

*If we are unable to enforce our intellectual property rights, we may not be able to commercialize our product candidates. Similarly, if we fail to sustain and further build our intellectual property rights, competitors may be able to develop competing therapies.*

Our success depends, in part, on obtaining and maintaining patent protection and successfully enforcing these patents and defending them against third-party challenges in the United States and other countries. We own multiple U.S. and foreign patents and pending patent applications for our technologies. We also have rights to issued U.S. patents, patent applications, and their foreign counterparts, relating to our monoclonal antibody and drug-based technologies. Our rights to these patents and patent applications are derived in part from worldwide licenses from Bristol-Myers Squibb, Arizona State University and Facet, among others. In addition, we have licensed our U.S. and foreign patents and patent applications to third parties.

Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. In addition, the U.S. Patent and Trademark Office may issue revised regulations affecting prosecution before that office, and various pieces of legislation, including patent reform acts, have been introduced or discussed in the U.S. Senate and Congress in the past few years. If implemented, or following final resolution of pending legislation, new regulations or legislation could, among other things, restrict our ability to prosecute applications in the U.S. Patent and Trademark Office, and may lower the threshold required for competitors to challenge our patents in the U.S. Patent and Trademark Office after they have been granted.

The standards that the U.S. Patent and Trademark Office and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents we currently own or obtain in the future may not contain claims that will permit us to stop competitors from using similar technology. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. As a result, the protection, if any, given by our patents if we attempt to enforce them or if they are challenged in court is uncertain.

We rely on trade secrets and other proprietary information where we believe patent protection is not appropriate or obtainable. However, trade secrets and other proprietary information are difficult to protect. We have taken measures to protect our unpatented trade secrets and know-how, including the use of confidentiality and assignment of inventions agreements with our employees, consultants and certain contractors. It is possible, however, that these persons may breach the agreements or that our competitors may independently develop or otherwise discover our trade secrets or other proprietary information.

Our research collaborators may publish data and information to which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information may be impaired.

*We may incur substantial costs and lose important rights as a result of litigation or other proceedings relating to patent and other intellectual property rights.*

We may face potential lawsuits by companies alleging infringement of its intellectual property. Because patent applications can take a few years to publish, there may be currently pending applications of which we are unaware that may later result in issued patents that affect the commercial development of our product candidates.

## **Table of Contents**

In addition, we are monitoring the progress of multiple pending patent applications of other companies that, if granted, may require us to license or challenge their validity upon commercialization of our product candidates.

The defense and enforcement of intellectual property rights in a court of law, U.S. Patent and Trademark Office interference or reexamination proceedings, foreign opposition proceedings and related legal and administrative proceedings in the United States and elsewhere involve complex legal and factual questions. These proceedings are costly and time-consuming. If we become involved in any litigation, interference or other administrative proceedings, we will incur substantial expense and it will divert the efforts of our technical and management personnel. An adverse determination may limit the scope of intellectual property protection for our proprietary technologies, subject us to significant liabilities or require us to seek licenses that may not be available from third parties on commercially reasonable terms, if at all. We may be restricted or prevented from developing and commercializing our product candidates in the event of an adverse determination in a judicial or administrative proceeding, or if we fail to obtain necessary licenses.

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

We are highly dependent on the efforts and abilities of the principal members of our senior management. Additionally, we have scientific personnel with significant and unique expertise in monoclonal antibodies, ADCs and related technologies. The loss of the services of any one of the principal members of our managerial or scientific staff may prevent us from achieving our business objectives.

In addition, the competition for qualified personnel in the biotechnology field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. In order to commercialize our products successfully, we will be required to expand our workforce, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development, sales and marketing. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing management personnel. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, as well as academic and other research institutions. To the extent we are not able to attract and retain these individuals on favorable terms, our business may be harmed.

***We face intense competition and rapid technological change, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.***

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. We are aware of many pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antibody therapy or that are otherwise developing various approaches to cancer and autoimmune disease therapy. Some of these competitors have successfully commercialized antibody products or are developing or testing product candidates that do or may in the future compete directly with our product candidates. For example, we believe that companies including Genentech, Amgen, Bayer, ImmunoGen, Biogen IDEC, Celgene, Cephalon, Genzyme, Medarex (a wholly owned subsidiary of Bristol-Myers Squibb), Eisai, Millennium, Novartis, Micromet and Wyeth (a wholly owned subsidiary of Pfizer) are developing and/or marketing products or technologies that may compete with ours, and some of these companies, including Wyeth, ImmunoGen and Medarex, have ADC technology. Other potential competitors include large, fully integrated pharmaceutical companies and more established biotechnology companies that have significant resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals and marketing. Also, academic institutions, government agencies and other public and private research organizations conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing. It is possible that these competitors will succeed in developing technologies that are more effective than our product candidates or that would render our technology obsolete or noncompetitive. Our competitors may, among other things:

develop safer or more effective products;

**Table of Contents**

implement more effective approaches to sales and marketing;

develop less costly products;

obtain quicker regulatory approval;

have access to more manufacturing capacity;

form more advantageous strategic alliances; or

establish superior proprietary positions.

In addition, if we receive regulatory approvals, we may compete with well-established, FDA-approved therapies that have generated substantial sales over a number of years. We anticipate that we will face increased competition in the future as new companies enter our market and scientific developments surrounding other cancer therapies continue to accelerate.

*We face product liability risks and may not be able to obtain adequate insurance to protect us against losses.*

We currently have no products that have been approved for commercial sale. However, the current and future use of our product candidates by us and our corporate collaborators in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made directly by consumers or healthcare providers or indirectly by pharmaceutical companies, our corporate collaborators or others selling such products. We may experience financial losses in the future due to product liability claims. We have obtained limited general commercial liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against all losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

*Our operations involve hazardous materials and are subject to environmental, health and safety controls and regulations.*

We are subject to environmental, health and safety laws and regulations, including those governing the use of hazardous materials, and we spend considerable time complying with such laws and regulations. Our business activities involve the controlled use of hazardous materials and although we take precautions to prevent accidental contamination or injury from these materials, we cannot completely eliminate the risk of using these materials. In the event of an accident or environmental discharge, we may be held liable for any resulting damages, which may materially harm our business, financial condition and results of operations.

*We may engage in future acquisitions that increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.*



We actively evaluate various strategic transactions on an ongoing basis, including licensing or acquiring complementary products, technologies or businesses. Any potential acquisitions may entail numerous risks, including increased operating expenses and cash requirements, assimilation of operations and products, retention of key employees, diversion of our management's attention and uncertainties in our ability to maintain key business relationships of the acquired entities. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

## **Table of Contents**

***Legislative actions, potential new accounting pronouncements and higher insurance costs are likely to impact our future financial position or results of operations.***

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and may occur again in the future and as a result we may be required to make changes in our accounting policies. Those changes could adversely affect our reported revenues, future profitability or financial position. Compliance with new regulations regarding corporate governance and public disclosure may result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from science and business activities to compliance activities.

***Current global credit and financial market conditions may negatively impact or impair the value of our current portfolio of cash equivalents, short-term investments and long-term investments, including auction rate securities, and our ability to fund our planned operations.***

Our cash, cash equivalents and investments are held in a variety of interest-bearing instruments and subject to investment guidelines allowing for investments in U.S. government and agency securities, high-grade corporate bonds, taxable municipal bonds, mortgage-backed securities, auction rate securities, or ARS, commercial paper and money market accounts. As a result of the current adverse global credit and financial market conditions, investments in some financial instruments, such as mortgage-backed securities and ARS, may pose risks arising from liquidity and credit concerns. For example, as of December 31, 2009 we held ARS valued at \$12.5 million that have failed at auction and are currently illiquid. Given that further deterioration in the global credit and financial markets is a possibility, no assurance can be made that losses, failed auctions or other significant deterioration in the fair value of our cash equivalents, short-term or long-term investments or ARS will not occur. If any such losses, failed auctions or other significant deteriorations occur, it may negatively impact or impair our current portfolio of cash equivalents, short-term or long-term investments or ARS and our ability to fund our planned operations. Further, unless and until the current global credit and financial market crisis has been sufficiently resolved, it may be difficult for us to liquidate our investments prior to their maturity without incurring a loss.

## **Risks Related to Our Stock**

***Our stock price is volatile and our shares may suffer a decline in value.***

The market price of our stock has in the past been, and is likely to continue in the future to be, very volatile. During the fourth quarter of 2009, our closing stock price fluctuated between \$8.74 and \$13.20 per share. As a result of fluctuations in the price of our common stock, you may be unable to sell your shares at or above the price you paid for them. The market price of our common stock may be subject to substantial volatility in response to many risk factors listed in this section, and others beyond our control, including:

announcements regarding the results of discovery efforts and preclinical and clinical activities by us or our competitors, especially the results of our pivotal trial of brentuximab vedotin;

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

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

establishment of new collaboration, partnering or licensing arrangements by us or our competitors;

announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;

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

our ability to raise capital;

**Table of Contents**

market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;

developments or disputes concerning our proprietary rights;

issuance of new or changed analysts' reports and recommendations regarding us or our competitors;

share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

changes in government regulations; and

economic or other external factors.

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. Recently, the financial markets faced significant uncertainty, resulting in a decline in investor confidence and concerns about the proper functioning of the securities markets, which decline in general investor confidence resulted in depressed stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These broad market fluctuations may adversely affect the trading price of our common stock. In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources, which could result in delays of our clinical trials or commercialization efforts.

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

Our executive officers and directors and holders of greater than five percent of our outstanding voting stock, together with entities that may be deemed affiliates of, or related to, such persons or entities, beneficially owned approximately 52 percent of our voting power as of March 10, 2010. As a result, these stockholders, acting together, may be able to control our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. Consequently, this concentration of ownership may have the effect of delaying, deferring or preventing a change in control, including a merger, consolidation, takeover or other business combination involving us or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control, which might affect the market price of our common stock.

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

Our Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by the stockholders. The rights of the holders of common stock may be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control of Seattle Genetics without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. Further, certain provisions of our charter documents, including provisions eliminating the ability of stockholders to take action by written consent and limiting the ability of stockholders to raise matters at a meeting of stockholders without giving advance notice, may have the effect of delaying or preventing changes in control or management of Seattle Genetics, which could have an adverse effect on the market price of our stock. In

addition, our charter documents provide for a classified board, which may make it more difficult for a third party to gain control of our Board of Directors. Similarly, state anti-takeover laws in Delaware and Washington related to corporate takeovers may prevent or delay a change of control of Seattle Genetics.

**Table of Contents**

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

None.

**Item 2. Properties.**

Our headquarters are in Bothell, Washington, where we lease approximately 113,900 square feet of office space that we use for laboratory, discovery, research and development and general and administrative purposes. The original lease agreement that we entered into in 2000 was for 63,900 square feet, which lease agreement was amended on July 1, 2008 to extend and modify the terms of the lease. During 2009, we received a tenant improvement allowance of \$958,500 which was used to offset some of the cost of improvements made to the facility to accommodate our growth. We have two renewal options of five years each and the option to terminate the lease effective June 2013 or June 2015 upon providing notice of our intent to accelerate the termination date of the lease and payment of a termination fee.

In June 2007, we entered into an operating lease for approximately 25,000 square feet of additional office space adjacent to our headquarters. The lease expires in June 2018 with two extension options, the first option for three years and the second option period for seven years. The lease allows for options to terminate the lease effective June 2011 or June 2014. In July 2008, we amended this lease to include an additional 25,000 square feet of office space under the same terms as the original lease.

**Item 3. Legal Proceedings.**

We are not a party to any material legal proceedings.

**Item 4. (Removed and Reserved).**

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.***Price Range of Our Common Stock*

Our common stock is traded on The NASDAQ Global Market under the symbol SGEN. As of March 10, 2010, there were 100,655,967 shares of our common stock outstanding, which were held by approximately 116 holders of record of our common stock. On March 10, 2010, the closing price of our common stock as reported by The NASDAQ Global Market was \$11.73 per share.

Our common stock has been quoted on The NASDAQ Global Market under the symbol SGEN since our initial public offering on March 6, 2001. The following table sets forth, for the periods indicated, the reported high and low sales prices per share of our common stock as reported by The NASDAQ Global Market:

	<b>High</b>	<b>Low</b>
<b>2008</b>		
First Quarter	\$ 11.98	\$ 7.20
Second Quarter	10.80	8.18
Third Quarter	13.40	7.80
Fourth Quarter	11.10	6.81
<b>2009</b>		
First Quarter	\$ 10.78	\$ 7.00
Second Quarter	10.47	7.91
Third Quarter	14.94	8.62
Fourth Quarter	14.06	8.26
<b>2010</b>		
First Quarter (through March 10, 2010)	\$ 12.15	\$ 9.24

*Dividend Policy*

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

*Sales of Unregistered Securities and Issuer Repurchases of Securities*

Other than sales disclosed in previous quarterly reports on Form 10-Q or current reports on Form 8-K, we did not make any unregistered sales of shares of our common stock in 2009. In addition, we did not repurchase any of our equity securities during the fourth quarter of 2009.





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

We show below the cumulative total return to our stockholders during the period from December 31, 2004 through December 31, 2009 in comparison to the cumulative return on The NASDAQ Pharmaceutical Index, The NASDAQ Composite Index and The NASDAQ Biotechnology Index during that same period. The results assume that \$100 was invested on December 31, 2004 in our common stock and each of the indexes listed above, including reinvestment of dividends, if any.

	Years ended					
	12/04	12/05	12/06	12/07	12/08	12/09
<b>Seattle Genetics, Inc.</b>	<b>100.00</b>	<b>72.28</b>	<b>81.62</b>	<b>174.58</b>	<b>136.91</b>	<b>155.59</b>
<b>NASDAQ Composite</b>	<b>100.00</b>	<b>101.33</b>	<b>114.01</b>	<b>123.71</b>	<b>73.11</b>	<b>105.61</b>
<b>NASDAQ Pharmaceutical</b>	<b>100.00</b>	<b>102.23</b>	<b>105.16</b>	<b>99.56</b>	<b>91.99</b>	<b>98.21</b>
<b>NASDAQ Biotechnology</b>	<b>100.00</b>	<b>117.54</b>	<b>117.37</b>	<b>121.37</b>	<b>113.41</b>	<b>124.58</b>

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

**Table of Contents****Item 6. Selected Financial Data.**

The following selected financial data should be read in conjunction with our consolidated financial statements and notes to our consolidated financial statements and Management's Discussion and Analysis of Financial Condition and Results of Operations contained elsewhere in this Annual Report on Form 10-K. The selected Consolidated Statements of Operations data for the years ended December 31, 2009, 2008 and 2007 and Consolidated Balance Sheet data as of December 31, 2009 and 2008 have been derived from our audited financial statements appearing elsewhere in this Annual Report on Form 10-K. The selected Consolidated Statements of Operations data for the years ended December 31, 2006 and 2005 and Consolidated Balance Sheet data as of December 31, 2007, 2006 and 2005 have been derived from our audited financial statements that are not included in this Annual Report on Form 10-K. Historical results are not necessarily indicative of future results.

	2009	Years Ended December 31,			2005
		2008	2007	2006	
		(in thousands, except per share amounts)			
<b>Consolidated Statements of Operations Data:</b>					
Revenues	\$ 51,965	\$ 35,236	\$ 22,420	\$ 10,005	\$ 9,757
Operating Expenses:					
Research and development	119,139	110,944	64,828	40,136	34,683
General and administrative	17,683	16,078	13,237	10,074	7,145
Loss from operations	(84,857)	(91,786)	(55,645)	(40,205)	(32,071)
Investment income, net	3,174	6,285	6,713	4,190	2,638
Net loss	\$ (81,683)	\$ (85,501)	\$ (48,932)	\$ (36,015)	\$ (29,433)
<b>Basic and diluted net loss per share attributable to common stockholders</b>					
	\$ (0.90)	\$ (1.09)	\$ (0.80)	\$ (0.74)	\$ (0.70)
<b>Weighted-average shares used in computing basic and diluted net loss per share</b>					
	90,988	78,724	61,293	48,659	42,238
	2009	2008	December 31, 2007	2006	2005
			(in thousands)		
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and investment securities	\$ 287,730	\$ 160,708	\$ 129,584	\$ 86,573	\$ 79,207
Working capital	244,081	70,496	90,003	76,880	33,048
Total assets	388,333	187,717	148,530	97,695	90,019
Stockholders' equity	206,200	79,018	53,986	88,234	75,458

---

## **Table of Contents**

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

#### **Forward-Looking Statements**

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

#### **Overview**

We are a clinical stage biotechnology company focused on the development and commercialization of monoclonal antibody-based therapies for the treatment of cancer and autoimmune diseases. We initiated a pivotal trial of our lead product candidate, brentuximab vedotin (SGN-35), during the first quarter of 2009 for patients with relapsed or refractory Hodgkin lymphoma under an SPA with the FDA. The trial was fully enrolled in August 2009 and we expect to report data from the trial in the second half of 2010. Brentuximab vedotin is empowered by our proprietary ADC technology comprising highly potent synthetic drugs and stable linkers for attaching the drugs to monoclonal antibodies. In addition, we have four other product candidates in ongoing clinical trials: lintuzumab (SGN-33), dacetuzumab (SGN-40), SGN-70 and SGN-75.

In December 2009, we entered into a collaboration agreement with Millennium to develop and commercialize brentuximab vedotin, under which Seattle Genetics has United States and Canadian commercial rights and Millennium has commercial rights in the rest of the world. We also have collaborations for our ADC technology with a number of leading biotechnology and pharmaceutical companies, including Bayer, Celldex, Daiichi Sankyo, Genentech, GSK, MedImmune, Millennium, and Progenics, as well as an ADC co-development agreement with Agensys.

We do not currently have any commercial products for sale. While certain of our product candidates are advancing into later stages of development, such as brentuximab vedotin, significant further research and development, financial resources and personnel will be required to develop commercially viable products and obtain regulatory approvals. As of December 31, 2009, we had an accumulated deficit of \$395.7 million. Over the next several years, we expect that we will incur substantial expenses, primarily the result of activities related to the potential regulatory approval and commercialization of brentuximab vedotin, including preparation for commercial manufacturing. We will also continue to invest in research, development and manufacturing as we plan to move toward potential commercialization of our other product candidates. Our commitment of resources to the approval and commercialization activities for brentuximab vedotin and the research and continued development and potential commercialization of our other product candidates will require substantial additional funds and resources and our operating expenses will also likely increase as a result of such activities. In addition, we may incur significant milestone payment obligations as our product candidates progress through clinical trials towards potential commercialization. We expect that a substantial portion of our revenues for the next several years will be the result of amortization of payments already received and expected to be received pursuant to our



## **Table of Contents**

collaboration agreements. Until such time as we have commercialized a product candidate, our revenues will also depend on the achievement of development and clinical milestones under our existing collaboration and license agreements, particularly our brentuximab vedotin collaboration with Millennium, as well as entering into new collaboration and license agreements. The majority of our revenues for the past three years resulted from our dacetuzumab collaboration agreement with Genentech. In December 2009, Genentech informed us of its decision to terminate the collaboration effective June 8, 2010. As of December 31, 2009, we had deferred revenue of \$66.8 million recorded on our balance sheet related to the dacetuzumab collaboration. As a result of the termination of the agreement, we expect to recognize this amount as revenue in the first half of 2010. In addition, as a result of the termination, if we decide to continue development of dacetuzumab, we will be responsible for and will be required to solely fund any new dacetuzumab development and clinical trial activities undertaken after the collaboration ends, which could result in a significant delay in the dacetuzumab development process. If we determine instead to discontinue the development of dacetuzumab, we will not receive any additional return on our investment from that product candidate. Our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period to period comparisons of our operating results may not be meaningful and you should not rely on them as indicative of our future performance.

## **Critical Accounting Policies**

The preparation of financial statements in accordance with generally accepted accounting principles requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. We believe the following critical accounting policies describe the more significant judgments and estimates used in the preparation of our financial statements.

**Revenue Recognition.** We have entered into licensing and collaboration agreements that contain multiple revenue elements including upfront payments, license fees, milestone payments, royalties, maintenance fees and payments for the delivery of supplies or services provided. Each agreement may contain some or all of these elements. Revenue recognition is predicated upon persuasive evidence of an agreement existing, delivery of materials or services being rendered, fees being fixed or determinable, and collectibility being reasonably assured. Agreements that include multiple elements are evaluated to determine whether the associated deliverables can be considered separate units of accounting. In order to be considered a separate unit of accounting, a deliverable must have standalone value to the customer and we must have objective and reliable evidence of its fair value. To date, the deliverables under our collaboration agreements have not qualified as separate units of accounting and revenue is typically recognized over our performance obligation period under each agreement. We generally use a time-based proportional performance model to recognize our revenue over the performance period as further discussed below. The assessment of multiple element arrangements requires judgment in order to determine the appropriate point in time, or period of time, that revenue should be recognized.

*Nonrefundable upfront license payments, option and maintenance fees and milestone payments:*

Our collaborative agreements may include nonrefundable upfront license payments, option and maintenance fees, and payments triggered by the achievement of development milestones by the other party or by us. When we have substantive continuing performance obligations under an arrangement, revenue is recognized over the performance period of the obligations. Under the time-based proportional performance method, revenue is recognized over the arrangement's estimated performance period based on the elapsed time compared to the total estimated performance period. Changes in estimates of the total expected performance period are accounted for prospectively when a change becomes known. Revenue recognized at any point in time is limited to the amount of non-contingent payments received or due. When we have no substantive continuing performance obligations under an arrangement, we recognize milestone payments as revenue upon achievement of the milestone event.

## **Table of Contents**

### *Research and development services:*

We may also perform research and development activities on behalf of collaborative partners that are paid for by the collaborator. When no other obligation to provide services is required by us, revenue from research and development services is generally recognized as the service is provided. However, if the arrangement provides for other ongoing services by us or contains multiple delivery elements which do not qualify as separate units of accounting, amounts due for such services are recognized as revenue over the service period.

### *Royalties:*

Revenues from royalties on third-party sales of licensed technologies are generally recognized in accordance with the contract terms when the royalties can be reliably determined and collectibility is reasonably assured. To date, we have not received significant royalty revenues.

We generally invoice our collaborators on a monthly or quarterly basis, or upon the completion of the effort, based on the terms of each agreement. Amounts due, but not billed to a collaborator, if any, are included in accounts receivable in our consolidated balance sheets. Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods when the applicable revenue recognition criteria have been met. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

**Investments.** Our investments are diversified among a variety of debt securities in accordance with our investment policy. We classify our investments as available-for-sale, which are reported at fair market value with the related unrealized gains and losses included in accumulated other comprehensive income or loss in stockholders' equity. Realized gains and losses and declines in value of investments judged to be other than temporary are included in investment income. To date, we have not deemed it necessary to record any charges related to other-than-temporary declines in the estimated fair values of our marketable debt securities. The fair value of our investments is subject to volatility. Declines in the fair value of our investments judged to be other than temporary could adversely affect our future operating results. As described below under **Liquidity and capital resources** we use a probability-weighted discounted cash flow analysis to value our investment in auction rate securities.

**Accrued Expenses.** As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of services performed and the associated costs incurred for such services where we have not yet been invoiced or otherwise notified of actual cost. We record these estimates in our consolidated financial statements as of each balance sheet date. Examples of estimated accrued expenses include fees due to contract research organizations and other costs in conjunction with clinical trials, fees due in conjunction with manufacturing clinical grade materials and professional service fees.

In accruing service fees, we estimate the time period over which services will be provided and the level of effort in each period. If the actual timing of the provision of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. In the event that we do not identify costs that have been incurred or we under or overestimate the level of services performed or the costs of such services, our actual expenses would differ from such estimates. The date on which some services commence, the level of services performed on or before a given date and the cost of such services are often subjective determinations. We make judgments based upon the facts and circumstances known to us at the time and in accordance with generally accepted accounting principles.

**Research and Development.** Research and development expenses consist of salaries, benefits and other headcount related costs of our research and development staff, preclinical activities, clinical trials, lab supplies, manufacturing costs for product candidates used in research and clinical trials, contract and outside service fees and facilities and overhead expenses. Research and development activities are expensed as incurred. In-licensing fees, including milestones and maintenance fees, and other costs to acquire technologies that are utilized in

## **Table of Contents**

research and development and that are not expected to have alternative future use are expensed when incurred. We account for our clinical trial costs by estimating the total cost to treat a patient in each clinical trial and recognize this cost, based on a variety of factors, beginning with the preparation for the clinical trial, continuing through patient accrual into the clinical trial and completion of the clinical trial. This estimated cost includes payments for clinical trial site and patient-related costs, including laboratory costs related to the conduct of the trial, and other costs. Costs associated with activities performed under research and development co-development collaborations are reflected in research and development expense. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are capitalized and recognized as expense as the related goods are delivered or the related services are performed.

**Share-based Compensation.** We expense the fair value of share-based payment transactions in our consolidated financial statements. We use the Black-Scholes option pricing model to estimate the fair value of options on the date of grant which requires certain estimates to be made by management, including the expected forfeiture rate and expected term of the options. Management also makes decisions regarding the method of calculating the expected stock price volatility and the risk free interest rate used in the model. Fluctuations in the market that affect these estimates could have an impact on the resulting compensation cost. For additional information see Note 9 of the Notes to the Consolidated Financial Statements included in this Annual Report on Form 10-K.

**Income Taxes.** We have net deferred tax assets which are fully offset by a valuation allowance due to our determination that it is more likely than not that the deferred assets will not be realized. We believe that a full valuation allowance is appropriate as we expect to incur operating losses for at least the next several years as we continue to pursue the development of our product candidates. In the event we were to determine that we would be able to realize our net deferred tax assets in the future, an adjustment to the deferred tax asset would be made, a portion of which would increase income (or decrease losses) in the period in which such a determination was made.

On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, investments, accrued expenses, research and development, share-based compensation and income taxes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions and conditions.

## **Results of Operations**

### **Years Ended December 31, 2009, 2008 and 2007**

#### **Revenues**

Total revenues in 2009 increased by 47% to \$52.0 million from 2008, and increased by 57% in 2008 to \$35.2 million from 2007. Our revenues reflect amounts earned under our dacetuzumab collaboration agreement with Genentech entered into in January 2007, the earned portion of technology access fees and milestone payments received under our ADC collaborations, including funded research and material supply fees, and to a lesser degree, our brentuximab vedotin collaboration agreement entered into with Millennium in December 2009. Revenues are summarized by collaborator as follows:

#### **Collaboration and license agreement revenue by collaborator**



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

(\$ in thousands)

	2009	2008	2007	Annual percentage change	
				2009/2008	2008/2007
Genentech	\$ 41,594	\$ 28,544	\$ 17,397	46%	64%
Agensys	4,029			N/A <sup>(1)</sup>	N/A <sup>(1)</sup>
Daiichi Sankyo	1,779	797		123%	N/A <sup>(1)</sup>
Millennium	1,690			N/A <sup>(1)</sup>	N/A <sup>(1)</sup>
Other collaborations	2,873	5,895	5,023	(51)%	17%
Total	\$ 51,965	\$ 35,236	\$ 22,420	47%	57%

---

**Table of Contents**

(1) No amount in comparable period.

Revenues earned under our dacetuzumab and our ADC collaborations with Genentech represented 80% of our total revenues in 2009, 81% of our total revenues in 2008 and 78% of our total revenues in 2007. Our revenues are impacted by progress-dependent milestones, annual maintenance fees and reimbursement of materials and support services as our collaborators advance their ADC product candidates through the development process and, in the case of our dacetuzumab collaboration with Genentech and our brentuximab vedotin collaboration with Millennium, the level of development activities that we perform. Genentech has notified us of its election to terminate the dacetuzumab collaboration effective June 8, 2010, following which time, if we decide to continue development of dacetuzumab, we will be responsible for and will be required to solely fund any new dacetuzumab development and clinical trial activities. As of December 31, 2009, we carried \$66.8 million in deferred revenue related to this collaboration that we expect to recognize as revenue during the first half of 2010. We expect that 2010 revenues will increase compared to 2009. This is primarily the result of the recognition of \$66.8 million in deferred revenue from the dacetuzumab collaboration as well as amounts expected to be earned under our new collaboration with Millennium for brentuximab vedotin. Revenue may vary substantially from year to year and quarter to quarter depending on the progress made by our collaborators with their ADC product candidates, the level of support we provide to our collaborators, the timing of milestones achieved and our ability to enter into additional collaboration agreements. In addition to amounts related to the dacetuzumab collaboration with Genentech, we have a significant balance of deferred revenue, representing prior payments from collaborators that have not yet been earned as revenue. This deferred revenue will be recognized as revenue in future periods using a time-based approach as we fulfill our performance obligations.

***Genentech***

We entered into an exclusive worldwide collaboration agreement with Genentech, a wholly-owned member of the Roche Group, in January 2007 for the development and commercialization of dacetuzumab. Under the terms of the agreement, we received an upfront payment of \$60 million and progress-dependent milestone payments of \$20 million. Genentech also funded ongoing research, development and manufacturing costs for dacetuzumab under the collaboration. In December 2009, Genentech informed us that it had elected to terminate the collaboration. Under the terms of the collaboration, the effective date of the termination will be June 8, 2010 at which time all rights to dacetuzumab will be returned to us. Genentech will remain responsible for funding development costs associated with completing all clinical trials for dacetuzumab that are ongoing as of the effective date of termination, and we will be required to bear all of such costs following such date which could result in a significant delay in the dacetuzumab development process. Our ADC collaboration with Genentech, described below, was unaffected by this termination.

Prior to Genentech's election to discontinue the dacetuzumab collaboration, we had been recognizing amounts received from Genentech under this collaboration as revenue over the six year development period of the agreement using a time-based method. Upon receipt of Genentech's notice to end the collaboration, the remaining term of the collaboration period was reduced to six months and amounts previously deferred are being recognized over this remaining period. As of December 31, 2009, we had \$66.8 million of deferred revenue on our balance sheet related to this collaboration.

In April 2002, we entered into an ADC collaboration with Genentech. Since entering into the multi-year agreement, Genentech has paid us more than \$33 million in upfront fees, milestones, access fees and equity purchases, including \$7.3 million during 2009. In addition, we received other fees as well as reimbursement payments for research and development services and materials provided to Genentech under the collaboration. These payments are deferred and recognized as revenue over the research term of the collaboration using a time-based approach. We are entitled to receive additional progress-dependent milestones, annual maintenance fees and support fees as Genentech's ADC product candidates progress through development and royalties on product sales of such product candidates.



## **Table of Contents**

### ***Agensys***

In January 2007, we entered into an agreement with Agensys to jointly research, develop and commercialize ADCs for cancer. The agreement was expanded and modified in November 2009. In connection with the expanded agreement, Agensys paid us an upfront payment of \$12 million. Agensys will conduct preclinical studies aimed at identifying ADC product candidates for multiple designated antigens. We are currently co-developing ASG-5ME, and we have the right to exercise a co-development option for two additional ADC product candidates upon submission of an IND. 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. Amounts received for product candidates being developed solely by Agensys will be recognized as revenue over the development term of the modified collaboration agreement using a time-based approach.

### ***Daiichi Sankyo***

In July 2008, we entered into an ADC collaboration agreement with Daiichi Sankyo. We received a \$4.0 million upfront fee for an exclusive license to our ADC technology to a single antigen target. The upfront fee and other payments received are being recorded as revenue over the three year development term of the collaboration agreement using a time-based approach. Revenues under our ADC collaboration with Daiichi Sankyo increased by \$1.0 million, or 123%, in 2009. Revenues during 2008, the first year of the collaboration, totaled \$797,000. Revenues reflect the earned portion of the upfront fee and reimbursement payments for materials and services supplied by us to Daiichi Sankyo under the collaboration. We are entitled to receive additional progress-dependent milestones, annual maintenance fees and support fees as Daiichi Sankyo's ADC product candidate progresses through development and royalties on product sales.

### ***Millennium***

In March 2009, we entered into an ADC collaboration agreement with Millennium. We received a \$4.0 million upfront fee for an exclusive license to our ADC technology for a single antigen. Millennium also can exercise options for exclusive licenses to two other antigens upon payment of additional fees to us. The upfront fee and other payments received are being recorded as revenue over the three year development term of the collaboration agreement using a time-based approach. Revenue in 2009 reflects the earned portion of the upfront fee and payments for materials and services supplied by us to Millennium under this collaboration. We are entitled to receive additional progress-dependent milestones, annual maintenance fees and support fees as Millennium's ADC product candidate progresses through development and royalties on net sales of resulting ADC products. Millennium is responsible for research, product development, manufacturing and commercialization of all products under the collaboration.

In December 2009, we entered into a collaboration agreement with Millennium to globally develop and commercialize brentuximab vedotin, under which Seattle Genetics has United States and Canadian commercial rights and Millennium has commercial rights in the rest of the world. Under the collaboration, we received an upfront payment of \$60 million and we are entitled to receive progress- and sales-dependent milestone payments in addition to royalties based on net sales of brentuximab vedotin within Millennium's licensed territories. We and Millennium are each funding 50 percent of the joint development costs under the collaboration. In Japan, Millennium is solely responsible for development costs. The upfront fee and other payments received will be recorded as revenue over the development term of the collaboration agreement, currently estimated at eight years, using a time-based approach.

### ***Other Collaborations***

Other collaboration revenue includes ADC collaboration agreements that generated lower amounts of revenue during the periods presented, collaborative agreements that have concluded, research agreements established to explore future business relationships and royalty payments from suppliers to which we have granted limited access to our technology under preferred provider agreements.

**Table of Contents****Research and development**

Research and development expenses increased 7% to \$119.1 million in 2009 from 2008, and increased 71% to \$110.9 million in 2008 from 2007. Our research and development expenses are summarized as follows:

Research and development (\$ in thousands)	2009	2008	2007	Annual percentage change	
				2009/2008	2008/2007
Research	\$ 12,423	\$ 15,219	\$ 14,915	(18)%	2%
Development and contract manufacturing	43,549	40,253	21,810	8%	85%
Clinical	55,855	49,058	22,759	14%	116%
Share-based compensation expense	7,312	6,414	5,344	14%	20%
<b>Total</b>	<b>\$ 119,139</b>	<b>\$ 110,944</b>	<b>\$ 64,828</b>	<b>7%</b>	<b>71%</b>

Research expenses include, among other things, personnel, occupancy and laboratory expenses associated with the discovery and identification of new monoclonal antibodies and related technologies and the development of novel classes of stable linkers and potent cell-killing drugs for our ADC technology. Research expenses also include research activities associated with our product candidates, such as preclinical translational biology and *in vitro* and *in vivo* studies. Research expenses decreased 18% during 2009 from 2008 due to reallocation of staffing to our development groups and reduced lab supplies costs as we have focused more of our resources on product development, manufacturing and clinical activities. Research expenses increased moderately during 2008 from 2007. The increase in 2008 resulted from building-related service costs and contracted costs.

Development and contract manufacturing expenses include personnel and occupancy expenses and external contract manufacturing costs for the scale up and manufacturing of drug product for use in our clinical trials as well as conformance lot and chemistry, manufacturing and controls, or CMC, activities in support of the planned NDA submission to the FDA for brentuximab vedotin in the first half of 2011. Development and contract manufacturing expenses also include quality control and assurance activities, including storage and shipment services of our product candidates for clinical trials. Development and contract manufacturing costs increased 8% to \$43.5 million in 2009 from 2008, and 85% to \$40.3 million in 2008 from 2007. These increases were primarily driven by increased manufacturing activities, including increased brentuximab vedotin manufacturing activities in 2009, and increased brentuximab vedotin and dacetuzumab manufacturing activities in 2008. Development and contract manufacturing expenses also increased in 2009 and 2008 as a result of higher compensation costs related to an increase in staffing levels.

Clinical expenses include personnel expenses, travel, occupancy costs and external clinical trial costs including clinical site expenses, clinical research organization charges, contractors and regulatory activities associated with conducting human clinical trials, including IND-enabling pharmacology and toxicology studies. Clinical costs increased 14% to \$55.9 million in 2009 from 2008, and increased 116% to \$49.1 million in 2008 from 2007. The increases related primarily to higher third party clinical trial costs for brentuximab vedotin in 2009, and for brentuximab vedotin, dacetuzumab and lintuzumab in 2008. In addition, compensation costs increased in both 2009 and 2008 as a result of increased staffing levels.

Share-based compensation expense reflects the non-cash charge associated with stock options and the employee stock purchase plan. The fair value of all employee share-based payments is charged to expense over the vesting period of the related share-based payment. Share-based compensation expense increased 14% to \$7.3 million in 2009 from 2008 and 20% to \$6.4 million in 2008 from 2007. The increase for 2009 was primarily attributable to a larger number of optioned shares subject to expense recognition during 2009 as a result of increased staffing levels. The increase in 2008 was primarily due to the higher weighted-average grant date fair value of stock options expensed in 2008 compared to

2007.

**Table of Contents**

Certain amounts reported in comparable prior periods in the table above have been reclassified to conform with the current period presentation as it relates to the categorization of certain expenses.

We utilize our employee and infrastructure resources across multiple development projects as well as our discovery and research programs directed towards identifying monoclonal antibodies and new classes of stable linkers and cell-killing drugs for our ADC program. We track human resource efforts expended on many of our programs for purposes of billing our collaborators for time incurred at agreed upon rates and for resource planning. We do not account for actual costs on a project-by-project basis as it relates to our infrastructure, facility, employee and other indirect costs. We do, however, separately track significant third party costs including clinical trial costs, manufacturing costs and other contracted service costs on a project-by-project basis.

The following table shows expenses incurred for preclinical study support, contract manufacturing for clinical supplies and clinical and regulatory services provided by third parties as well as milestone payments for in-licensed technology for each of our product candidates. The table also presents other costs and overhead consisting of personnel, facilities and other indirect costs not directly charged to development programs:

Product candidates (\$ in thousands)	2009	2008	2007	Annual Percentage Change		(5 years) January 1, 2005 to December 31, 2009
				2009/2008	2008/2007	
Brentuximab vedotin (SGN-35)	\$ 30,983	\$ 17,090	\$ 2,685	81%	536%	\$ 55,339
Dacetuzumab (SGN-40)	13,848	19,134	8,615	(28)%	122%	47,702
Lintuzumab (SGN-33)	9,604	14,740	9,038	(35)%	63%	35,888
ASG-5ME	3,111	663	159	369%	317%	3,933
SGN-75	2,454	2,929	382	(16)%	667%	6,094
SGN-70	840	1,868	4,428	(55)%	(58)%	10,303
Total third party costs	60,840	56,424	25,307	8%	123%	159,259
Other costs and overhead	50,987	48,106	34,177	6%	41%	188,331
Share-based compensation expense	7,312	6,414	5,344	14%	20%	22,139
Total research and development expenses	\$ 119,139	\$ 110,944	\$ 64,828	7%	71%	\$ 369,729

Our third party costs for brentuximab vedotin increased by 81% in 2009 from 2008, due to increased manufacturing and clinical trials costs. Increased clinical trials costs reflected our pivotal trial of brentuximab vedotin in patients with relapsed or refractory Hodgkin lymphoma that was initiated in early 2009, and a phase II clinical trial in patients with relapsed or refractory sALCL, together with phase I clinical trials. Increased manufacturing costs include the costs of resupply of drug product for clinical trials and manufacturing activities in support of the planned NDA submission to the FDA for brentuximab vedotin in the first half of 2011. Third party costs for brentuximab vedotin increased 536% in 2008 from 2007, primarily due to manufacturing costs at our contract manufacturing organizations to provide clinical supplies of drug product. Higher costs in 2008 also reflected the expansion of phase I clinical trials of brentuximab vedotin during the year.

Our third party costs for dacetuzumab decreased by 28% in 2009 from 2008. This decrease was primarily due to decreased manufacturing activity. Third party costs for dacetuzumab increased by 122% in 2008 from 2007, reflecting manufacturing activities for additional drug product and clinical trials costs related to our phase I and phase II trials, most notably the phase IIb clinical trial evaluating dacetuzumab in combination with standard therapy in relapsed or refractory non-Hodgkin lymphoma patients. Under our dacetuzumab collaboration agreement, Genentech currently reimburses us for activities that we perform under the agreement. Expenses that we incur under the dacetuzumab collaboration are included in our research and development expense, while reimbursements of those expenses by Genentech are recognized as revenues over the development term of the agreement. As previously discussed, this collaboration is expected to terminate on June 8, 2010, after which time if we decide to continue development of dacetuzumab, we will be responsible for and will be required to solely fund any new



development costs.

## **Table of Contents**

Our third party costs for lintuzumab decreased by 35% in 2009 from 2008. This decrease was primarily due to decreased clinical trial costs, primarily related to the ongoing phase IIb trial evaluating the combination of lintuzumab with low-dose cytarabine in patients with AML, which completed patient enrollment in early 2009. Our third party costs for lintuzumab increased by 63% in 2008 from 2007. The increase was attributable to clinical trial activities, particularly the ongoing phase IIb trial. Data from this trial are expected in the second quarter of 2010.

Our third party costs for ASG-5ME increased by 369% in 2009 from 2008 primarily as a result of manufacturing costs incurred to begin securing drug product for phase I clinical trials planned for 2010. Third party costs increased 317% in 2008 from 2007 reflecting growth in the program which began during 2007.

Our third party costs for SGN-75 moderately decreased in 2009 compared to 2008 and increased in 2008 compared to 2007 reflecting pharmacology/toxicology activities and manufacturing costs incurred in 2008 to enable the IND submission that occurred in 2009. A phase I clinical trial was initiated in late 2009.

Our third party costs for SGN-70 decreased in 2009 and in 2008. The decrease in 2009 reflected lower pharmacology/toxicology and clinical trials costs. The decrease in 2008 reflected lower scale-up and GMP manufacturing costs of drug product.

Other costs and overhead included costs associated with personnel and facilities. These costs increased by 6% in 2009 and by 41% in 2008, primarily reflecting an increase in staffing levels in our development and clinical groups from the comparable prior year periods.

Our expenditures on current and future preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. In order to advance our product candidates toward commercialization, the product candidates are tested in numerous preclinical safety, toxicology and efficacy studies. We then conduct clinical trials for those product candidates that take several years or more to complete. The length of time varies substantially based upon the type, complexity, novelty and intended use of a product candidate. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including:

the number of patients who participate in the trials;

the length of time required to enroll trial participants;

the number and location of sites included in the trials;

the costs of producing supplies of the product candidates needed for clinical trials and regulatory submissions;

the safety and efficacy profile of the product candidate;

the use of clinical research organizations to assist with the management of the trials; and

the costs and timing of, and the ability to secure, regulatory approvals.

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

We anticipate that our total research, development, contract manufacturing and clinical expenses will increase in the foreseeable future as we prepare to seek regulatory approval for and potentially commercialize brentuximab vedotin, as well as continue our preclinical activities and advance new product candidates into clinical trials. In particular, we expect that development costs for brentuximab vedotin will increase in 2010

**Table of Contents**

compared to 2009, reflecting clinical development and manufacturing activities as well as CMC activities associated with our planned NDA submission in 2011. We expect our development costs for dacetuzumab to decrease in 2010 compared to 2009, reflecting lower manufacturing and clinical trials activities for this program in 2010. Expenses will fluctuate based upon many factors including the degree of collaborative activities, timing of manufacturing campaigns, numbers of patients enrolled in our clinical trials and the outcome of each clinical trial event. For example, we currently anticipate that data will be available for the phase IIb trial of lintuzumab in combination with low-dose cytarabine in the second quarter of 2010. If the results of this trial are positive, we expect that third-party costs associated with the lintuzumab program will increase.

The risks and uncertainties associated with our research and development projects are discussed more fully in Item 1A Risk Factors. As a result of the uncertainties discussed above, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, anticipated completion dates or when and to what extent we will receive cash inflows from the commercialization and sale of a product candidate.

**General and administrative**

General and administrative (\$ in thousands)	2009	2008	2007	Annual percentage change	
				2009/2008	2008/2007
General and administrative, excluding share-based compensation expense	\$ 13,146	\$ 12,080	\$ 10,653	9%	13%
Share-based compensation expense	4,537	3,998	2,584	13%	55%
<b>Total general and administrative expenses</b>	<b>\$ 17,683</b>	<b>\$ 16,078</b>	<b>\$ 13,237</b>	<b>10%</b>	<b>21%</b>

Total general and administrative expenses increased 10% to \$17.7 million in 2009, and 21% to \$16.1 million in 2008. General and administrative expenses, excluding share-based compensation expense, increased 9% in 2009 from 2008, and 13% in 2008 from 2007. These increases were primarily attributable to compensation costs related to higher staffing levels, offset slightly in 2008 by lower patent and intellectual property costs. Share-based compensation expense reflects the non-cash charge associated with stock options and our employee stock purchase plan. The fair value of all employee share-based payments is charged to expense over the vesting period of the related share-based payment. Share-based compensation expense included in general and administrative expenses increased 13% to \$4.5 million in 2009 from 2008, and 55% to \$4.0 million in 2008 from 2007. The increase for 2009 was primarily attributable to a larger number of optioned shares subject to expense recognition during 2009 as a result of our increased staffing level. The increase in 2008 was primarily due to the higher weighted-average grant date fair value of stock options expensed in 2008 compared to 2007. We anticipate that general and administrative expenses will continue to increase as we prepare for the potential commercial launch of brentuximab vedotin and continue to establish our commercial infrastructure.

**Investment income, net**

Investment income, net (\$ in thousands)	2009	2008	2007	Annual percentage change	
				2009/2008	2008/2007
<b>Total</b>	<b>\$ 3,174</b>	<b>\$ 6,285</b>	<b>\$ 6,713</b>	<b>(49)%</b>	<b>(6)%</b>

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

Investment income decreased 49% to \$3.2 million in 2009 and 6% to \$6.3 million in 2008 reflecting lower average yields on our investments, partially offset by higher average cash balances. We expect investment income in 2010 to decrease from 2009 levels as we expect a further lowering of the yield earned on our investments.

**Table of Contents****Liquidity and capital resources**

Selected cash flow and balance sheet data (\$ in thousands)	December 31,		
	2009	2008	2007
Cash, cash equivalents and short-term and long-term investments	\$ 287,730	\$ 160,708	\$ 129,584
Working capital	244,081	70,496	90,003
Stockholders' equity	206,200	79,018	53,986

  

	Years ended December 31,		
	2009	2008	2007
Cash provided by (used in):			
Operating activities	\$ (61,783)	\$ (62,630)	\$ 39,830
Investing activities	(147,418)	(67,828)	4,073
Financing activities	196,887	101,614	6,604

We have financed the majority of our operations through the issuance of equity securities and by amounts received pursuant to our dacetuzumab collaboration agreement with Genentech and our ADC collaborations. To a lesser degree, we have also financed our operations through interest earned on cash, cash equivalents and investment securities. These financing sources have historically allowed us to maintain adequate levels of cash and investments.

Our combined cash, cash equivalents and investment securities increased to \$287.7 million at December 31, 2009, compared to \$160.7 million at December 31, 2008 and \$129.6 million at December 31, 2007. These increases reflect proceeds from the sale of common stock totaling \$196.9 million in 2009, \$101.6 million in 2008, and \$6.6 million in 2007. We used \$61.8 million in 2009 and \$62.6 million in 2008 to fund our operating activities. In 2007, we generated \$39.8 million from operating activities, which included \$80.5 million received from Genentech under our dacetuzumab and ADC collaborations. Our working capital was \$244.1 million at December 31, 2009, compared to \$70.5 million at December 31, 2008 and \$90.0 million at December 31, 2007. We have structured our investment portfolio to provide working capital as needed. Our cash, cash equivalents and investments are held in a variety of interest-bearing instruments and subject to investment guidelines allowing for holdings in U.S. government and agency securities, corporate bonds, taxable municipal bonds, mortgage-backed securities, auction-rate securities, commercial paper and money market accounts. As of December 31, 2009, we held auction rate securities valued at \$12.5 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to either a successful auction process, redemption of the investment, sale of the security in a secondary market or a negotiated or adjudicated resolution. Each of the securities continues to pay interest according to the stated terms on a monthly basis. The interest rate on these auction rate securities is no longer established based on an auction process but is established according to the terms of the issue, which as of the date of this filing, is set at the 30-day London Interbank Offering rate plus 225 basis points. Based on our available cash, expected operating cash requirements and our belief that the holdings in auction rate securities will likely be liquidated in approximately one to three years at par, we believe it is more likely than not that we have the ability to hold, and we intend to hold, these investments until they recover substantially all of their cost basis. This belief is based on our current assessment of our future operating plans and assessment of the individual securities and general market conditions. We periodically reassess this conclusion based on several factors, including the continued failure of future auctions, failure of the investments to be redeemed, further deterioration of the credit rating of the investments, market risk and other factors. Any such future reassessment that results in a conclusion that the unrealized losses on these investments are other than temporary would result in a write down in the fair value of these investments. Such a write down would be recognized in our operating results. These securities are valued based on unobservable inputs (Level 3) as further discussed in Note 2 to the consolidated financial statements.

The global credit and financial markets have experienced a period of unusual volatility and illiquidity. Our investment portfolio is structured to provide for investment maturities and access to cash to fund our anticipated

## **Table of Contents**

working capital needs. However, if our liquidity needs should be accelerated for any reason in the near term, or investments do not pay at maturity, we may be required to sell investment securities in our portfolio prior to their scheduled maturities, which may result in a loss. As of December 31, 2009, our cash, cash equivalents and investment securities are presented net of a cumulative \$1.2 million unrealized loss. This amount represents the difference between our amortized cost and the fair market value of the investments and is included in accumulated other comprehensive loss. As of December 31, 2009, we had \$260.8 million held in cash reserves or debt securities scheduled to mature within the next twelve months. In addition, in January 2010, we received \$60 million in cash from our brentuximab vedotin collaboration with Millennium and \$12 million in cash from our ADC collaboration with GSK.

Included in net cash used in investing activities in 2009 are capital expenditures related to the purchase of laboratory equipment in support of our research and development activities and for leasehold improvements. We expect that our 2010 capital expenditures will be comparable to 2009.

At our currently planned spending rate, we believe that our financial resources, in addition to the expected fees and milestone payments earned under our existing collaboration and license agreements, will be sufficient to fund our operations into at least 2012. Changes in our spending rate may occur that would consume available capital resources sooner, such as increased manufacturing and clinical trial expenses and the expansion of our sales and marketing organization preceding commercialization of a product candidate. Additionally, we may not receive the fees and milestone payments that we currently expect under our existing collaboration and license agreements, including the brentuximab vedotin collaboration agreement with Millennium, which may shorten the timeframe through which we are able to fund operations. For example, in the event of a termination of the brentuximab vedotin collaboration agreement with Millennium, we would not receive development cost sharing benefits, nor would we receive milestone payments or royalties for the development or sale of brentuximab vedotin. In addition, as a result of the termination of the dacetuzumab collaboration agreement with Genentech, if we decide to continue development of dacetuzumab, we will be responsible for and will be required to solely fund any new dacetuzumab development and clinical trial activities undertaken after the effective date of the termination, which could result in a significant delay in the dacetuzumab development process. If we determine instead to discontinue the development of dacetuzumab, we will not receive any future return on our investment from that product candidate.

We expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees and support our preclinical development, manufacturing and clinical trial activities, as well as position our product candidates, specifically brentuximab vedotin, for potential regulatory approval and commercial sale, and we will therefore continue to need significant amounts of additional capital. We may seek additional funding through some or all of the following methods: corporate collaborations, licensing arrangements, public or private debt or equity financings. However, the global credit markets and the financial services industry have recently experienced a period of unusual volatility and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the U.S. government. These events have generally made equity and debt financing more difficult to obtain. As a result of these recent events and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If we are unable to raise additional funds when we need them, we may be required to delay, reduce the scope of, or eliminate one or more of our development programs, which may adversely affect our business and operations.

We anticipate that our 2010 revenues will be in the range of \$95 million to \$105 million. These revenues are expected to be generated from fees, milestones and reimbursements earned through our dacetuzumab, brentuximab vedotin and ADC collaborations. Revenues are expected to include approximately \$70 million related to our dacetuzumab collaboration that will end in June 2010, primarily driven by amounts previously received and included in deferred revenue that are expected to be recognized as revenue in the first half of 2010.

**Table of Contents**

Total 2010 operating expenses are expected to be in the range of \$160 million to \$180 million. Operating expenses will be primarily directed towards brentuximab vedotin development and pre-commercialization activities, as well as development and clinical activities for lintuzumab, SGN-75 and ASG-5ME. Brentuximab vedotin development expenses incurred by us under the brentuximab vedotin collaboration with Millennium will be recognized as expense as incurred. Millennium will co-fund 50% of the joint development costs incurred under the collaboration. Expenses will fluctuate based upon many factors including the degree of collaborative activities, timing of manufacturing campaigns, numbers of patients enrolled in our clinical trials and the outcome of each clinical trial. Included in our 2010 operating expense estimate are non-cash amounts expected to be in the range of \$17 million to \$20 million, primarily attributable to share-based compensation expense. This estimate is based on a number of assumptions, including future stock prices and the number and timing of option grants, and may therefore change.

We expect that our net cash used in operating activities for the year 2010 will be less than \$20 million, and that we will end 2010 with more than \$265 million in total cash, cash equivalents, short-term and long-term investments. These amounts reflect up-front payments totaling \$72 million that we received in January 2010 related to our collaboration agreements with Millennium and GSK that were entered into in December 2009. Certain external factors may influence our cash spending, including the cost of filing and enforcing patent claims and other intellectual property rights, competing technological and market developments and the progress of our collaborators.

**Commitments**

Some of our manufacturing, license and collaboration agreements provide for periodic maintenance fees over specified time periods, as well as payments by us upon the achievement of development and regulatory milestones and the payment of royalties based on commercial product sales. We do not expect to pay any royalties on net sales of products under any of these agreements unless and until we have a product approved for commercial sale. The amounts set forth below for any given year could be substantially higher if we make certain development progress that requires us to make milestone payments or if we receive regulatory approvals or achieve commercial sales and are required to pay royalties.

The following are our future minimum contractual commitments for the periods subsequent to December 31, 2009 (in thousands):

	<b>Total</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>Thereafter</b>
Operating leases	\$ 25,544	\$ 2,715	\$ 2,795	\$ 2,836	\$ 2,917	\$ 3,014	\$ 11,267
Manufacturing, license and other agreements	27,787	23,426	2,364	996	1,001		
<b>Total</b>	<b>\$ 53,331</b>	<b>\$ 26,141</b>	<b>\$ 5,159</b>	<b>\$ 3,832</b>	<b>\$ 3,918</b>	<b>\$ 3,014</b>	<b>\$ 11,267</b>

Operating lease obligations do not assume the exercise by us of any termination or extension options. The minimum payments under manufacturing, license and collaboration agreements primarily represent contractual obligations related to performing scale-up and GMP manufacturing for our product candidates for use in our clinical trials. The above table excludes royalties and up to approximately \$9.4 million in potential future milestone payments to third parties under manufacturing, license and collaboration agreements for our current development programs, which generally become due and payable only upon achievement of certain developmental, clinical, regulatory and/or commercial milestones. Because the achievement of these milestones is neither probable nor reasonably estimable with respect to timing, such contingent payments have not been included in the above table and will not be included until the event triggering such payment has occurred.

**Recent accounting pronouncements**



In October 2009, the Financial Accounting Standards Board (FASB) issued an accounting standards update entitled Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force.

**Table of Contents**

This standard prescribes the accounting treatment for arrangements that contain multiple-deliverable elements and enables vendors to account for products or services (deliverables) separately rather than as a combined unit in certain circumstances. Prior to this standard, only certain types of evidence were acceptable for determining the relative selling price of deliverables under an arrangement. If that evidence was not available, the deliverables were treated as a single unit of accounting. This updated standard expands the nature of evidence which may be used to determine the relative selling price of separate deliverables to include estimation. This standard is applicable to arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted; however, if the standard is adopted early, and the period of adoption is not the beginning of our fiscal year, we would be required to apply the amendments retrospectively from the beginning of our fiscal year. We have not yet adopted this standard or determined the impact of this standard on our results of operations, cash flows and financial position.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.*****Interest Rate Risk***

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. In accordance with our investment policy, we do not have any derivative financial instruments in our investment portfolio. We invest in high quality interest-bearing instruments consisting of U.S. government and agency securities, corporate bonds, taxable municipal bonds, auction rate securities, commercial paper and money market accounts. Our investment securities consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
Short-term investments	\$ 242,319	\$ 64,379
Long-term investments	26,925	65,529
Other non-current assets	299	301
Total	\$ 269,543	\$ 130,209

Included in long-term investments as of December 31, 2009 are auction-rate securities, valued at \$12.5 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to either a successful auction process, redemption of the investment, a sale of the security in a secondary market or a negotiated or adjudicated resolution. Given that further deterioration in the global credit and financial markets is a possibility, no assurance can be made that further downgrades, losses or other significant deterioration in the fair value of our cash equivalents, short-term or long-term investments will not occur. If any such further downgrades, losses, or other significant deteriorations occur, it may negatively impact or impair our current portfolio of cash equivalents, short-term or long-term investments.

We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of \$1.3 million in the fair value of our investments as of December 31, 2009. In addition, a hypothetical decrease of 10% in the effective yield of our investments would reduce our expected investment income by approximately \$205,000 in 2010.

***Foreign Currency Risk***

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

All of our revenues and the majority of our expenses are denominated in U.S. dollars and as a result, we have not experienced significant foreign currency transaction gains and losses to date. We have conducted some transactions in foreign currencies during the fiscal year ended December 31, 2009, primarily related to contract manufacturing and ex-U.S. clinical trial activities, and we expect to continue to do so. Our primary exposure is to fluctuations in the Euro and British Pound. We do not anticipate that foreign currency transaction gains or losses will be significant at our current level of operations. However, transaction gains or losses may become significant in the future as we continue to expand our operations internationally. We have not engaged in foreign currency hedging to date. However, we may do so in the future.

**Table of Contents**

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

**Seattle Genetics, Inc.**

**Index to Financial Statements**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	56
<u>Consolidated Balance Sheets</u>	57
<u>Consolidated Statements of Operations</u>	58
<u>Consolidated Statements of Stockholders' Equity</u>	59
<u>Consolidated Statements of Cash Flows</u>	60
<u>Notes to Consolidated Financial Statements</u>	61

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders

Seattle Genetics, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Seattle Genetics, Inc. and its subsidiaries at December 31, 2009 and 2008 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Seattle, Washington

March 11, 2010



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

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 18,486	\$ 30,800
Short-term investments	242,319	64,379
Interest receivable	1,350	1,888
Accounts receivable	80,122	8,186
Prepaid expenses and other	6,302	5,463
Total current assets	348,579	110,716
Property and equipment, net	12,325	10,996
Long-term investments	26,925	65,529
Other non-current assets	504	476
Total assets	\$ 388,333	\$ 187,717
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable and accrued liabilities	\$ 19,496	\$ 15,879
Current portion of deferred revenue	85,002	24,341
Total current liabilities	104,498	40,220
Long-term liabilities		
Deferred revenue, less current portion	74,866	66,958
Deferred rent and other long-term liabilities	2,769	1,521
Total long-term liabilities	77,635	68,479
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000 shares authorized; none issued and outstanding		
Common stock, \$0.001 par value, 150,000 shares authorized; 100,554 shares issued and outstanding at December 31, 2009 and 79,791 shares issued and outstanding at December 31, 2008	101	80
Additional paid-in capital	603,053	394,338
Accumulated other comprehensive loss	(1,249)	(1,378)
Accumulated deficit	(395,705)	(314,022)
Total stockholders' equity	206,200	79,018
Total liabilities and stockholders' equity	\$ 388,333	\$ 187,717

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



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

	<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Revenues from collaboration and license agreements	\$ 51,965	\$ 35,236	\$ 22,420
Operating expenses			
Research and development	119,139	110,944	64,828
General and administrative	17,683	16,078	13,237
Total operating expenses	136,822	127,022	78,065
Loss from operations	(84,857)	(91,786)	(55,645)
Investment income, net	3,174	6,285	6,713
Net loss	\$ (81,683)	\$ (85,501)	\$ (48,932)
Net loss per share basic and diluted	\$ (0.90)	\$ (1.09)	\$ (0.80)
Shares used in computation of net loss per share basic and diluted	90,988	78,724	61,293

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

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

	Preferred stock		Common stock			Accumulated deficit	Accumulated other comprehensive income (loss)	Total stockholders equity
	Shares	Amount	Shares	Amount	Additional paid-in capital			
Balances at December 31, 2006	1,500	\$ 2	51,030	\$ 51	\$ 267,807	\$ (179,589)	\$ (37)	\$ 88,234
Net loss						(48,932)		(48,932)
Unrealized gain							152	152
Comprehensive loss								(48,780)
Issuance of common stock for employee stock purchase plan			147		532			532
Stock option exercises			1,222	2	5,289			5,291
Warrant exercises			125		781			781
Conversion of Series A Convertible Preferred Stock into common stock	(1,500)	(2)	15,000	15	(13)			
Share-based compensation					7,928			7,928
Balances at December 31, 2007			67,524	68	282,324	(228,521)	115	53,986
Net loss						(85,501)		(85,501)
Unrealized loss							(1,493)	(1,493)
Comprehensive loss								(86,994)
Issuance of common stock for employee stock purchase plan			240		1,032			1,032
Stock option exercises			527	1	2,953			2,954
Public offering			11,500	11	97,617			97,628
Share-based compensation					10,412			10,412
Balances at December 31, 2008			79,791	80	394,338	(314,022)	(1,378)	79,018
Net loss						(81,683)		(81,683)
Unrealized gain							129	129
Comprehensive loss								(81,554)
Issuance of common stock for employee stock purchase plan			146		1,240			1,240
Stock option exercises			654	1	3,505			3,506
Issuance of common stock			19,568	20	192,121			192,141
Warrant exercise			395					
Share-based compensation					11,849			11,849
Balances at December 31, 2009		\$	100,554	\$ 101	\$ 603,053	\$ (395,705)	\$ (1,249)	\$ 206,200

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

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

	Years Ended December 31,		
	2009	2008	2007
<b>Operating activities</b>			
Net loss	\$ (81,683)	\$ (85,501)	\$ (48,932)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities			
Share-based compensation expense	11,849	10,412	7,928
Depreciation and amortization	3,260	3,415	2,548
Amortization of investments	3,622	1,669	(707)
Deferred rent and other long-term liabilities	1,248	1,111	(39)
Changes in operating assets and liabilities			
Interest receivable	538	(1,130)	(219)
Accounts receivable	(71,936)	(2,198)	(5,090)
Prepaid expenses and other	(839)	(4,219)	(14)
Other non-current assets	(28)		
Accounts payable and accrued liabilities	3,617	6,171	4,255
Deferred revenue	68,569	7,640	80,100
Net cash provided by (used in) operating activities	(61,783)	(62,630)	39,830
<b>Investing activities</b>			
Purchases of securities available for sale	(396,840)	(154,337)	(185,917)
Proceeds from maturities of securities available for sale	251,919	84,393	190,023
Proceeds from sales of securities available for sale	2,092	7,000	4,250
Purchases of property and equipment	(4,589)	(4,884)	(4,283)
Net cash provided by (used in) investing activities	(147,418)	(67,828)	4,073
<b>Financing activities</b>			
Net proceeds from issuance of common stock	192,141	97,628	
Proceeds from exercise of options and warrants to purchase common stock	4,746	3,986	6,604
Net cash provided by financing activities	196,887	101,614	6,604
Net increase (decrease) in cash and cash equivalents	(12,314)	(28,844)	50,507
Cash and cash equivalents, at beginning of period	30,800	59,644	9,137
Cash and cash equivalents, at end of period	\$ 18,486	\$ 30,800	\$ 59,644

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

**Table of Contents**

**Seattle Genetics, Inc.**

**Notes to Consolidated Financial Statements**

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

*Nature of business and basis of presentation*

The accompanying consolidated financial statements reflect the accounts of Seattle Genetics, Inc. and its wholly-owned subsidiary, Seattle Genetics UK, Ltd. (collectively "Seattle Genetics" or the "Company"). The Company is a clinical-stage biotechnology company focused on the development and commercialization of monoclonal antibody-based therapies for the treatment of cancer and autoimmune diseases. The Company's pipeline of product candidates is based upon three technologies: engineered monoclonal antibodies, antibody-drug conjugates, or ADCs, and a process for increasing the potency of monoclonal antibodies through enhanced effector function. These technologies enable the Company to develop monoclonal antibodies that can kill target cells on their own as well as to increase the potency of monoclonal antibodies by linking them to a cell-killing payload to form an ADC. The resulting ADCs are designed to be stable in the bloodstream but to release their drug payload once internalized within tumor cells, thereby increasing activity and minimizing normal tissue toxicity. The Company operates in one reporting segment: the development of pharmaceutical products on its own behalf or in collaboration with others.

*Capital Requirements*

The Company will continue to need significant amounts of capital and may seek additional funding through public or private financings, including equity financings, and through other means, including collaborations and license agreements. If the Company cannot maintain adequate funds, it will be required to delay, reduce the scope of or eliminate one or more of its development programs. Additional financing may not be available when needed, or if available, the Company may not be able to obtain financing on favorable terms.

*Use of estimates*

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

*Cash and cash equivalents*

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

*Investments*

Short-term and long-term investments consist of U.S. government and U.S. government agency securities, corporate notes, auction rate securities and taxable municipal bonds. The Company classifies its securities as available-for-sale, which are reported at estimated fair value with unrealized gains and losses included in accumulated other comprehensive loss in stockholders' equity. Investments in securities with maturities of less than one year, or where management's intent is to use the investments to fund current operations, or to make them available for current operations, are classified as short-term investments.

If the estimated fair value of a security is below its carrying value, the Company evaluates whether it is more likely than not that it will sell the security before its anticipated recovery in market value and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. The Company also evaluates whether or not it intends to sell the investment. If the impairment is considered to be other-than-temporary, the security is written down to its estimated fair value. In addition, the Company considers whether credit losses exist for any securities. A credit loss exists if the present

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

value of cash flows expected to be collected is less than the amortized cost basis of the security. Other-than-temporary declines in estimated fair value and credit losses are charged against investment income. The Company has not deemed it necessary to record any charges related to other-than-temporary declines in the estimated fair values of its marketable debt securities or credit losses.

Realized gains, realized losses and declines in the value of securities judged to be other than temporary, are included in investment income. Cost of investments for purposes of computing realized and unrealized gains and losses are based on the specific identification method. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Amortization of premiums and accretion of discounts are included in investment income, net. Interest and dividends earned on all securities are included in investment income.

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

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly;
- Level 3: Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The determination of a financial instrument's level within the fair value hierarchy is based on an assessment of the lowest level of any input that is significant to the fair value measurement.

*Property and equipment*

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

	<b>Years</b>
Laboratory equipment	5
Furniture and fixtures	5
Computers, software and office equipment	3

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

Leasehold improvements are amortized over the shorter of the remaining lease term of the applicable lease or the useful life of the asset. Gains and losses from the disposal of property and equipment are reflected in the consolidated statement of operations at the time of disposition and have not been significant. Expenditures for additions and improvements to the Company's facilities are capitalized and expenditures for maintenance and repairs are charged to expense as incurred. Concessions received by the Company in connection with leases are deferred and recognized as a reduction in rent expense over the term of the applicable lease.

### *Impairment of long-lived assets*

The Company assesses the impairment of long-lived assets, primarily property and equipment, whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. When such events occur, management determines whether there has been an impairment in value by



**Table of Contents**

**Seattle Genetics, Inc.**

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

comparing the asset's carrying value with its fair value, as measured by the anticipated undiscounted net cash flows of the asset. If an impairment in value exists, the asset is written down to its estimated fair value. The Company has not recognized any impairment losses through December 31, 2009 as there have been no events warranting an impairment analysis.

*Revenue recognition*

The Company has entered into licensing and collaboration agreements that contain multiple revenue elements including upfront payments, license fees, milestone payments, royalties, maintenance fees and payments for the delivery of supplies or services provided. Each agreement may contain some or all of these elements. Revenue recognition is predicated upon persuasive evidence of an agreement existing, delivery of materials or services being rendered, fees being fixed or determinable, and collectibility being reasonably assured. Agreements that include multiple elements are evaluated to determine whether the associated deliverables can be considered separate units of accounting. In order to be considered a separate unit of accounting, a deliverable must have standalone value to the customer and we must have objective and reliable evidence of its fair value. To date, the deliverables under the Company's collaboration agreements have not qualified as separate units of accounting and revenue is typically recognized over its performance obligation period under each agreement. The Company generally uses a time-based proportional performance model to recognize our revenue over the performance period as further discussed below. The assessment of multiple element arrangements requires judgment in order to determine the appropriate point in time, or period of time, that revenue should be recognized.

*Nonrefundable upfront license payments, option and maintenance fees and milestone payments:*

The Company's collaboration agreements may include nonrefundable upfront license payments, option and maintenance fees, and payments triggered by the achievement of development milestones by the other party or by the Company. When the Company has substantive continuing performance obligations under an arrangement, revenue is recognized over the performance period of the obligations using a time-based proportional performance approach. Under the time-based method, revenue is recognized over the arrangement's estimated performance period based on the elapsed time compared to the total estimated performance period. Changes in estimates of the service obligation time period are accounted for prospectively when a change becomes known. Revenue recognized at any point in time is limited to the amount of non-contingent payments received or due. When the Company has no substantive continuing performance obligations under an arrangement, it recognizes revenue as the related fees become due.

*Research and development services:*

The Company may also perform research and development activities on behalf of collaborative partners that are paid for by the collaborator. When no other obligation to provide services is required by the Company, revenue from research and development services is generally recognized as the service is provided. However, if the arrangement provides for other ongoing services by the Company or contains multiple delivery elements for which verifiable and objective evidence of fair value cannot be established for each element, payments for such services are recognized as revenue over the service period.

*Royalties:*

Revenues from royalties on third-party sales of licensed technologies are generally recognized in accordance with the contract terms when the royalties can be reliably determined and collectibility is reasonably assured. To date, the Company has not received significant royalty revenues.

The Company generally invoices its collaborators on a monthly or quarterly basis, or upon the completion of the effort, based on the terms of each agreement. Amounts due, but not billed to a collaborator, if any, are

**Table of Contents**

**Seattle Genetics, Inc.**

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

included in accounts receivable in the accompanying consolidated balance sheets. Deferred revenue arises from payments received in advance of the culmination of the earnings process and is recognized as revenue in future periods when the applicable revenue recognition criteria have been met. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

*Research and development expenses*

Research and development, or R&D, expenses consist of salaries, benefits and other headcount related costs, clinical trial and related clinical manufacturing costs, contract and outside service fees and facilities and overhead expenses for research, development and preclinical studies focused on drug discovery, development and testing. R&D activities are expensed as incurred. In-licensing fees, including milestones, maintenance fees and other costs to acquire technologies that are utilized in R&D and that are not expected to have alternative future use are expensed when incurred. Costs associated with activities performed under R&D co-development collaborations are reflected in R&D expense. Non-refundable advance payments for goods or services that will be used or rendered for future R&D activities are capitalized and recognized as expense as the related goods are delivered or the related services are performed. This results in the temporary deferral of charges to expense of amounts incurred for research and development activities from the time payouts are made until the time goods or services are provided.

*Fair value of financial instruments*

The recorded amounts of certain financial instruments, including cash and cash equivalents, interest receivable, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. Short-term and long-term investments that are classified as available-for-sale are recorded at fair value. See *Investments* above for a discussion of the methodology used to measure fair value.

*Concentration of credit risk*

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

*Major collaborators*

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

One of the Company's collaborators accounted for 80%, 81% and 78% of total revenues in 2009, 2008 and 2007, respectively. Two collaborators accounted for 92% of accounts receivable as of December 31, 2009. One collaborator accounted for 87% and 92% of accounts receivable at December 31, 2008 and 2007, respectively.

### *Major suppliers*

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

**Table of Contents**

**Seattle Genetics, Inc.**

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

*Income taxes*

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

*Share-based compensation*

The Company uses the graded-vesting attribution method for recognizing share-based compensation expense. Compensation expense is recognized on awards ultimately expected to vest and reduced for forfeitures that are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The Company makes a determination of the amount of eligible windfall tax benefits created if the expense deduction taken for tax purposes exceeds the share-based compensation recognized in the consolidated financial statements (the pool of windfall tax benefits). The pool of windfall tax benefits is used to offset future shortfalls, where the tax deduction is less than the share-based compensation recognized. The Company has elected to calculate its historical pool of windfall tax benefits using the short-cut method. The Company will continue to track the balance of the pool of windfall tax benefits based on windfalls or shortfalls.

*Comprehensive income/loss*

Comprehensive income/loss is the change in stockholders' equity from transactions and other events and circumstances other than those resulting from investments by stockholders and distributions to stockholders. The Company's other comprehensive income/loss is comprised of net loss and unrealized gains and losses on investments.

*Certain risks and uncertainties*

The Company's products and services are concentrated in a highly competitive market that is characterized by lengthy development and evolving regulatory requirements and industry standards. Failure to anticipate or respond adequately to changes in regulatory requirements or industry standards, or any significant delays in the development or introduction of planned products or services, could have a material adverse effect on the Company's business and operating results.

*Guarantees*

In the normal course of business, the Company indemnifies certain employees and other parties, such as collaboration partners, lessors and other parties that perform certain work on behalf of, or for the Company or take licenses to the Company's technologies. The Company has agreed to hold these parties harmless against losses arising from the Company's breach of representations or covenants, intellectual property infringement or other claims made against these parties in performance of their work with the Company. These agreements typically limit the time within which the party may seek indemnification by the Company and the amount of the claim. It is not possible to prospectively determine the maximum potential amount of liability under these indemnification agreements since the Company has not had any prior indemnification claims on which to base the calculation. Further, each potential claim would be based on the unique facts and circumstances of the claim and the particular provisions of each agreement.

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

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The Company has excluded all convertible preferred stock, options and warrants to purchase common stock from the calculation of diluted net loss per share, as such securities are antidilutive for all periods presented.

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

	<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Convertible preferred stock			5,380
Warrants to purchase common stock	1,651	1,925	2,018
Options to purchase common stock	9,661	8,023	7,085
Total	11,312	9,948	14,483

In January and February 2007, holders of the Company's Series A Convertible Preferred Stock converted an aggregate of 571,500 shares of Series A Convertible Preferred Stock into 5,715,000 shares of common stock. In July 2007, the Company exercised its right to convert all remaining 928,500 shares of outstanding Series A Convertible Preferred Stock into 9,285,000 shares of common stock in accordance with the terms of the Certificate of Designations of Series A Convertible Preferred Stock.

*Subsequent events*

The Company considered subsequent events through the date the financial statements were available for issuance. There were no subsequent events requiring recognition or disclosure in the financial statements.

*Recent accounting pronouncements*

In October 2009, the Financial Accounting Standards Board (FASB) issued an accounting standards update entitled Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force. This standard prescribes the accounting treatment for

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

arrangements that contain multiple-deliverable elements and enables vendors to account for products or services (deliverables) separately rather than as a combined unit in certain circumstances. Prior to this standard, only certain types of evidence were acceptable for determining the relative selling price of the deliverables under an arrangement. If that evidence was not available, the deliverables were treated as a single unit of accounting. This updated standard expands the nature of evidence which may be used to determine the relative selling price of separate deliverables to include estimation. This standard is applicable to arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted; however, if the standard is adopted early, and the period of adoption is not the beginning of a company's fiscal year, the company will be required to apply the amendments retrospectively from the beginning of the company's fiscal year. The Company has not yet adopted this standard or determined the impact of this standard on its results of operations, cash flows and financial position.



**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)****2. Investments**

Investments consisted of available-for-sale securities as follows (in thousands):

	Amortized cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2009				
U.S. government and agencies	\$ 220,442	\$ 109	\$ (51)	\$ 220,500
Corporate obligations	33,253	674	(11)	33,916
Auction rate securities	14,450		(1,991)	12,459
U.S. municipal bonds	2,647	21		2,668
<b>Total</b>	<b>\$ 270,792</b>	<b>\$ 804</b>	<b>\$ (2,053)</b>	<b>\$ 269,543</b>
Contractual Maturities				
Due in one year or less	\$ 241,979			\$ 242,319
Due in one to three years	14,363			14,765
Due in 2017	14,450			12,459
<b>Total</b>	<b>\$ 270,792</b>			<b>\$ 269,543</b>
December 31, 2008				
U.S. government and agencies	\$ 14,637	\$ 214	\$	\$ 14,851
Corporate obligations	85,560	318	(941)	84,937
Auction rate securities	14,450		(1,067)	13,383
U.S. municipal bonds	16,940	124	(26)	17,038
<b>Total</b>	<b>\$ 131,587</b>	<b>\$ 656</b>	<b>\$ (2,034)</b>	<b>\$ 130,209</b>
Contractual Maturities				
Due in one year or less	\$ 64,583			\$ 64,680
Due in one to three years	52,554			52,146
Due in 2017	14,450			13,383
<b>Total</b>	<b>\$ 131,587</b>			<b>\$ 130,209</b>

Investments are presented in the accompanying consolidated balance sheets as follows (in thousands):

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

	December 31,	
	2009	2008
Short-term investments	\$ 242,319	\$ 64,379
Long-term investments	26,925	65,529
Other non-current assets	299	301
Total	\$ 269,543	\$ 130,209

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

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

	Period of continuous unrealized loss		Period of continuous unrealized loss	
	12 months or less	Greater than 12 months	12 months or less	Greater than 12 months
	Fair value	Gross unrealized losses	Fair value	Gross unrealized losses
December 31, 2009				
U.S. government and agencies	\$ 127,347	\$ (51)	\$ NA	\$ NA
Corporate obligations	NA	NA	986	(11)
Auction rate securities	NA	NA	12,459	(1,991)
Taxable municipal bonds	NA	NA	NA	NA
Total	\$ 127,347	\$ (51)	\$ 13,445	\$ (2,002)

As of December 31, 2009, the Company held auction rate securities valued at \$12.5 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to either a successful auction process, redemption of the investment, a sale of the security in a secondary market or a negotiated or adjudicated resolution. Each of the securities continues to pay interest according to the stated terms on a monthly basis. The interest rate on these securities is no longer established based on an auction process but is established according to the terms of the issue. As of December 31, 2009, the interest rate on the Company's holdings in auction rate securities was set at the 30-day London Interbank Offering rate plus 225 basis points. The Company considers the market for these securities to be inactive and distressed. Accordingly, fair value for the Company's auction rate securities has been determined based on a probability-weighted discounted cash flow analysis. This analysis relies upon certain estimates, including the probability-weighted term to an orderly liquidation and the discount rate applied to future cash flows. The discount rate used to determine fair value is based on the observed comparable yield of securities with similar characteristics, adjusted for illiquidity and other risk factors. Due to the expected time to a liquidation event, investments in auction rate securities are presented as long-term investments in the accompanying consolidated balance sheets.

Based on the Company's available cash, expected operating cash requirements and its belief that the holdings in auction rate securities can be liquidated in approximately one to three years at par, the Company believes it is more likely than not that it has the ability to hold, and intends to hold, these investments until they recover substantially all of their cost basis. This belief is based on a current assessment of the Company's future operating plans and assessment of the individual securities and general market conditions. The Company periodically assesses this conclusion based on several factors, including the continued failure of future auctions, failure of the investment to be redeemed, further deterioration of the credit rating of the investment, market risk and other factors. Any such future reassessment that results in a conclusion that the unrealized losses on these investments are other than temporary would result in a write down in the fair value of these investments. Such a write down would be recognized in operating results.

**Table of Contents**

## Seattle Genetics, Inc.

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

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

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Fair Value Measurement Using:		Total
		Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
As of December 31, 2009:				
Cash equivalents money market funds	\$ 14,423			\$ 14,423
Short-term investments:				
U.S. government and agencies	\$ 215,109	\$ 5,093	\$	\$ 220,202
Corporate obligations		22,117		22,117
Long-term investments:				
Corporate obligations		14,466		14,466
Auction rate securities			12,459	12,459
Other non-current assets U.S. government and agencies	299			299
Total	\$ 229,831	\$ 41,676	\$ 12,459	\$ 283,966
As of December 31, 2008	\$ 301	\$ 116,525	\$ 13,383	\$ 130,209

Level 3 investments consist of auction rate securities and account for approximately 5% and 10% of total investment securities measured at fair value as of December 31, 2009 and 2008, respectively.

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

	Fair Value
Balance as of December 31, 2008	\$ 13,383
Unrealized loss reflected as a component of other comprehensive income (loss)	(924)
Balance as of December 31, 2009	\$ 12,459

For the year ended December 31, 2009, the Company recognized in other comprehensive loss net unrealized gains of \$129,000.

**3. Property and equipment**

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

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
Leasehold improvements	\$ 11,866	\$ 10,496
Laboratory equipment	12,197	10,027
Computers and office equipment	3,768	3,323
Furniture and fixtures	2,737	2,269
	30,568	26,115
Less: accumulated depreciation and amortization	(18,243)	(15,119)
<b>Total</b>	<b>\$ 12,325</b>	<b>\$ 10,996</b>

Depreciation and amortization expenses on property and equipment totaled \$3.3 million, \$3.4 million and \$2.5 million for the years ended December 31, 2009, 2008 and 2007, respectively.

**Table of Contents****Seattle Genetics, Inc.****Notes to Consolidated Financial Statements (Continued)****4. Accounts payable and accrued liabilities**

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

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
Clinical trial costs	\$ 8,084	\$ 5,130
Compensation and benefits	6,930	5,333
Trade accounts payable	2,886	3,253
Contract manufacturing	1,408	2,010
Other	188	153
Total	\$ 19,496	\$ 15,879

**5. Income taxes**

Because of the Company's historical net operating losses, it has not paid income taxes since its inception and the Company had no material unrecognized tax benefits as of December 31, 2009 or 2008. As a result, the Company has no uncertain tax positions that could affect the Company's financial statements.

The Company's deferred tax assets primarily consist of net operating loss, or NOL, carryforwards, deferred revenue, capitalized research and development expense and tax credit carryforwards. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which is uncertain. Accordingly, the deferred tax assets have been fully offset by a valuation allowance. At December 31, 2009, the Company has NOL carryforwards of \$188.6 million expiring from 2018 to 2029 if not utilized, and tax credit carryforwards of \$22.2 million expiring from 2020 to 2029.

Utilization of the NOL and tax credit carryforwards may be subject to a substantial annual limitation in the event of a change in ownership as set forth in Section 382 of the Internal Revenue Code of 1986, as amended. The Company has performed an ownership analysis as of August 2009. Based upon this analysis, the Company believes that substantially all of its NOL carryforwards as of December 31, 2009 have, or are expected to, become available to offset taxable income. The Company has not performed a change in ownership analysis for any period subsequent to August 2009. It is possible that there has been, or in the future will be, a change in ownership, which would limit the amount of NOL available to be used in the future. Any limitation may result in the expiration of the NOL and tax credit carryforwards before utilization.

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

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

	December 31,	
	2009	2008
Deferred tax assets		
Net operating loss carryforwards	\$ 66,006	\$ 38,307
Deferred revenue	25,033	28,819
Capitalized research and development	31,424	27,807
Tax credit carryforwards	22,235	10,642
Share-based compensation	5,038	3,039
Depreciation and amortization	1,425	1,360
Other	4,280	3,051
Total deferred tax assets	155,441	113,025
Less: valuation allowance	(155,441)	(113,025)
Net deferred tax assets	\$	\$

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

Increases in the valuation allowance were \$42.4 million in 2009, \$30.2 million in 2008 and \$19.0 million in 2007.

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

	<b>Years ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Statutory federal income tax rate	(35%)	(34%)	(34%)
Tax credits	(14)	(3)	(4)
Other	(3)	2	(1)
Valuation allowance	52	35	39
Effective tax rate	0%	0%	0%

The Company does not anticipate any significant changes to its unrecognized tax positions or benefits during the next twelve months. Interest and penalties related to the settlement of uncertain tax positions, if any, will be reflected in income tax expense. Tax years 1999 to 2009 remain subject to future examination for federal income taxes.

**6. Collaboration, license, manufacturing and other agreements**

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

	<b>Years ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Genentech	\$ 41,594	\$ 28,544	\$ 17,397
Agensys	4,029		
Daiichi Sankyo	1,779	797	
Millennium	1,690		
Other collaborations	2,873	5,895	5,023
Totals	\$ 51,965	\$ 35,236	\$ 22,420

*Product Collaboration Agreements*



*Dacetuzumab (SGN-40) product collaboration with Genentech*

In January 2007, the Company entered into a collaboration agreement with Genentech, a wholly-owned member of the Roche Group, for the development and commercialization of dacetuzumab. Under the terms of the agreement, the Company received an upfront payment of \$60 million, and progress-dependent milestone payments of \$20 million. Genentech has also funded research, development and manufacturing costs for dacetuzumab under the collaboration. In December 2009, Genentech provided notice to the Company of its decision to terminate the collaboration effective June 8, 2010, at which time all rights to dacetuzumab will be returned to the Company. Payments received from Genentech, consisting of the upfront payment, milestone payments and payments for services provided by the Company to Genentech under this agreement, are being recognized as revenue over the remaining development period of the agreement using a time-based method. As of December 31, 2009, the Company has \$66.8 million of deferred revenue related to this collaboration. Genentech will remain responsible for funding development costs associated with completing all ongoing clinical trials for dacetuzumab as of the effective date of termination. The Company's ADC collaboration with Genentech, described below, was unaffected by this termination.

**Table of Contents**

**Seattle Genetics, Inc.**

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

*Brentuximab Vedotin (SGN-35) product collaboration with Millennium*

In December 2009, the Company entered into a collaboration agreement with Millennium: The Takeda Oncology Company, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited (Millennium), to develop and commercialize brentuximab vedotin (SGN-35). Brentuximab vedotin is an antibody-drug conjugate (ADC) targeting CD30 that is in late-stage clinical trials for the treatment of relapsed and refractory Hodgkin lymphoma and a phase II trial for systemic anaplastic large cell lymphoma (sALCL).

Under the collaboration, the Company received an upfront payment of \$60 million in January 2010 and has retained full commercialization rights for brentuximab vedotin in the United States and Canada. Millennium has exclusive rights to commercialize the product candidate in all countries other than the United States and Canada. The Company is entitled to receive progress- and sales-dependent milestone payments and is entitled to receive tiered double-digit royalties based on net sales of brentuximab vedotin within Millennium's licensed territories. The Company and Millennium will each fund 50% of worldwide joint development costs performed under the collaboration. In Japan, Millennium will be solely responsible for development costs. The upfront fee and other payments received are deferred and will be recognized as revenue over the development term of the collaboration agreement, currently estimated as eight years, using a time-based approach.

*ADC collaboration agreements*

*Genentech*

In April 2002, the Company entered into an ADC collaboration with Genentech. Since entering into the multi-year agreement, Genentech has paid the Company more than \$33 million in upfront fees, milestones, access fees and equity purchases, including \$7.3 million during 2009. In addition, the Company receives other fees as well as reimbursement payments for research and development services and materials provided to Genentech under the collaboration. These payments are deferred and recognized as revenue over the development period of the collaboration using a time-based approach. The Company is entitled to receive additional progress-dependent milestones, annual maintenance fees and support fees as Genentech's ADC product candidates progress through development and royalties on product sales.

*Daiichi Sankyo*

In July 2008, the Company entered into an ADC collaboration agreement with Daiichi Sankyo. The Company received a \$4.0 million upfront fee for an exclusive license to the Company's ADC technology for a single antigen. The upfront fee and other payments received are deferred and recognized as revenue over the three year development term of the collaboration agreement using a time-based approach. The Company is entitled to receive additional progress-dependent milestones, annual maintenance fees and support fees as Daiichi Sankyo's ADC product candidate progresses through development and royalties on net sales of resulting ADC products. Daiichi Sankyo is responsible for research,

product development, manufacturing and commercialization of all products under the collaboration.

*Millennium*

In March 2009, the Company entered into an ADC collaboration agreement with Millennium. The Company received a \$4.0 million upfront fee for an exclusive license to the Company's ADC technology for a single antigen. Millennium also can exercise options for exclusive licenses to two other antigens upon payment of additional fees to the Company. The upfront fee and other payments received are deferred and recognized as revenue over the three year development term of the collaboration agreement using a time-based approach. The

**Table of Contents**

**Seattle Genetics, Inc.**

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

Company is entitled to receive additional progress-dependent milestones, annual maintenance fees and support fees as Millennium's ADC product candidate progresses through development as well as royalties on net sales of resulting ADC products. Millennium is responsible for research, product development, manufacturing and commercialization of all products under the collaboration.

*GlaxoSmithKline*

In December 2009, the Company entered into an ADC collaboration agreement with GSK. The Company received a \$12.0 million upfront fee in January 2010 for rights to utilize the Company's ADC technology with multiple antigens to be named by GSK. The upfront fee and other payments received are deferred and recognized as revenue over the four year development term of the collaboration agreement using a time-based approach. The Company is entitled to receive additional licensing fees, progress-dependent milestones, annual maintenance fees and support fees as GSK's ADC product candidates progress through development and royalties on net sales of resulting ADC products. GSK is responsible for research, product development, manufacturing and commercialization of all products under the collaboration.

*Collaboration and co-development agreement*

*Agensys*

In January 2007, the Company entered into an agreement with Agensys, now an affiliate of Astellas, to jointly research, develop and commercialize ADCs for cancer. The collaboration encompasses combinations of the Company's ADC technology with antibodies developed by Agensys to proprietary cancer targets. Under the terms of the multi-year agreement, Agensys and the Company will jointly screen and select ADC product candidates to an initial target, ASG-5ME, co-fund all development and commercialization costs and share equally in any profits. The agreement was expanded and modified in November 2009 to provide for additional licensed antigens to Agensys in exchange for a \$12 million payment and future milestone payments and royalties. Under the amended agreement, Agensys can conduct preclinical studies aimed at identifying ADC product candidates for multiple additional targets. The Company has the right to exercise a co-development option for two of these additional ADC product candidates upon submission of an IND. Agensys has the right to develop and commercialize the other ADC product candidates on its own, subject to paying the Company fees, milestones and royalties. Either party may opt out of co-development and profit-sharing in return for receiving milestones and royalties from the continuing party.

The Company and Agensys are currently collaborating on preclinical development of ASG-5ME ADC for the treatment of solid tumors. Costs associated with co-development activities performed under this collaboration are included in research and development expense in the accompanying consolidated statement of operations. Amounts received for product candidates being developed solely by Agensys will be recognized as revenue over the seventy-eight month development term of the modified collaboration agreement using a time-based approach. The Agensys collaboration agreement defines a mechanism for calculating the costs of co-development activities and for reimbursing the other party in order to maintain an equal sharing of development costs. Third-party costs are billed at actual cost and internal labor and support costs are billed at a contractual rate. The following table summarizes research and development expenses incurred by the Company and payments made to, or received from, Agensys under the collaboration (in thousands):

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

	<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Research and development expense using contractual rates	\$ 4,824	\$ 859	\$ 752
Reimbursement payable to Agensys	764	768	141
<b>Total</b>	<b>\$ 5,588</b>	<b>\$ 1,627</b>	<b>\$ 893</b>

**Table of Contents**

**Seattle Genetics, Inc.**

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

*License and other agreements*

*Bristol-Myers Squibb*

In March 1998, the Company obtained rights to certain of its technologies and product candidates, portions of which are exclusive, through a license agreement with Bristol-Myers Squibb. Through this license, the Company secured rights to monoclonal antibody-based cancer targeting technologies, including issued patents, monoclonal antibodies, chemical linkers, and other technologies. Under the terms of the license agreement, the Company is required to pay royalties on net sales of future products, including brentuximab vedotin, incorporating technology licensed from Bristol-Myers Squibb.

*PDL BioPharma*

In January 2004, PDL BioPharma and the Company entered into a license agreement that granted the Company a license and options for two additional licenses under PDL BioPharma's antibody humanization patents. This agreement was entered into as part of the expansion of the ADC collaboration with PDL BioPharma pursuant to which the Company agreed to provide additional support to PDL BioPharma in exchange for increased fees, milestones and royalties on net sales of products developed pursuant to the ADC collaboration. The Company used the initial antibody humanization license for the Company's dacetuzumab product candidate. Under the terms of the license agreement, the Company is required to pay PDL BioPharma annual maintenance fees and royalties on net sales of products using PDL BioPharma's antibody humanization technology.

*Facet Biotech Corporation*

In April 2005, the Company entered into a license agreement with PDL BioPharma for exclusive rights to PDL BioPharma's anti-CD33 program, which is the basis for the Company's lintuzumab product candidate. In December 2008, PDL BioPharma transferred its rights under this agreement to Facet as part of a corporate reorganization. The Company's rights and obligations under the agreement were not changed as a result of the transfer. Under the license agreement, the Company received rights to patents and patent applications, as well as supplies of clinical-grade materials and a nonexclusive antibody humanization license for the CD33 antigen. The Company is obligated to pay progress-dependent payments totaling up to an additional \$6.0 million based on the future achievement of clinical development and regulatory approval milestones, as well as royalties on net sales of any resulting products. In addition, the Company agreed to reduce royalties otherwise payable by Facet with respect to products targeting one antigen under the ADC collaboration between the companies. The companies have also granted each other a co-development option for second generation anti-CD33 antibodies with improved therapeutic characteristics developed by either party.

*Development, supply and other agreements:*

*Sigma Aldrich Fine Chemicals*

In 2009, the Company entered into agreements with Sigma Aldrich Fine Chemicals, or SAFC, a division of Sigma-Aldrich, Inc. The agreements include GMP manufacturing of the proprietary drug-linker system employed in its antibody drug conjugate product candidates, including brentuximab vedotin. The volume, pricing and specifications for manufacture and supply agreements with SAFC are determined on a project by project basis.

The Company has also entered into a preferred provider agreement with SAFC to enable its ADC collaborators to order drug-linker materials directly from SAFC to support the collaborators' development of ADCs utilizing the Company's technology. The Company is entitled to receive royalty payments from SAFC under the preferred provider agreement.

**Table of Contents**

**Seattle Genetics, Inc.**

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

*Abbott Laboratories, Inc.*

In 2009, the Company amended its 2004 agreement with Abbott Laboratories, Inc., or Abbott, for manufacture of the antibody component of brentuximab vedotin. The Company also has an agreement with Abbott for the manufacture of its dacetuzumab product candidate. Abbott has performed GMP manufacturing for clinical trials for brentuximab vedotin and dacetuzumab, and has agreed to supply commercial-grade material to support potential regulatory approval and commercial launch. The volume, pricing and specifications for manufacture and supply agreements with Abbott are determined on a project by project basis.

*Piramal Healthcare (formerly NPIL Pharma)*

In 2009, the Company entered into agreements with Piramal Healthcare, a division of Nicholas Piramal India Limited, for GMP manufacturing for the conjugation of its proprietary drug-linker to the antibody in its brentuximab vedotin product candidate. Additionally, the Company engaged Piramal for the process validation and manufacture of conformance materials of bulk drug substance to support the Company's planned NDA submission to the FDA for brentuximab vedotin in the first half of 2011. The volume, pricing and specifications are determined on a project by project basis.

*Pierre Fabre Medicament Production, S.A.S.*

In 2009, the Company entered into a manufacturing and supply agreement with Pierre Fabre Medicament Production, S.A.S., or PFMP, for the cGMP fill/finish manufacture of pilot, placebo, clinical, and commercial quantities of drug product for its brentuximab vedotin product candidate.

The Company from time to time engages other vendors in the manufacture and supply of our product candidates on a project basis. The volume, pricing and specifications are determined on a project by project basis.

**7. Commitments and contingencies**

In December 2000, the Company leased an approximately 63,900 square foot facility. In July 2008, the Company entered into a lease amendment to extend the term of the lease through June 2018 and to modify certain other terms including a reduction in the base rent and a reduction in level of security pledged by the Company under the lease. The Company has two renewal options of five years each and has the option to terminate the lease effective June 2013 or June 2015 upon providing notice of its intent to accelerate the termination date of the lease



and payment of a termination fee.

In June 2007, the Company entered into an operating lease for approximately 25,000 square feet of additional office space. The lease expires in June 2018 with two extension options, the first option for three years and the second option period for seven years. The lease allows for options to terminate the lease effective June 2011 or June 2014. In July 2008, the Company amended this lease to include an additional 25,000 square feet of office space under the same terms as the original lease.

The lease agreements contain scheduled rent increases, and provide for tenant improvement allowances. Accordingly, the Company has recorded a deferred rent liability of \$2.3 million and \$1.2 million at December 31, 2009 and 2008, respectively. The Company has also entered into operating lease obligations through March 2012 for certain office equipment.

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

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

Years ending December 31,	
2010	\$ 2,715
2011	2,795
2012	2,836
2013	2,917
2014	3,014
Thereafter	11,267
	\$ 25,544

Rent expense attributable to noncancelable operating leases totaled approximately \$2.8 million for the years ended December 31, 2009 and 2008 and \$2.2 million for the year ended December 31, 2007.

In addition, the minimum contractual payments to be made by the Company under its license and contract manufacturing agreements are expected to aggregate to approximately \$23.4 million in 2010, \$2.4 million in 2011, \$1.0 million in 2012 and \$1.0 million in 2013; however, the timing of such payments is uncertain. These amounts do not include up to \$9.4 million in additional payments that are contingent upon achievement of certain milestones, as well as the payment of royalties based on net sales of commercial products. These amounts have been excluded because the events triggering the obligations have not yet occurred.

**8. Stockholders' equity***Common stock*

In August 2009, the Company completed an underwritten public offering of 12,650,000 shares of its common stock at a price to the public of \$10.75 per share, resulting in net proceeds of \$128.2 million. In February 2009, the Company completed an underwritten public offering of 5,740,000 shares of its common stock at \$9.72 per share resulting in net proceeds of \$52.5 million. In May 2009, the Company completed a private placement of 1,178,163 shares of its common stock at \$9.72 per share to Baker Brothers Life Sciences, L.P. and its affiliated investment funds (BBLs). Net proceeds of the private placement were approximately \$11.5 million. Felix Baker, Ph.D., one of the Company's directors, is a Managing Director of Baker Bros. Advisors, LLC, which is affiliated with BBLs and its affiliated investment funds. As a result, the sale and issuance of these shares was subject to stockholder approval which was obtained at the Company's annual meeting of stockholders held on May 15, 2009.

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

In January 2008, the Company completed a public offering of 11,500,000 shares of common stock at a price to the public of \$9.00 per share, resulting in net proceeds to the Company of approximately \$97.6 million.

The Company is authorized to issue up to 150,000,000 shares of common stock. At December 31, 2009, shares of common stock reserved for future issuance are as follows (in thousands):

Stock options outstanding	10,682
Warrants outstanding	1,113
Stock options available for grant	741
Employee stock purchase plan shares available for issuance	201
	12,737

---

**Table of Contents**

**Seattle Genetics, Inc.**

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

*Stock purchase warrants*

In connection with an equity financing completed in July 2003, the Company issued warrants to purchase 2,050,000 shares of common stock with an exercise price of \$6.25 per share and an expiration date of December 31, 2011. In August 2009, an institutional investor and its affiliated entities that held privately placed warrants to purchase an aggregate of 812,500 shares of the Company's common stock exercised their warrants under the net exercise provisions of the warrants. As a result, 395,214 shares of the Company's common stock were issued to the warrant holders upon exercise of the warrants on a net, or cashless, basis. In October 2007, warrants to purchase 125,000 shares of common stock were exercised. Warrants to purchase 1,112,500 shares of common stock were outstanding as of December 31, 2009.

*Employee Stock Purchase Plan*

The Company has a 2000 Employee Stock Purchase Plan (the "Stock Purchase Plan") with a total of 201,393 shares of common stock available for issuance as of December 31, 2009. The number of shares reserved for issuance under the Stock Purchase Plan is subject to an automatic annual increase on the first day of each calendar year through 2010 that is equal to the lesser of (i) 300,000 shares; (ii) 1% of the Company's outstanding common stock on the last day of the immediately preceding fiscal year; or (iii) such lesser number of shares as the Board of Directors determines. A total of 146,692 shares were sold to employees during 2009 at a weighted average purchase price of \$8.46 per share, 240,190 shares were sold to employees during 2008 at a weighted average purchase price of \$4.30 per share and 147,881 shares were sold to employees during 2007 at a weighted average purchase price of \$3.60 per share. Subject to certain exceptions, under the terms of the Stock Purchase Plan, shares are purchased at 85 percent of the fair market value of the Company's common stock on either the first day of an offering period or the last day of each six month purchase period, whichever is lower. An offering period may last up to two years.

**9. Stock option plans**

*2007 Equity Incentive Plan*

The Company adopted the 2007 Equity Incentive Plan (the "Option Plan") effective as of December 23, 2007, which was amended and restated in August 2009, whereby 5,000,000 shares of the Company's common stock were reserved for issuance to employees, including officers, directors and consultants of the Company and its affiliates. Upon the effective date of the Option Plan, the Company ceased granting awards under its 1998 Stock Option Plan (the "1998 Plan"). As of December 31, 2009, 441,464 shares were available for future grant under the Option Plan, and a total of 10,237,300 shares were subject to outstanding options granted under the Option Plan and the 1998 Plan. The types of awards that may be granted under the Option Plan are stock options (including incentive stock options and nonstatutory stock options), restricted stock, restricted stock units, stock appreciation rights and other similar types of awards. No awardee may be granted, in any calendar year under the Option Plan, options or stock awards covering more than 1,000,000 shares. The Option Plan will terminate in December 2017 unless it is terminated earlier pursuant to its terms.

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

Incentive stock options under the Option Plan may be granted only to employees of the Company or its subsidiaries. The exercise price of an incentive stock option or a nonstatutory stock option may not be less than 100% of the fair market value of the common stock on the date the option is granted and have a maximum term of ten years from the date of grant. In the case of options granted to holders of more than 10% of the voting power of the Company, the exercise price may not be less than 110% of the fair market value of the common stock on the date the option is granted and the term of the option may not exceed five years. The Company may grant options with exercise prices lower than the fair market value of its common stock on the date of grant in connection with an acquisition by the Company of another company. Options become exercisable in whole or in part from time to time as determined by the Board of Directors, which administers the Option Plan. Generally,

---

**Table of Contents**

**Seattle Genetics, Inc.**

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

options granted under the Option Plan vest 25% one year after the beginning of the vesting period and thereafter ratably each month over the following three years. On August 5, 2009, the Company's Board of Directors approved the amendment and restatement of the Option Plan and the 1998 Plan. The Plans were each amended to provide for (i) the full acceleration of vesting of stock awards, including stock options, upon a change in control (as defined in the Plans) if the successor company does not assume, substitute or otherwise replace the stock awards upon the change in control; and (ii) the full acceleration of vesting of any stock awards, including stock options held by a holder of such stock awards, if at the time of, immediately prior to or within twelve months after a change in control of the Company, the holder of such stock awards is involuntarily terminated without cause or is constructively terminated by the successor company that assumed, substituted or otherwise replaced such stock awards in connection with the change in control.

Stock awards under the Option Plan may be restricted stock grants, restricted stock units, stock appreciation rights or other similar stock awards (including awards that do not require the awardee to pay any amount in connection with receiving the shares or that have an exercise or purchase price that is less than the grant date fair market value of the Company's stock). Restricted stock grants are awards of a specific number of shares of the Company's common stock. Restricted stock units represent a promise to deliver shares of the Company's common stock, or an amount of cash or property equal to the value of the underlying shares, at a future date. Stock appreciation rights are rights to receive cash and/or shares of the Company's common stock based on the amount by which the exercise date fair market value of a specific number of shares exceeds the grant date fair market value of the exercised portion of the stock appreciation right.

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

During 2007, the Company recorded a non-cash, share-based compensation charge of approximately \$520,000 for accelerated vesting of stock options in connection with employee severance.

*2000 Directors' Stock Option Plan*

The Company has a 2000 Directors' Stock Option Plan (the Directors' Plan). Under the terms of the Directors' Plan, each non-employee director is automatically granted a nonstatutory stock option to purchase 25,000 shares of common stock on the date on which such individual first becomes a member of the Board of Directors. Each initial option vests at the rate of 25% of the total number of shares subject to such option twelve months after the date of grant, with the remaining shares vesting thereafter in equal monthly installments over three years. In addition, on the dates of each annual stockholder meeting, each non-employee director who has been a member of the Board of Directors for at least six months is automatically granted a nonstatutory stock option to purchase 10,000 shares of common stock. Each annual option vests at the rate of 100% of the total number of shares subject to such option on the day before the one-year anniversary of the grant date.

All options granted under the Directors Plan have a term of ten years and an exercise price equal to the fair value of the underlying shares on the date of grant. A total of 900,000 shares of common stock have been

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

reserved for issuance under the Directors' Plan as of December 31, 2009. As of December 31, 2009 stock options to acquire a total of 444,595 shares of common stock were outstanding and 300,000 shares were available for grant under the Directors' Plan.

*Share-based compensation expense*

The impact on the Company's results of operations of share-based payment awards was as follows (in thousands):

	Year Ended December 31, 2009	Year Ended December 31, 2008	Year Ended December 31, 2007
Research and development	\$ 7,312	\$ 6,414	\$ 5,344
General and administrative	4,537	3,998	2,584
<b>Total</b>	<b>\$ 11,849</b>	<b>\$ 10,412</b>	<b>\$ 7,928</b>

No tax benefit was recognized related to share-based compensation expense since the Company has never reported taxable income and has established a full valuation allowance to offset all of the potential tax benefits associated with its deferred tax assets. In addition, no amounts of share-based compensation costs were capitalized for the periods presented.

*Valuation assumptions*

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

	Stock Option Plans			Employee Stock Purchase Plan		
	Years ended December 31,			Years ended December 31,		
	2009	2008	2007	2009	2008	2007
Risk-free interest rate	2.3%	3.0%	4.4%	1.2%	2.5%	4.9%
Expected lives in years	5.5	5.5	5.4	1.3	2.2	1.5
Expected dividends	0%	0%	0%	0%	0%	0%
Expected volatility	56%	57%	63%	50%	56%	64%



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

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for the expected life of the award. The Company's computation of expected life was determined based on its historical experience with similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and expectations of future employee behavior. A forfeiture rate is estimated at the time of grant to reflect the amount of options that are granted, but are expected to be forfeited by the option holder prior to vesting. The estimated forfeiture rate applied to these amounts is derived from historical stock option forfeiture behavior. The Company has never paid cash dividends and does not currently intend to pay cash dividends, thus has assumed a 0% dividend yield. The Company's computation of expected volatility is based on the historical volatility of the Company's stock price. Determination of all of these assumptions involves management's best estimates at the time, which impact the fair value of the option calculated under the Black-Scholes methodology, and ultimately the expense that will be recognized over the life of the option.

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

A summary of stock option activity for the Option Plan, the Directors' Plan and the 1998 Plan (collectively, the Stock Option Plans) is as follows:

	Shares available for grant	Options outstanding Number of shares	Weighted- average exercise price per share
Balance, December 31, 2006	2,045,808	6,671,432	\$ 5.48
Additional shares reserved	6,100,000		
Option Plan shares expired	(677,267)		
Granted	(2,303,450)	2,303,450	9.85
Exercised		(1,221,759)	4.33
Forfeited/expired	294,909	(294,909)	5.37
<b>Balance, December 31, 2007</b>	<b>5,460,000</b>	<b>7,458,214</b>	<b>7.02</b>
Granted	(2,367,548)	2,367,548	10.69
Exercised		(526,237)	5.44
Forfeited/expired	33,983	(250,425)	8.38
<b>Balance, December 31, 2008</b>	<b>3,126,435</b>	<b>9,049,100</b>	<b>8.04</b>
Granted	(2,489,824)	2,489,824	11.33
Exercised		(653,054)	5.37
Forfeited/expired	104,853	(203,975)	9.84
<b>Balance, December 31, 2009</b>	<b>741,464</b>	<b>10,681,895</b>	<b>8.93</b>

The weighted average grant-date fair value of options granted with exercise prices equal to market were \$5.84, \$5.65 and \$5.75 for the years ended December 31, 2009, 2008 and 2007, respectively. As of December 31, 2009 there were 9.8 million options vested or expected to vest with a weighted-average exercise price of \$8.79, a weighted-average remaining contractual term of 6.94 years and an aggregate intrinsic value of \$18.1 million.

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company's common stock for all options that were in-the-money at December 31, 2009. The aggregate intrinsic value at December 31, 2009 for options outstanding was \$18.6 million and for options exercisable was \$16.2 million. The aggregate intrinsic value of options exercised under the Stock Option Plans was \$4.4 million during 2009, \$11.5 million during 2008 and \$7.7 million during 2007, determined as of the date of option exercise. As of December 31, 2009, there was approximately \$14.0 million of total unrecognized compensation cost related to unvested

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

share-based compensation arrangements, as adjusted for expected forfeitures, granted under the Stock Option Plans. That cost is expected to be recognized over a weighted-average period of 1.4 years. The weighted-average remaining contractual term of options exercisable at December 31, 2009 was 5.6 years.

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

The following table summarizes information about options outstanding for the Stock Option Plans at December 31, 2009:

Range of exercise price	Number of shares	Options outstanding	Weighted-average exercise price per share	Options exercisable	
		Weighted-average remaining contractual life (in years)		Number of shares	Weighted-average exercise price per share
\$2.33 - \$ 5.49	1,495,002	5.51	\$ 4.49	1,304,251	\$ 4.49
\$5.50 - \$ 6.72	1,556,868	4.48	6.01	1,544,974	6.01
\$6.74 - \$ 9.08	1,579,007	5.62	8.24	1,053,811	8.03
\$9.10 - \$ 10.28	1,110,654	8.29	9.62	471,372	9.85
\$10.29 - \$ 10.52	1,347,328	7.18	10.31	832,667	10.31
\$10.70 - \$11.36	1,775,309	8.62	11.04	594,202	11.05
\$11.53 - \$14.03	1,817,727	9.61	12.19	24,312	11.69
\$2.33 - \$14.03	10,681,895	7.09	8.93	5,825,589	7.50

**10. Employee benefit plan**

The Company has a 401(k) Plan for all of its employees. The Plan allows eligible employees to defer, at the employee's discretion, up to 50% of their pretax compensation up to the IRS annual limit. This limit was \$16,500 (or \$22,000 for employees who are 50 years old or older) in calendar year 2009. The Company has a 401(k) matching program whereby the Company contributes 50% of the first 6% (4% for 2007) of a participant's contributions, not to exceed a prescribed annual limit. Under this matching program, the Company contributed a total of approximately \$798,000 in 2009, \$527,000 in 2008 and \$274,000 in 2007.

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

The following table contains selected unaudited statement of operations information for each quarter of 2009 and 2008. The unaudited information should be read in conjunction with the Company's financial statements and related notes included elsewhere in this report. The Company believes that the following unaudited information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

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

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

	Three Months Ended			
	March 31	June 30	September 30	December 31
<b>2009</b>				
Revenues	\$ 9,142	\$ 9,408	\$ 11,646	\$ 21,769
Net loss	\$ (27,268)	\$ (22,471)	\$ (19,827)	\$ (12,117)
Net loss per share basic and diluted	\$ (0.33)	\$ (0.26)	\$ (0.21)	\$ (0.12)
<b>2008</b>				
Revenues	\$ 7,085	\$ 10,004	\$ 8,079	\$ 10,068
Net loss	\$ (17,112)	\$ (16,028)	\$ (21,764)	\$ (30,597)
Net loss per share basic and diluted	\$ (0.22)	\$ (0.20)	\$ (0.27)	\$ (0.38)

## **Table of Contents**

### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

### **Item 9A. Controls and Procedures.**

(a) *Evaluation of disclosure controls and procedures.* Our Chief Executive Officer and the Chief Financial Officer have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this annual report. Based on that evaluation, they have concluded that, as of the end of the period covered by this annual report, our disclosure controls and procedures were, in design and operation, effective.

(b) *Changes in internal control over financial reporting.* There have not been any changes in our internal control over financial reporting during the quarter ended December 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

(c) *Management's Report on Internal Control Over Financial Reporting.* Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its evaluation under the framework in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2009.

The effectiveness of our internal control over financial reporting as of December 31, 2009 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included in Item 8 in this Annual Report on Form 10-K.

### **Item 9B. Other Information.**

*Long term incentive plan.* The Compensation Committee of the Board of Directors recommended and the Board of Directors approved in March 2010 a Long Term Incentive Plan, or Plan, based on the projected approval of brentuximab vedotin. The Plan provides for a cash award and, for employees at the associate director level and above, a stock award, based on such employee's position with Seattle Genetics in March 2010. Eligible employees who join Seattle Genetics after March 31, 2010 are eligible for a pro-rated award based on their dates of employment prior to the submission of an NDA to the FDA for brentuximab vedotin. The awards will be paid upon approval of the NDA by the FDA and will be adjusted up or down based on the date of such approval up to a certain specified date, after which, no awards will be made. The stock awards, if granted, will vest two years after the date of the NDA approval of brentuximab vedotin. The Compensation Committee and the Board of Directors believe that this Plan is based upon an event that will add significant value to the company and for our stockholders and that the vesting period for the stock awards will properly retain senior management past the achievement of the goal of FDA approval of brentuximab vedotin to carry out the commercial activities associated with launching a biotechnology product. The foregoing is only a brief description of the material terms of the Plan, does not purport to be complete and is qualified in its entirety by reference to the Plan that is filed as an exhibit to this annual report on Form 10-K for the year ending December 31, 2009 as Exhibit 10.51.



**Table of Contents**

**PART III**

The information required by Part III is omitted from this report because we will file a definitive proxy statement within 120 days after the end of our 2009 fiscal year pursuant to Regulation 14A for our 2010 Annual Meeting of Stockholders (the 2010 Proxy Statement ), and the information to be included in the 2010 Proxy Statement is incorporated herein by reference.

**Item 10. Directors, Executive Officers and Corporate Governance.**

(1) The information required by this Item concerning our executive officers and our directors and nominees for director, including information with respect to our audit committee and audit committee financial expert, may be found under the section entitled Proposal No. 1 Election of Directors appearing in the 2010 Proxy Statement. Such information is incorporated herein by reference.

(2) The information required by this Item concerning our code of ethics may be found under the section entitled Proposal No. 1 Election of Directors Code of Ethics appearing in the 2010 Proxy Statement. Such information is incorporated herein by reference.

(3) The information required by this Item concerning compliance with Section 16(a) of the Securities Exchange Act of 1934 may be found in the section entitled Section 16(a) Beneficial Ownership Reporting Compliance appearing in the 2010 Proxy Statement. Such information is incorporated herein by reference.

**Item 11. Executive Compensation.**

The information required by this Item may be found under the sections entitled Proposal No. 1 Election of Directors Director Compensation and Compensation of Executive Officers appearing in the 2010 Proxy Statement. Such information is incorporated herein by reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

(1) The information required by this Item with respect to security ownership of certain beneficial owners and management may be found under the section entitled Security Ownership of Certain Beneficial Owners and Management appearing in the 2010 Proxy Statement. Such information is incorporated herein by reference.

(2) The information required by this Item with respect to securities authorized for issuance under our equity compensation plans may be found under the sections entitled Equity Compensation Plan Information appearing in the 2010 Proxy Statement. Such information is incorporated herein by reference.



**Item 13. Certain Relationships and Related Transactions, and Director Independence.**

(1) The information required by this Item concerning related party transactions may be found under the section entitled **Certain Relationships and Related Party Transactions** appearing in the 2010 Proxy Statement. Such information is incorporated herein by reference.

(2) The information required by this Item concerning director independence may be found under the section entitled **Proposal No. 1 Election of Directors** appearing in the 2010 Proxy Statement. Such information is incorporated herein by reference.

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

The information required by this Item may be found under the section entitled **Proposal No. 3 Ratification of Appointment of Independent Registered Public Accounting Firm** appearing in the 2010 Proxy Statement. Such information is incorporated herein by reference.

**Table of Contents**

**PART IV**

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

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

- (1) Financial Statements and Report of Independent Registered Public Accounting Firm
- (2) Financial Statement Schedules

Financial Statement Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

- (3) Exhibits are incorporated herein by reference or are filed with this report as indicated below (numbered in accordance with Item 601 of Regulation S-K).

**(b) Exhibits**

<b>Number</b>	<b>Description</b>
3.1(15)	Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.
3.2(14)	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.
3.3(5)	Amended and Restated Bylaws of Seattle Genetics, Inc.
4.1(1)	Specimen Stock Certificate.
4.2(4)	Form of Common Stock Warrant.
4.3(15)	Investor Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders.
4.4(5)	Amendment to Amended and Restated Investors Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders.
10.1 (1)	License Agreement dated March 30, 1998 between Seattle Genetics, Inc. and Bristol-Myers Squibb Company.
10.2 (1)	Amendment Letter to the Bristol-Myers Squibb Company License Agreement dated August 10, 1999 between Seattle Genetics, Inc. and Bristol-Myers Squibb Company.
10.3(1)	Amendment Agreement to the Bristol-Myers Squibb Company License Agreement dated July 26, 2000 between Seattle Genetics, Inc. and Bristol-Myers Squibb Company.
10.4 (1)	License Agreement dated June 14, 1998 between Seattle Genetics, Inc. and Mabtech AB.
10.5 (1)	First Amendment to the Mabtech License Agreement dated January 31, 2000 between Seattle Genetics, Inc. and Mabtech AB.
10.6 (1)	License Agreement dated September 20, 1999 between Seattle Genetics, Inc. and the University of Miami.
10.7 (1)	Amendment No. 1 to the University of Miami License Agreement dated August 4, 2000 between Seattle Genetics, Inc. and the University of Miami.

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

- 10.8 (1) License Agreement dated February 3, 2000 between Seattle Genetics, Inc. and the Arizona Board of Regents.
- 10.9 (1) Lease Agreement dated December 1, 2000 between Seattle Genetics, Inc. and WCM132-302, LLC.
- 10.10(20)\* Amended and Restated 1998 Stock Option Plan, effective as of August 4, 2009.

**Table of Contents**

<b>Number</b>	<b>Description</b>
10.11(8)*	Form Notice of Grant and Stock Option Agreement under Amended and Restated 1998 Stock Option Plan.
10.12(8)*	Form Notice of Grant and Stock Option Agreement under 2000 Directors Stock Option Plan.
10.13*	2000 Directors Stock Option Plan, as amended February 5, 2010.
10.14(1)*	2000 Employee Stock Purchase Plan.
10.15(1)*	Form of Indemnification Agreement between Seattle Genetics, Inc. and each of its officers and directors.
10.16 (2)	Contract Manufacturing Agreement dated January 3, 2003 between Seattle Genetics, Inc. and ICOS Corporation.
10.17 (3)	License Agreement dated March 6, 2003 between Seattle Genetics, Inc. and Genentech, Inc.
10.18 (3)	Non-Exclusive Cabilly Patent License Agreement dated March 6, 2003 between Seattle Genetics, Inc. and Genentech, Inc.
10.19 (5)	First Amendment to Lease dated May 28, 2003 between Seattle Genetics, Inc. and B&N 141-302, LLC.
10.20 (6)	Patent Rights Master Agreement and Research License Agreement dated January 9, 2004 between Seattle Genetics, Inc. and Protein Design Labs, Inc.
10.21 (6)	Patent License Agreement dated January 9, 2004 between Seattle Genetics, Inc. and Protein Design Labs, Inc.
10.22 (6)	Development and Supply Agreement dated February 23, 2004 between Seattle Genetics, Inc. and Abbott Laboratories.
10.23 (7)	Amendment No. 3 to License Agreement dated August 17, 2004 between Seattle Genetics, Inc., and Arizona Science & Technology Enterprises d/b/a Arizona Technology Enterprises.
10.24 (9)	Development and Supply Agreement dated February 18, 2005 between Seattle Genetics, Inc. and Abbott Laboratories.
10.25 (10)	License Agreement dated April 12, 2005 between Seattle Genetics, Inc. and Protein Design Labs, Inc.
10.26 (10)	Manufacturing and Supply Agreement dated May 4, 2005 between Seattle Genetics, Inc. and Organichem Corporation.
10.27 (11)	Biopharmaceutical Manufacturing Services Agreement dated April 24, 2006 between Seattle Genetics, Inc. and Laureate Pharma, Inc.
10.28 (12)	Collaboration and License Agreement dated January 7, 2007 between Seattle Genetics, Inc. and Agensys, Inc.
10.29 (12)	Collaboration Agreement dated February 5, 2007 between Seattle Genetics, Inc. and Genentech, Inc.
10.30(18)*	Seattle Genetics, Inc. 2009 Senior Executive Annual Bonus Plan.
10.31 (14)	First Amendment to Development and Supply Agreement dated April 17, 2008 between Seattle Genetics, Inc. and Abbott Laboratories, Inc.
10.32 (14)	First Amendment to Development and Supply Agreement dated May 7, 2008 between Seattle Genetics, Inc. and Abbott Laboratories, Inc.
10.33 (15)	Second Amendment to Lease dated July 1, 2008 between Seattle Genetics, Inc. and B&N 141-302, LLC.

**Table of Contents**

<b>Number</b>	<b>Description</b>
10.34(20)*	Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan.
10.35(19)*	Form Stock Option Agreement under 2007 Equity Incentive Plan.
10.36(16)	Stock Purchase Agreement, dated January 27, 2009, by and between Seattle Genetics, Inc. and Baker Brothers Life Sciences, L.P.
10.37(18)*	Seattle Genetics, Inc. 2010 Senior Executive Annual Bonus Plan.
10.38(19)*	Amended and Restated Employment Agreement, dated December 15, 2008, between Seattle Genetics, Inc. and Clay B. Siegall.
10.39(19)*	Amended and Restated Employment Agreement, dated December 15, 2008, between Seattle Genetics, Inc. and Todd E. Simpson.
10.40(19)*	Amended and Restated Employment Agreement, dated December 15, 2008, between Seattle Genetics, Inc. and Eric L. Dobmeier.
10.41(19)*	Amended and Restated Employment Agreement, dated December 15, 2008, between Seattle Genetics, Inc. and Thomas C. Reynolds.
10.42(19)*	Amended and Restated Employment Agreement, dated December 15, 2008, between Seattle Genetics, Inc. and Morris Rosenberg.
10.43*	Employment Agreement, dated April 1, 2009, between Seattle Genetics, Inc. and Vaughn Himes.
10.44*	Employment Agreement, dated October 12, 2009, between Seattle Genetics, Inc. and Bruce Seeley.
10.45(19)	Option and License Agreement between Seattle Genetics, Inc. and CLB-Research and Development dated July 5, 2001.
10.46(19)	Amendment No. 1 to Option and License Agreement between Seattle Genetics, Inc. and CLB-Research and Development dated September 27, 2004.
10.47(19)*	Consulting Agreement between Seattle Genetics, Inc. and Hoth Consulting Inc. dated June 1, 2006.
10.48*	Compensation Information for Executive Officers and Directors.
10.49	Amendment to the Collaboration and License Agreement between Seattle Genetics, Inc. and Agensys, Inc. dated November 9, 2009.
10.50	Collaboration Agreement between Seattle Genetics, Inc. and Millennium Pharmaceuticals dated December 14, 2009.
10.51*	Seattle Genetics Long Term Incentive Plan effective March 11, 2010.
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.

- (1) Previously filed as an exhibit to Registrant's registration statement on Form S-1, File No. 333-50266, originally filed with the Commission on November 20, 2000, as subsequently amended, and incorporated herein by reference.

**Table of Contents**

- (2) Previously filed as an exhibit to Registrant's annual report on Form 10-K for the year ended December 31, 2002 and incorporated herein by reference.
- (3) Previously filed as an exhibit to Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2003 and incorporated herein by reference.
- (4) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on May 15, 2003.
- (5) Previously filed as an exhibit to Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2003 and incorporated herein by reference.
- (6) Previously filed as an exhibit to Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2004 and incorporated herein by reference.
- (7) Previously filed as an exhibit to Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2004 and incorporated herein by reference.
- (8) Previously filed as an exhibit to Registrant's annual report on Form 10-K for the year ended December 31, 2004 and incorporated herein by reference.
- (9) Previously filed as an exhibit to Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2005 and incorporated herein by reference.
- (10) Previously filed as an exhibit to Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2005 and incorporated herein by reference.
- (11) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2006 and incorporated herein by reference.
- (12) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2007 and incorporated herein by reference.
- (13) Previously filed as Addendum B to Registrant's definitive proxy statement on Schedule 14A, File No. 000-32405, filed with the Commission on April 17, 2007 and incorporated herein by reference.
- (14) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference.
- (15) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2008 and incorporated herein by reference.
- (16) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on January 27, 2009 and incorporated herein by reference.

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

- (17) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on February 19, 2009 and incorporated herein by reference.
- (18) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on February 12, 2010 and incorporated herein by reference.
- (19) Previously filed as an exhibit to the Registrant's annual report on Form 10-K filed with the Commission on March 13, 2009 and incorporated herein by reference.
- (20) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2009 and incorporated herein by reference.

Pursuant to a request for confidential treatment, portions of this Exhibit have been redacted from the publicly filed document and have been furnished separately to the Securities and Exchange Commission as required by Rule 24b-2 under the Securities Exchange Act of 1934.

\* Indicates a management contract or compensatory plan or arrangement.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SEATTLE GENETICS, INC.

Date: March 12, 2010

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

*President & Chief Executive Officer*

*(Principal Executive Officer)*

Date: March 12, 2010

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

*Chief Financial Officer*

*(Principal Financial and Accounting Officer)*

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ CLAY B. SIEGALL  Clay B. Siegall	Director, President & CEO (Principal Executive Officer)	March 12, 2010
/s/ TODD E. SIMPSON  Todd E. Simpson	Chief Financial Officer (Principal Financial and Accounting Officer)	March 12, 2010
/s/ FRANKLIN M. BERGER  Franklin M. Berger	Director	March 12, 2010
/s/ DAVID W. GRYSKA  David W. Gryska	Director	March 12, 2010
/s/ MARC E. LIPPMAN  Marc E. Lippman	Director	March 12, 2010



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

/s/ SRINIVAS AKKARAJU	Director	March 12, 2010
Srinivas Akkaraju		
/s/ FELIX BAKER	Director	March 12, 2010
Felix Baker		
/s/ DANIEL F. HOTH	Director	March 12, 2010
Daniel F. Hoth		
/s/ JOHN P. McLAUGHLIN	Director	March 12, 2010
John P. McLaughlin		
/s/ DANIEL G. WELCH	Director	March 12, 2010
Daniel G. Welch		